

**Pharmaceutical Patent Protection and Development in Sub-Saharan Africa:  
Laws, Institutions, Practices, and Politics**

By

**Poku Adusei**

Faculty of Law  
McGill University  
Montréal

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## **Abstract**

This thesis critically investigates patent protection of medicines in light of the threats posed by HIV/AIDS, malaria and tuberculosis epidemics to the citizens of countries in Sub-Saharan Africa (hereinafter SSA or Africa). The thesis begins by outlining the systemic problems associated with the prevailing globalized patent regime and the regime's inability to promote access to life-saving medicines at affordable prices in poor regions such as SSA. The thesis then goes on to argue that for pharmaceutical patents to retain their relevance in SSA countries human development concepts must be integrated into global patent law- and policy-making. An integrative approach here implies developing additional public health and human development exceptions/limitations to the exercise of patent rights with the goal of scaling up access to medicines to treat epidemics in SSA. The interplay of the sub-themes of laws, institutions, practices, and politics as chief instruments in the planning and design of international norms on patents will bring to the fore the urgent quest for pharmaceutical patent reforms to accommodate the need for human development in countries in SSA.

Further, I suggest that SSA countries adopt an evidenced-based approach to implementing the newly reconfigured global patent standards in domestic jurisdictions. This evidence-based approach would include mechanisms like local needs assessments and the use of empirical data to shape domestic patent law making endeavors. The approach also implies revising patent rules and policies with a pro-poor and pro-health emphasis so that medicines will be more affordable and accessible to the citizens of SSA countries. It also suggests considering the opinions of individuals and pro-access institutions in enacting crucial pieces of health-related statutes in SSA countries. The approach I propose in this thesis is sensitive to the public health needs of the citizens affected by epidemics, and to the imperative of building local manufacturing capabilities in pharmaceutical research and development in SSA.

## Résumé

Cette thèse examine de manière critique la protection des brevets médicamenteux à la lumière des menaces que représentent les épidémies du SIDA, de la malaria et de la tuberculose pour les citoyens des pays d'Afrique subsaharienne (ci-dessous, ASS). Tout d'abord, cette thèse souligne les problèmes systémiques associés au régime global de brevets actuel et à l'inaptitude de ce régime à promouvoir l'accès aux médicaments vitaux à des prix abordables dans les régions pauvres telles que l'ASS. Ensuite, la thèse défend que pour que les brevets pharmaceutiques conservent leur pertinence dans les pays de l'ASS, des concepts de développement humain doivent être intégrés au droit global des brevets – et à la prise de décision afférente. Une approche intégrée implique en ce cas de développer des exceptions/des limites additionnelles à l'exercice des droits liés aux brevets relatives à la sante publique et au développement humain, dans le but de maximiser l'accès aux médicaments afin de traiter les épidémies dans les pays de l'ASS. L'interaction des sous-thèmes du droit, des institutions, de la pratique et de la politique comme instruments de choix dans la planification et la conception des normes internationales sur les brevets mettra en valeur l'urgence de la quête de reformes des brevets pharmaceutiques afin d'accommoder le besoin de développement dans les pays de l'ASS.

De plus, je suggère que les pays de l'ASS adoptent une approche de la mise en œuvre des standards de brevets internationaux nouvellement reconfigurés au sein de leurs juridictions domestiques fondée sur des données probantes. Cette approche fondée sur des données probantes inclurait des mécanismes tels que des évaluations des besoins locaux et l'utilisation de données empiriques afin de structurer les projets de loi sur les brevets domestiques. L'approche implique aussi de réviser les règles et les politiques liées aux brevets en mettant l'accent sur la défense des pauvres et de la santé afin que les médicaments soient plus abordables et accessibles pour les citoyens des pays de l'ASS. Elle suggère aussi de prendre en compte les opinions des individus et des institutions pro-

accès lors de l'établissement de normes liées à la santé dans les pays de l'ASS. L'approche que je propose dans cette thèse est sensible aux besoins en santé publique des citoyens affectés par les épidémies, et à l'impératif de développer des capacités de fabrication locale dans le secteur de la recherche pharmaceutique et du développement dans l'ASS.

## Acknowledgments

Mahatma Gandhi (1869-1948) once identified two of the seven sins in the world as: “commerce without morality” and “science without humanity.” I do not know if Gandhi’s advice to moderate trade and science for the benefit of humanity had anything to do with patent law. But such a humanist approach to life is what many voices from different parts of the globe have articulated in policy and academic discourse on patents, and mine is no exception.

The exercise of writing *Pharmaceutical Patent Protection and Development in Sub-Saharan Africa* was challenging and at times solitary. But the presence and support of a number of individuals and institutions made this process seem painless. First, I owe a debt of gratitude to Professor Tina Piper for dedicating her time and efforts to the supervision this doctoral dissertation. Professor Piper’s critical approach to scholarship has helped shape my academic worldview. From the embryonic stage of this research to the end, Tina was with me every step of the way; she made very insightful comments on all the chapters of this dissertation, and further assisted me financially in the most crucial times. Without such support and goodwill, it would have been impossible to continue climbing the hilly-Peel Street in Montreal for almost four years.

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## Chapter 1

### General Introduction and Overview

#### I. Statement of Problem

This study was inspired by the absence of a comprehensive study of the connections between patents, access to medicine, and development in Sub-Saharan Africa (hereinafter SSA or Africa).<sup>1</sup> My interest in this topic developed from witnessing first-hand the hardships that individuals go through in parts of Africa to obtain treatment for otherwise curable diseases. I hope that this study will provide a legal framework for the adoption of pharmaceutical patents that serve human development needs in SSA.

This thesis critically investigates patent protection of medicines *vis-à-vis* SSA's quest for sustainable human development. It focuses on the pandemic situations in SSA by unravelling some of the not-so-evident patent regulatory lapses that impede access to medicines in Africa. It underscores the point that the patent system over-relies on property rights and/or efficiency-based utilitarian justifications with little or no regard to the social importance of limits on patent rights.<sup>2</sup> Equally the patent system, which is the most widely used form of juridical control of pharmaceuticals, privileges private property interests over the public interest to deliver medicines to those who need them the most. This traditional bias in favour of private proprietary interests in turn undermines the policy objective of patent law to promote social benefits. To achieve the social benefit

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<sup>1</sup> Sub-Saharan Africa comprises 48 countries. The countries are: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, and Zimbabwe.

<sup>2</sup> See Ruth L Okediji, "Africa and the Global Intellectual Property System: Beyond the Agency Model" (2004) 12 Afri YB Int'l L 207 at 214.

goals of a functional (i.e. a well balanced<sup>3</sup>) patent regulatory regime, the globalized pharmaceutical patent system should be equitable and human-development oriented. This study will explore ways to achieve this objective.

The study makes a case for re-constructing the globalized pharmaceutical patent framework to be responsive to the needs of the citizens of SSA. This reconstruction implies the infusion of the human development considerations of the world's poor into the formulation of pharmaceutical patent regulatory policies so as to achieve sustainable human progress. It proposes a framework that meshes multiple human development principles with the globalized pharmaceutical regulatory regime, including: one that is rooted in robust human rights and progressive human development principles; one that meets human needs and shows respect for communal interests; a model that admits of differences and is amenable to change in the light of socio-economic needs; a regulatory model that confronts 'unfreedoms' which constrain human development;<sup>4</sup> one that respects principles of substantive equality, fairness and equity;<sup>5</sup> one that is anchored on deliberative democracy and genuine participation by countries in SSA in international patent law making;<sup>6</sup> and, a model by which matters of public health and needs take

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<sup>3</sup> The word 'balance' is a term from physics coined to describe a desirable equilibrium between at least two forces which is characterized by cancellation of all forces by equal opposing forces. For a detailed analysis of the term 'balance' in IP law and policy see: Andrea Wechsler, "Spotlight on China: Piracy, Enforcement, and the Balance Dilemma in Intellectual Property Law" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 61.

<sup>4</sup> See Amartya Sen, *Development as Freedom* (New York: Anchor Books, 1999); Martha Nussbaum, *Women and Human Development: The Capabilities Approach* (New York: Cambridge University Press, 2000) [Nussbaum, *Women and Human Development*].

<sup>5</sup> See Joseph E Stiglitz, *Globalization and Its Discontents* (New York: W.W. Norton & Co., 2002); Joseph E Stiglitz & Andrew Charlton, *Fair Trade for All: How Trade Can Promote Development* (Oxford: Oxford University Press, 2005); Margaret Chon, "Intellectual Property and the Development Divide" (2006) 27 Cardozo L Rev 2821.

<sup>6</sup> See Jurgen Habermas, *Theory of Communicative Action* (Cambridge: Polity Press, 1987); Ximena Fuentes, "International Law-Making in the Field of Sustainable Development: The Unequal Competition between Development and the Environment" in Nico Schrijver & Friedl Weiss, eds, *International Law and Sustainable Development* (Leiden: Martinus Nijhoff, 2004) 1 [Fuentes, "International Law-Making"].

precedence over private property right concerns. To achieve this vision, I propose and justify the creation of additional exceptions/limitations to patents with the goal of scaling up access to medicines to treat epidemics in poor regions such as SSA. This vein of argument stresses the positive gains that can be derived from an equitable and a human-oriented approach to pharmaceutical patent regulation in parts of Africa devastated by diseases such as Human immunodeficiency virus/Acquired immunodeficiency syndrome (HIV/AIDS), malaria, and tuberculosis (TB).

This study does not endorse the extremist position that pharmaceutical patents should be discarded outright as that is tantamount to legal nihilism. Machlup's oft-cited *locus classicus* applies: "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."<sup>7</sup> Perhaps, more enlightening are studies that have concluded that the international patent system is economically and socially unsound for less developed countries if an overwhelming majority of patents are granted to foreign nationals and western corporations.<sup>8</sup> Viewed this way, SSA countries would be encouraged to recalibrate the TRIPS<sup>9</sup> benchmarks on

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<sup>7</sup> Fritz Machlup, *An Economic Review of the Patent System* (1958, Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, United States Senate, 85<sup>th</sup> Congress, 2<sup>nd</sup> Session. Study No. 15). If such an irresolute conclusion was reached as to the net benefits of a patent system in the context of a developed country, such as the United States how much more a LDC in SSA?

<sup>8</sup> See e.g. Edith Tilton Penrose, *The Economics of the International Patent System* (Westport, Connecticut: Greenwood Press, 1973) [Penrose, *Economics of the International Patent System*]. For more of such studies see: A Samuel Oddi, "The International Patent System and Third World Development: Reality or Myth?" (1987) 63 Duke LJ 831 at 832, 843-853 [Oddi, "The International Patent System"]; Ikechi Mgbeoji, "TRIPS and TRIPS-Plus Impacts in Africa" in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 259 at 292 [Mgbeoji, "TRIPS and TRIPS-Plus in Africa"] [The reality is that the majority of patents issued in Africa are pharmaceutical patents, and the bulk of such patent-grants are owned by big pharma located mainly in the developed world].

<sup>9</sup> *Agreement on Trade Related Aspects of Intellectual Property Rights*, 1994, 33 ILM 81 [TRIPS or *TRIPS Agreement*]. This treaty was one of the 28 international instruments that concluded the Uruguay Round of Multilateral Trade Negotiations, which began in 1986 at Punta del Este, Uruguay. The final

patents in order to address public health challenges that confront their citizens. Also, given that TRIPS – and patents – are here to stay, the globalized patent regime and its domestic prototypes must be recalibrated to serve human development needs in SSA.

What distinguishes this study from other patent and development studies<sup>10</sup> is that I advocate including human development principles as an integral part of pharmaceutical patent protection. As a consequence, the human development concepts that are articulated in this study are universal norms that transcend differences in domestic culture and class. For instance, Baruah, in commenting on the ‘human capabilities approach’<sup>11</sup> to development, perspicaciously observes that “universal norms are actually required if we are to protect diversity, plurality and freedom, treating each human being as an active agent instead of as a means to an end.”<sup>12</sup> The fundamental challenges posed by diseases in SSA, coupled with the lack of access to medicines to treat same, recur across the entire region. The globalized patent rules seemingly disregard the world’s cultural diversity and social values. Therefore, the proposed pharmaceutical patent regulatory prescriptions (meshed with practical human development-oriented concepts) can ameliorate human conditions across SSA, no matter the cultural differences and domestic conditions. The proposed patent regulatory framework can co-exist with a plurality of domestic culture, politics and history in SSA.

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Act was adopted on 15 April 1994 in Marrakesh, Morocco, and it entered into force on 1 January 1995 as part of the founding of the WTO.

<sup>10</sup> See e.g. Denis Borges Barbosa et al, “Slouching Towards Development in International Intellectual Property” (2007) *Mich St L Rev* 71 at 75 [much of the patent and development rhetoric has been confined to economic development and increase in gross national income]; Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth*, 2<sup>nd</sup> ed (Geneva: WIPO, 2003) at 135 [IP is the Cinderella for economic growth and development].

<sup>11</sup> The capability theory has been the mantra of renowned scholars such as Amartya Sen (winner of the 1998 Nobel Prize in economics) and Martha Nussbaum. See: Sen, *Development as Freedom*, *supra* note 4; Nussbaum, *Women and Human Development*, *supra* note 4. See also Martha C Nussbaum, “Capabilities and Human Rights” (1997) 66 *Fordham L Rev* 273.

<sup>12</sup> Bipasha Baruah, “Human Capabilities and Gender Justice: A South Asian Perspective” in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003) 19 at 23.

## A. Hypotheses

This study proceeds on the fundamental conceptual premise that patents can play a seminal role in scaling up access to medicines in SSA. The patent system is a social institution established for a social purpose, namely, to enable society to express its commitment to achieve human development and progress.<sup>13</sup> As such, a patent regulatory framework that facilitates access to medicines will alleviate human suffering and, as a corollary, promote human development. It will further facilitate public health programs in poor countries in Africa. Regrettably, the globalized pharmaceutical patent system was developed without serious consideration of the interests of the disempowered poor, especially those in SSA. The globalized pharmaceutical patent regulatory framework (sustained by laws, institutional arrangements, practices, and politics) neglects human needs and the concerns of the world's poor, and thereby produces and perpetuates inhumane deprivations of catastrophic dimensions. It makes patented medicines unaffordable and/or inaccessible to the suffering masses in SSA. Also, patents do not always promote the development of socially beneficial drugs, especially those that can treat neglected/tropical diseases that afflict the poor in SSA.

Further, I argue that countries in SSA and their citizenry have been marginalized from both international and domestic policies that touch on matters of access to pharmaceuticals. This exclusion (or lack of involvement), it will be argued, adversely affects how both the domestic and global patent regimes work and eventually contributes to impoverishing countries in SSA. In addition, the drivers of the international patent regulatory framework have reneged on a central goal of patent law: to promote social benefits. This goal is confirmed by Articles 7 and 8 of the *TRIPS Agreement* which provide that intellectual property (IP) protection should be seen as a social policy instrument for societal benefits and the promotion of economic welfare, public health, and public interest. Thus far, countries have sought to champion this social benefit goal

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<sup>13</sup> Penrose, *Economics of the International Patent System*, *supra* note 8 at 22.

by insisting that IP should “benefit society as a whole” rather than aiming at “the mere protection of private rights.”<sup>14</sup>

More specifically, I will be working from the hypothesis that the globalized pharmaceutical patent regulatory framework now primarily serves the needs of big pharma. Any allusion to alleviating human suffering is instrumental rhetoric behind which lurks the governing commercial imperative of wealth accumulation and shareholder value.<sup>15</sup> Western-engineered policies as regards pharmaceutical patents fail to adequately recognize the wide gap between human conditions in the north and south. In addition, the underlying public policy objectives of international patent institutions and actors to deliver development and technology transfer to the south have been largely unmet while people die from otherwise ‘curable’ diseases.<sup>16</sup> Thus, the central goal of a pharmaceutical patent regulatory framework to promote social benefits is not being realized.

What makes the situation worse is that those limitations that could serve as checks-and-balances against excessive exploitation of pharmaceutical patents are being gradually eroded to serve the interests of private innovators. As will be shown, emblematic of this erosion of the public interest is the recent push for African countries to accept increased standards of protection for pharmaceuticals, among others, via bilateral trade agreements with the West. The surge in bilateralism threatens to undercut any gains made in the last decade to mitigate the hardships associated with the globalized patent regime. The

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<sup>14</sup> See submission to the TRIPS Council by the African Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela, IP/C/W/296, June 19, 2001.

<sup>15</sup> Margaret Llewelyn, “Schrodinger’s Cat: An Observation on Modern Patent Law” in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 11 at 14.

<sup>16</sup> See generally: Robert C Bird, “Developing Nation and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects” (2009) *Pharmaceutical Regulations* 209; William W Fisher & Talha Syed, “Global Justice in Healthcare: Developing Drugs for the Developing World” (2007) 40 *UC Davis L Rev* 581.

globalized pharmaceutical patent regime, in its present form, is thus a drawback to the pursuit of human development in SSA.

Worse still, the participation of countries in SSA to ameliorate and change the situation has been lacklustre for two reasons. First, negotiations that led to the globalized patent framework epitomize what Fuentes refers to as a ‘democratic deficit’<sup>17</sup>, a common phenomenon that has characterised the international legal order.<sup>18</sup> Second, the participation of the citizens of countries in SSA in domestic decision-making processes and the drafting of pharmaceutical patent regulatory policies defy basic tenets of democratic deliberation. Western ‘experts’ are unleashed onto SSA countries to draft domestic patent laws in compliance with international law without taking into account the needs of the people affected.<sup>19</sup>

The failure of deliberation and democratic safeguards has rendered many western-sponsored pharmaceutical patent laws inimical to human development needs of the citizens of SSA. Patent laws have been enacted in many SSA countries without serious consideration of local sensibilities and realities, including access to medicine challenges and the high incidences of epidemics. Also, pharmaceutical patents are granted in SSA without significant input from national patent offices and local lawyers, except the collection of filing and professional fees. Patent laws and institutions have thus failed to promote diversity by inhibiting the ability of policy-makers to formulate policies that strike a chord with the dire human conditions in SSA. These regulatory deficiencies will be highlighted in chapters 3, 4 and 5 of this study.

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<sup>17</sup> This refers to the lack of meaningful public participation in the decision-making processes, which lead to the adoption of policies that affect a state and its citizenry.

<sup>18</sup> Fuentes, “International Law-Making”, *supra* note 6 at 12-14.

<sup>19</sup> Oddi, “The International Patent System”, *supra* note 8 at 854.

This lack of reflection on the concerns and interests of less developed countries<sup>20</sup> by the international polity leads to pharmaceutical patent protection that accentuates rather than alleviates the sufferings of the citizens of SSA. Existing pharmaceutical patent protections do not encourage pharmaceutical companies to develop new medicines to treat diseases prevalent in less developed countries,<sup>21</sup> serve the instrumentalist goals of powerful multinational corporations, marginalize the voiceless in the south and create social disparities.<sup>22</sup> Patent protection undermines efforts to develop regulatory policies aimed at promoting affordability of and/or access to essential life-saving medicines needed to achieve sustainable human development in SSA. Patents also undermine public health policies in SSA, and the consequences for human development agendas in those countries are staggering. To address the excesses of the globalized patent regime, I propose and justify the need to create additional exceptions/limitations to the exercise of pharmaceutical patent rights in order to scale up access to medicines to treat epidemics and, as a corollary, promote human development in SSA.

Admittedly, no cluster of approaches can solve the myriad problems that confront the African continent. Indeed, it would be naïve to profess that reforming the pharmaceutical patent regulatory framework alone will be enough to solve the multi-faceted problems that confront persons in SSA. There cannot be a single ‘silver-bullet’ regulatory prescription for tackling the myriad of development challenges, including poverty, corruption, and political upheavals that confront countries in Africa. The ability of the pharmaceutical regulatory environment to promote human needs and welfare depends on

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<sup>20</sup> In this study, I use the phrase ‘less developed countries’ in reference to both developing and least developed countries, especially in SSA. However, in discussing the details of the *TRIPS Agreement* and other internationally recognized classifications, I separate developing countries from least developed countries. Also, in citing other works, I retain the terminologies used in the original sources.

<sup>21</sup> Sumner La Croix & Ming Liu, “Patents and Access to Essential Medicines” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 423 at 429 [Croix & Liu, “Patents and Access to Medicines”].

<sup>22</sup> Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006) at 2 [Mgbeoji, *Global Biopiracy*].

the economic and patent institutional arrangements in place. These institutional arrangements include: a functioning public health care system, public health insurance schemes, and health infrastructure. But as it stands, some of these regulatory and institutional arrangements to scale up access to medicines to treat pandemics are either lacking or pitiable. For instance, Rwanda with a population of approximately 9.3 million has only 30 hospitals in the entire country and there is only one physician for every 60,000 people.<sup>23</sup> Although poverty- and other economic-related activities are equally important, they need not detain us here. Indeed, chapter 6 of this study will show that patenting of pharmaceuticals, and its effects on medicine pricing, remains an important factor for the lack of sufficient access to medicines in SSA.

Also, the realization of some of the regulatory proposals that I will suggest in this study will require industrial and scientific capacity-building in SSA, such as building a critical mass of scientists and industrial/manufacturing capabilities. An UNCTAD report confirms that there are only 83 scientists and engineers per 1 million populations in SSA.<sup>24</sup> This limited capacity is recognized by the African Union, which has urged member states to formulate a plan of action that facilitates increased drug manufacturing in the region and bolsters research and development.<sup>25</sup> A work such as this cannot find an overall cure to the oligarchic maladies that plague SSA. It will only give modest directions on the need to infuse human development principles into pharmaceutical patent regulatory regimes and suggest mechanisms as to how to undertake that task.

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<sup>23</sup> See Christina Cotter, “The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries” (2008) 5 *Loy U Chi Int’l L Rev* 177 at 179-180.

<sup>24</sup> United Nations Conference on Trade and Development (UNCTAD), *Foreign Direct Investment and the Challenge of Development*, in *World Investment Report* (1999). The total pharmaceutical patents those scientists hold in SSA also remain a matter for debate.

<sup>25</sup> See African Union, *The First of the Technical Committee on the Pharmaceutical Manufacturing Plan for Africa* (2007) Addis Ababa, TCPMPA/RPT (1), online at <<http://www.african-union.org/root/au/Conferences/2007/october/sa/Pharmaceutical/DOCS/REPORT.do>>.

In sum, like the title of Tina Turner's famous song 'What's Love Got to Do with It?': what's pharmaceutical patent regulation got to do with development? The answer in this work is that pharmaceutical patent protection has got a lot to do with social agendas and, for that matter, human development agendas in SSA. Patents occupy a central place in the innovation system, which delivers medicines to the masses<sup>26</sup>; the regime of patents affects medicine pricing on the markets and, for that matter, access to life-saving medicines at affordable prices in SSA. Patents can also stall the supply of cheaper generics to poor countries in SSA. On the flip side, adopting pro-access patent regulatory and institutional mechanisms can provide avenues for tackling burgeoning threats of pandemics such as HIV/AIDS, malaria, and TB in SSA.

## II. Pandemics at a Glance

This study focuses on three epidemics – HIV/AIDS, malaria, and TB – that have ravaged, and continue to ravage, countries in SSA. Focusing on HIV/AIDS, malaria, and TB is not accidental; the trio constitute the most fundamental threat to human survival in SSA. They have also been consistently ignored by big pharma.<sup>27</sup> They are considered as neglected/tropical diseases, if not a black man's burden, with its racial colorations. As a consequence, big pharma do not feel obligated to supply medicines to treat 'neglected diseases' as they are less of a problem in the developed world.<sup>28</sup> Also, those who suffer

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<sup>26</sup> See Richard Gold et al, "Toward a New Era of Intellectual Property: From Confrontation to Negotiation" (2008) *A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property*, online: [http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf).

<sup>27</sup> The phrase 'big pharma' refers to the world's fifteen largest pharmaceutical companies, which dominate the global drug-market economy. They are: Pfizer (US), Johnson & Johnson (US), Bayer (Germany), Roche (Switzerland), Novartis (Switzerland), GlaxoSmithKline (UK), Sanofi-Aventis (France), AstraZeneca (UK/Sweden), Abbott Laboratories (US), Merck & Co. (US), Bristol-Myers Squibb (US), Eli Lilly & Company (US), Boeringer Ingelheim (Germany), Takeda Pharmaceutical Co. (Japan), and Amgen (US). These pharmaceutical giants own 66 per cent of the world's pharmaceutical market. Out of the remaining 34 per cent market share, 24 per cent is owned by the supporting nexuses (i.e. biotech firms) of those same big pharma and 10 per cent belongs to the generic companies.

<sup>28</sup> Michele Boldrin & David K Levine, *Against Intellectual Monopoly* (Cambridge: Cambridge University Press, 2008) 71. This contrasts with the widely reported mad rush in the west to find vaccines to treat H1N1 flu ('swine flu') pandemic because it is a western burden?

from diseases such as malaria and TB are overwhelmingly poor, a further disincentive for pharmaceutical corporations to invest capital in medicine research and development (R&D) efforts.<sup>29</sup>

The good news is that, recently, a number of global initiatives to combat pandemics have focused on these three epidemics. For instance, recent World Health Organization (WHO) initiatives have focused on finding treatments for HIV/AIDS, malaria, and TB cases in Africa, among others.<sup>30</sup> An ongoing initiative by the international drug agency UNITAID to establish a patent pool to boost innovation and access to medicines has focused on the HIV/AIDS, malaria, and TB epidemics.<sup>31</sup> Further, the UN Millennium Development Goals (MDGs) advocate the need to combat the HIV pandemic, malaria and other diseases in order to ensure sustainable development. The fact that there are available statistical data about these three pandemics makes them suitable for this enquiry.

A major drawback, however, is that most of the statistical data about HIV/AIDS, malaria, and TB are dated. The timelines between when the information was gathered and published make some of the data deceptive by understating the true extent of the

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<sup>29</sup> Mattias Ganslandt et al, “Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal” in Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005) 207 at 208 [Ganslandt et al, “Developing and Distributing Medicines”].

<sup>30</sup> An instance is the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property’s implementation of the World Health Assembly’s Resolution 59.24 to secure “an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.” In May 2008, another World Health Assembly Resolution 61.21 was passed to address the issues of need, access and production of health care products in developing countries. See also paragraph 1 of the Doha Declaration’s acknowledgement of the gravity of public health issues facing developing countries such as *HIV/AIDS*, *TB*, *malaria* and other epidemics. Although this latter outcome was reached within the WTO system, the WTO’s pro-medicine-access policies championed that cause to make access to medicines in less developed countries a priority.

<sup>31</sup> UNITAID, online: <<http://www.unitaid.eu/>>. UNITAID, on its website, has declared its mission “to contribute to scaling up access to treatment for *HIV/AIDS*, *malaria* and *tuberculosis*, primarily for people in low-income countries, by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available” (emphasis added).

pandemics. Quite naturally, some of the infections, as reported, have increased consonant with population increase.<sup>32</sup> At times, the absence of up-to-date data in connection with these three pandemics gives a false sense of comfort as regards their impact on human development and leaves room for ‘global success-stories’ of dubious merit.

HIV/AIDS, malaria, and TB epidemics threaten the moral, economic and political fabric of societies in SSA. While for some like Nigeria’s ex-President, Olusegun Obasanjo, the prospect of extinction of the entire African continent looms larger and larger due to the threat of the HIV/AIDS pandemic,<sup>33</sup> for others, Obasanjo’s assertion may be viewed as too polemical, as a UN report in 2011 has revealed that there had been a nearly 25 per cent decline in new HIV infections and a reduction in AIDS-related deaths during the past decade.<sup>34</sup> The relative success in improving access to life-saving medications has reduced HIV/AIDS-related mortality rates in SSA.

However, despite claims of progress in the fight against the HIV/AIDS epidemic in some parts of Africa, SSA still remains the epicenter of the AIDS epidemic.<sup>35</sup> By conservative estimates, two-thirds of the world’s HIV infection is in SSA, and more than three in four (76 per cent) AIDS-related deaths occur in SSA.<sup>36</sup> Worse still, the Africa region accounts for 67 per cent of the world’s Least Developed Countries (LDCs) and as a result millions of people infected with HIV do not have access to medicines. It has been estimated that only 2 per cent of persons needing antiretroviral treatments in Africa are actually

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<sup>32</sup> There are several reports of the upsurge in the AIDS crisis in parts of Africa. See e.g. BBC, “World ‘losing fight against Aids’” (23 July 2007), online: <<http://news.bbc.co.uk/2/hi/asia-pacific/6911736.stm>>; Sara Woolf, “Moving beyond the Horror” *McGill Reporter* (10 September 2009) at 7.

<sup>33</sup> This point was taken from Wesley A Cann, “On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism” (2004) 25 U Pa J Int’l Econ L 755 at 765 [Cann, “IP Rights and Less Developed Countries”].

<sup>34</sup> See UNAIDS, *AIDS at 30: Nations at the Crossroads* (2011), online: <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

<sup>35</sup> See UNAIDS & WHO, *Sub-Saharan Africa: AIDS Epidemic Update Regional Summary* (2008), online: <[http://data.unaids.org/pub/Report/2008/JC1526\\_epibriefs\\_subsaharanafrica\\_en.pdf](http://data.unaids.org/pub/Report/2008/JC1526_epibriefs_subsaharanafrica_en.pdf)>.

<sup>36</sup> See *2007 AIDS Epidemic Update*, UNAIDS/07.27E/JC1322E (Geneva: UNAIDS & WHO, 2007).

receiving them.<sup>37</sup> People cannot afford to buy patented brand name medicines and, most often, people on antiretroviral regimen experience treatment interruptions due to financial difficulties.<sup>38</sup>

There is also ample evidence to support the fact that HIV/AIDS has become a national emergency in parts of Africa, especially in Southern Africa, and it could as well become an uncontrollable epidemic in the future. For instance, Ganslandt et al have revealed that:

In Botswana, 36 percent of adults are now infected with HIV, whereas in South Africa, the figure is 20 percent. South Africa has 4.2 million infected people, the largest number in the world. These figures are rising at alarming rates....Economic studies suggests that the South African gross domestic product (GDP) will be 17 percent lower in 2010 than it would be without AIDS, removing US\$22 billion in output from the economy. In Botswana, there could be a 13 to 15 percent reduction in the income of the poorest households.<sup>39</sup>

HIV/AIDS is not the only challenge confronting countries in SSA. More conservative estimates of the number of malaria cases (over 300 million) show an alarming number of malaria-related deaths in Africa.<sup>40</sup> Presently, malaria remains the number-one killer-disease in SSA. Forty-five countries within the WHO African region were said to be endemic for malaria in 2008.<sup>41</sup> Malaria maims children and causes millions of maternal deaths. The disease is reported to have accounted for nearly 1 million global deaths in 2008, with 91 per cent in Africa. Despite progress in malaria control interventions, through public health services, access to treatment and prevention is reportedly

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<sup>37</sup> See Cann, "IP Rights and Less Developed Countries", *supra* note 33 at 765.

<sup>38</sup> See Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) at 5, citing MSF Report, "Forcing Patients to Pay for AIDS Care Endangers Treatment Success" (2005).

<sup>39</sup> Ganslandt et al, "Developing and Distributing Medicines", *supra* note 29 at 212.

<sup>40</sup> Paula E. Brentlinger, "Health, Human Rights, and Malaria Control: Historical Background and Current Challenges" (2006) 9(2) Health and Hum Rts 11 at 12, citing WHO, *World Malaria Report*, (Geneva: WHO, 2005) [Brentlinger, "Health, Human Rights, and Malaria"].

<sup>41</sup> WHO, *World Malaria Report* (2008), online: <<http://apps.who.int/malaria/wmr2008/malaria2008.pdf>>.

inadequate.<sup>42</sup> This situation is further exacerbated by inequities in access to malaria prevention and treatment efforts in Africa.<sup>43</sup> In addition, there is insufficient R&D into new anti-malarial vaccines and medicines.<sup>44</sup> The high rate of malaria-related deaths in Africa does not, however, negate the possibility that HIV/AIDS epidemic in SSA (if unchecked) could surpass the threat of malaria in the near future.

Likewise, the threat of TB looms large across SSA. The Africa region accounted for 31 per cent of the global 9.27 million reported cases of TB in 2007.<sup>45</sup> Tuberculosis remains prevalent among infants in SSA. For example, the reported TB incidences in 2007 represented a modest increase in TB infections as compared to those of 2006 (9.24 million). Within that period, Nigeria and South Africa accounted for nearly 1 million of the global reported TB cases. What makes TB more lethal is that a sizeable number of persons infected and affected by TB are also HIV-positive, especially in SSA.<sup>46</sup>

As the statistics suggest, the effects of diseases such as HIV/AIDS, malaria, and TB on SSA are not a simple health crisis; rather, those diseases represent the most immediate and long-term threats to sustainable human development in SSA.<sup>47</sup> The AIDS pandemic impacts on all sectors of national activity and on human lives: first, by killing the labour force at its prime; second, by increasing the costs associated with health care provision, prevention efforts, and the sustainability of health care institutions; third, by diverting money from other equally important initiatives like education and rural development.<sup>48</sup> Also, costs associated with the treatment of health-related afflictions caused by malaria

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<sup>42</sup> WHO, *World Malaria Report 2008*, *ibid*.

<sup>43</sup> Brentlinger, "Health, Human Rights, and Malaria", *supra* note 40 at 13.

<sup>44</sup> Ganslandt et al, "Developing and Distributing Medicines", *supra* note 29 at 212.

<sup>45</sup> WHO, *Global Tuberculosis Control* (2009), online: [http://www.who.int/tb/publications/global\\_report/2009/pdf/full\\_report.pdf](http://www.who.int/tb/publications/global_report/2009/pdf/full_report.pdf).

<sup>46</sup> WHO, *Global Tuberculosis Control 2009*, *ibid*.

<sup>47</sup> Bjorg Sandkjaer, "HIV/AIDS and African Sustainable Development" (2007) 3(1) McGill JSDLP 1 at 2.

<sup>48</sup> See Sandkjaer, "HIV/AIDS and African Sustainable Development", *ibid* at 9.

and TB have ballooned and diverted resources away from other human development goals.

Supposed progress in combating the three pandemics cannot caricature the realities on the ground. The reality that confronts SSA is that countries lag behind in comfortably sharing in the ‘global success stories’ in the fight against the above epidemics. Generally, fears of discrimination, stigma, and social exclusion, coupled with limited access to medicines to treat those pandemics negatively affect the people in SSA. According to a recent UN report, “53% of Rwandans living with HIV have been verbally insulted, 33% of rural Zambians living with HIV have experienced physical violence, and 65% of Rwandans living with HIV have lost a job or income opportunity.”<sup>49</sup> Therefore, relieving countries of these human tragedies is perhaps the most important issue that should be on the agenda of policy-makers. An equitable and human-oriented patent regulatory framework can play that essential role in relieving these quagmires and helping to ensure sustainable human development in SSA. This study will thus seek to establish and elucidate the above contentious points through a multidisciplinary approach to legal research.

### **III. Methodology**

This study employs a multidisciplinary approach to legal research. It links seemingly disconnected pharmaceutical patent-related negotiations, processes and events that expose the continued alienation of persons and countries in SSA from the domestic and international patent polity. It draws on history, philosophy, law, economics, policy studies, and development theory as foundations for arguing for pharmaceutical patent reforms in SSA. It undertakes a detailed review of primary documents and secondary literature that portray the dire reality of the human situation in SSA of HIV infections, malaria and other debilitating diseases. The breadth of materials will ensure impartial and

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<sup>49</sup> UNAIDS, “Grounding the Response in Human Rights and Gender Equality” in *AIDS at 30: Nations at the Crossroads* (2011), online: <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

critical consideration of the pharmaceutical patents and development debate in a poly-centric manner. It is also hoped that relying on these multiple sources will assist in overcoming some of the limitations associated with disciplinary fixation (i.e., recounting legal rules without reflecting social reality). Elsewhere, researchers have sought to overcome this deficiency in patent law via the use of a ‘trans-disciplinary approach’<sup>50</sup> to investigate the subject of biotechnology protection.<sup>51</sup>

In addition to the above, the study will analyze relevant instruments belonging to regional institutional bodies, such as the African Regional Intellectual Property Organization (ARIPO)<sup>52</sup> based in Harare, Zimbabwe, in order to understand the state of patent regulation in SSA. Similarly, available and relevant pharmaceutical patent-related instruments from ARIPO’s counterpart for nations of francophone Africa – Organisation Africaine de la Propriété Intellectuelle (OAPI)<sup>53</sup> – will be examined. This will enrich my perspective and analysis of the context and the issues discussed.

Further, this study will employ practical evidence from patent administrators, scholars and practitioners in affirming its claims. The experience of policy-makers in SSA during negotiations that led to the establishment of the globalized pharmaceutical patent regime will be employed to substantiate other claims in the literature. The evidence from policy-makers will also assist in making concrete suggestions for improvements in

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<sup>50</sup> This involves an evaluative approach that builds on disciplinary assumptions while at the same time advocating a move beyond disciplinary biases. The methodological approach employed in this study draws some inspiration from this ‘trans-disciplinary’ evaluative model.

<sup>51</sup> See E Richard Gold et al, “The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation” (2004) 18(4) Public Affairs Quarterly 299. In this study, Gold et al describe seven probes that facilitate a more subtle, contextual and structural analysis of patents in the field of biotechnology.

<sup>52</sup> ARIPO was established at a diplomatic conference held at Lusaka, Zambia, in 1976. At present, its membership comprises 18 countries: Botswana, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Somalia, Sudan, Swaziland, Uganda, Tanzania, Zambia, and Zimbabwe.

<sup>53</sup> OAPI was established in 1962 at Libreville. Presently, it has 16 member-states, which consist of Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo.

pharmaceutical patent regulation in SSA. Additionally, the patent legislation of four countries in SSA will be examined in chapter 5 of this study. These countries include Ghana, Uganda, Botswana, and South Africa. The South African experience will lead the way in this discussion, however. The discussion of the statutory frameworks of the four selected countries will be employed to draw conclusions about patent protection *vis-à-vis* efforts to tackle epidemics in countries in SSA.

These four countries were chosen for three reasons. The first reason is geographical. At least one country from each sub-regional component of the Africa region should be chosen to give a balanced representation of the patent regulatory environments in the whole region. The second reason is that those four countries have relatively well established institutional and regulatory infrastructure that can facilitate this research. The third reason is based on the prevalence of the pandemics in SSA. A balanced portrayal of the pandemic situations across all parts of SSA will assist in making concrete proposals for change. Thus, focusing entirely on a country that is densely affected with, let's say, an HIV/AIDS epidemic will distort the reality in other places that are less densely affected.

For instance, Ghana among all the four countries has the lowest reported HIV infection rate. The WHO's estimated national rate of HIV infection as of 2005 stood at 2.7 per cent.<sup>54</sup> This estimate is based on 30 per cent of actual reported AIDS cases in Ghana. The prevalence rate among persons in Ghana between the ages of 25 and 29 years stood at 3.8 per cent and that of persons between the ages of 45 and 49 years stood at 5 per cent. A 2007 report by the UNAIDS however indicates a reduction in the national HIV prevalence to 1.9 per cent.<sup>55</sup>

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<sup>54</sup> See WHO, *Ghana Annual Report* (2005), online: [http://www.who.int/countries/gha/publications/WHO\\_Ghana\\_2005\\_Report\\_Final.pdf](http://www.who.int/countries/gha/publications/WHO_Ghana_2005_Report_Final.pdf).

<sup>55</sup> See UNAIDS, *Ghana Situation* (2008), online: [http://data.unaids.org/pub/FactSheet/2008/sa08\\_gha\\_en.pdf](http://data.unaids.org/pub/FactSheet/2008/sa08_gha_en.pdf).

Uganda stands in the intermediate position with an infection rate of about 6.3 per cent among persons between the ages of 15 and 59 years.<sup>56</sup> This figure is hailed as a significant reduction in the HIV prevalence rate in Uganda since previous reports had quoted 30 per cent.<sup>57</sup> Botswana and South Africa represent the worst infection case scenario in SSA. The national averages for both Botswana and South Africa are estimated at 30 per cent or more.<sup>58</sup> The above reported cases of infections among the four countries give a fair indication about the trend of HIV/AIDS pandemic in SSA. Malaria and TB infections cut across the entire SSA but are very predominant in the western and southern parts.

In conclusion, extrapolating from multiple evidentiary sources has several virtues. It enables pharmaceutical regulatory policies to be examined from perspectives supported by concrete evidence which previous research has not undertaken. The practical evidence is also used to validate anecdotes and claims in other written sources from which this study draws heavily. It provides the opportunity to objectively analyze the peculiar circumstances of the world's poorest region that has long been forgotten, both literally and figuratively. It also provides the opportunity to shed light on how marginalization of SSA in international patent polity has been replicated in policies pertaining to access to medicines in SSA countries. It is through this analysis that we can make concrete and realistic suggestions for patent regulatory and institutional changes in SSA.

The analysis of the above primary and secondary sources takes place against a framework of laws, institutions, practices, and politics employed in this study. The concepts of laws, institutions, practices, and politics (discussed in greater depth in chapter 2) are referred to

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<sup>56</sup> See Ugandan AIDS Commission, *UNGASS Uganda Progress Country Report* (2008), online: <[http://datAunaid.org/pub/Report/2008/uganda\\_2008\\_country\\_progress\\_report\\_en.pdf](http://datAunaid.org/pub/Report/2008/uganda_2008_country_progress_report_en.pdf)>.

<sup>57</sup> See WHO/AFRO, *Uganda Country Health Profiles*, online: <<http://www.afro.who.int/uganda/aids.html>>.

<sup>58</sup> See UNAIDS, *Sub-Saharan Africa: AIDS Epidemic Update* (2008), online: <[http://datAunaid.org/pub/Report/2008/JC1526\\_epibriefs\\_subsaharanafrica\\_en.pdf](http://datAunaid.org/pub/Report/2008/JC1526_epibriefs_subsaharanafrica_en.pdf)>.

as a ‘quadripartite framework.’ The interaction between laws, institutions, practices, and politics is employed as a methodological guide to elucidate the actual impact of the globalized patent regime on human lives in SSA and suggest realistic reforms. Thus, to fully understand the literature, the culture of western domination and the ensuing asphyxiation of the public access-to-medicine goals in SSA, one needs to appreciate the workings of the legal, institutional, political, and practical developments in the pharmaceutical patent industry, both at the domestic and at the international levels. Suffice it to say that this examination of the impacts of the globalized pharmaceutical patent regime and the quest for regulatory reforms to promote human development will be undertaken within the context of SSA, which I introduce below.

#### **IV. Sub-Saharan Africa**

##### **A. SSA in Global Matrices**

The global economy is delineated by overlapping spheres of north and south, developed and developing, industrialized and non-industrialized, west and non-west, colonializer and colonializee, civilized and uncivilized, and so forth. Countries in SSA are mostly consigned to the latter categorizations. And, their people, according to Oguamanam, are “mainly depicted in derogatory terms such as wild, primitive, undomesticated hunter-gatherers, savages and barbarians who were in dire need of civilization and transformation into decent or modern societies.”<sup>59</sup> Indeed, other categorizations rank a number of countries in SSA as third world, under-developed, LDCs and as subaltern states.<sup>60</sup> These categorizations have been criticized as contributing to the continued

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<sup>59</sup> Chidi Oguamanam, “Local Knowledge as Trapped Knowledge: Intellectual Property, Culture, Power and Politics” (2008) 11 *Journal of World Intellectual Property* 29 at 33 [Oguamanam, “Local Knowledge as Trapped Knowledge”].

<sup>60</sup> See e.g. Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003).

marginalization of non-western states so as to perpetuate a neoliberal agenda<sup>61</sup> and have also been criticized as derogatory, anachronistic and misleading.<sup>62</sup>

Perhaps blaming the plight of non-western states on neoliberal categorizations alone is an exaggeration. It diverts attention from real issues and focuses too much on form rather than substance. After all, “the diversity of the social world has not prevented the consolidation and articulation of international [patent] law in universal abstractions.”<sup>63</sup> The categorizations merely emphasize the wide schism between rich-west and poor-south. Indeed, the TRIPS patent regulatory framework categorizes World Trade Organization (WTO) member-states into developed, developing, and least developed countries. Therefore, as a convenient tool of analysis in this study, I employ terminologies such as less developed countries, developing and least developed countries in reference to countries in SSA.

## **B. Focus on the Africa Region**

This study focuses on SSA, with particular regard being paid to the pandemic situations and the patent systems in four countries: Ghana, Uganda, Botswana, and South Africa. The SSA-region-wide evidence relating to HIV/AIDS, malaria and TB infections will be taken into account. The study will draw heavily from available but relevant evidence from countries in the entire SSA region. In addition to relying on general evidence from SSA, this study will examine country-specific patent regulatory frameworks of Ghana, Uganda, Botswana and South Africa to make generalizations to cover the entire region. In addition, experiences of other countries and regions will be brought to bear on the way

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<sup>61</sup> See BS Chimni, “Third World Approaches to International Law: A Manifesto” in Antony Anghie *et al*, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003) 47.

<sup>62</sup> See Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (Cambridge: Cambridge University Press, 2005) at 3.

<sup>63</sup> Chimni, “Third World Approaches to International Law”, *supra* note 61 at 49.

forward for SSA in designing pro-access patent regulatory and institutional mechanisms for sustainable human development.

As earlier indicated, SSA comprises 48 countries. The countries are: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, and Zimbabwe. The thread that runs through all these countries is that the rate of pandemics such as HIV/AIDS, malaria, and TB is relatively high as compared to that of other regions of the world. Also, the human development indexes of most countries in SSA near or fall below 0.5 per cent, representing a critical threshold of low-level human development.<sup>64</sup>

In addition, statistics from the United Nations indicate that out of the above 48 countries in SSA, 34 are LDCs; they are: Angola, Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, Sudan, Tanzania, Togo, Uganda, and Zambia. Cumulatively, the total number of 34 LDCs in Africa (out of the 49 worldwide LDCs) constitutes more than 67 per cent (two-thirds of the world's LDCs), and their overall share in world trade is less than 1 per cent. For instance, a country such as Senegal was once a developing state until it regressed to LDC status. Indeed, Kenya has also

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<sup>64</sup> See Ubong E Effeh, "Back to the Future: The UNDRD as a Blueprint for the Realization of Human Rights and Sustainable Development in Sub-Saharan Africa" (2008) 4 McGill JSDLP 133 at 137 [Effeh, "Back to the Future"].

contemplated joining the LDC category in the past. Besides those *de jure* LDCs recognised by the UN, developing countries, such as Zimbabwe, have devolved from being developing states to becoming *de facto* LDC. Africa's leadership challenges have caused many states to flounder.

More specifically to this study, LDCs such as Benin, Burkina Faso, Burundi, Chad, Central African Republic, Democratic Republic of Congo, Gambia, Guinea, Guinea-Bissau, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Swaziland, Tanzania, Togo, Uganda, and Zambia, have all provided protection for pharmaceutical patents since 2006.<sup>65</sup> Another study has confirmed that all but three LDCs in SSA comply with the standards of the *TRIPS Agreement* in domestic IP laws.<sup>66</sup> These countries' far-reaching protections for pharmaceutical products and processes fly in the face of the moratorium under international law, notably the TRIPS/Doha Declaration, which allows LDCs to deny protection to pharmaceuticals until 2016.<sup>67</sup> As I explain in chapter 3 of this study, technical assistance initiatives provided by the developed world in domesticating TRIPS obligations have steered policy makers to adopt strong pro-patent rules in SSA.

### C. Why focus on SSA?

Focusing on SSA as a region is important for several reasons. First, it is the entire SSA region that is worst hit by diseases such as HIV/AIDS, malaria, and TB. Recent UNDP human development index (HDI) confirms that 28 of the world's 31 LDCs with the worst life expectancy and standard of living are located in SSA. They rank below 0.5 per cent,

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<sup>65</sup> Croix & Liu, "Patents and Access to Medicines", *supra* note 21 at 439.

<sup>66</sup> See Mgbeoji, "TRIPS and TRIPS-Plus in Africa", *supra* note 8 at 290-291.

<sup>67</sup> See Decision by the Council for TRIPS of June 27, 2002, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for LDC Members for Certain Obligations with respect to Pharmaceutical Products*, WTO Doc IP/C/25, 1 July 2005. Besides pharmaceuticals, protection for other IP rights in LDCs was deferred until 1 July 2013. On this point see Decision of the Council for TRIPS, *Extension of the Transition Period under Article 66.1 for Least-Developed Country Members* (29 November 2005). This latter decision re-enforces the former decision.

representing a very low level of human development.<sup>68</sup> Therefore, in the context of access to medicines and its regulatory framework thereto, SSA is most suited for this enquiry. Second, most available statistical data about HIV/AIDS, malaria, and TB infections treat SSA as a composite whole or region. This study follows that approach. Third, according to Kihwelo, although SSA is rich in terms of natural resources, including potentially patentable biological resources, the region is the least beneficiary of its own lore and resources.<sup>69</sup> They serve as suppliers or, more appropriately, as conduits for funnelling biological resources to the industrialised world, with relatively meagre returns.<sup>70</sup> The question as to why countries in SSA least benefit from the globalized regulatory regime is apt for this enquiry. In this respect, the doors of that enquiry cannot be closed to parts of SSA.

Admittedly, countries in SSA have had their own internal problems with conflicts, dictatorships, corruption and so forth, but an examination of these ill-fated issues is beyond the scope of this study.<sup>71</sup> The region also has differences in terms of culture, religion, and customary practices among the people of the countries that constitute the region. It suffices to state that diseases such as the HIV, Malaria, and TB epidemics do not respect these cultural variations. The constitution of the human system is such that once a person contracts the virus or the parasite that gives AIDS or malaria, respectively,

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<sup>68</sup> See United Nations Development Programme (UNDP) *Human Development Reports* (2006), online: <<http://hdr.undp.org/en/reports/global/hdr2006/chapters/>>. This indexing is the most widely accepted measure of life expectancy, literacy, education, and standard of living. It focuses on human well-being rather than rankings based on gross national product.

<sup>69</sup> Paul F Kihwelo, "Indigenous Knowledge: What is it? How and why do we protect it?" (2005) 8 *Journal of World Intellectual Property* 345 at 346. See also Mgbeoji, *Global Biopiracy*, *supra* note 22 at 92.

<sup>70</sup> See Oguamanam, "Local Knowledge as Trapped Knowledge", *supra* note 59 at 33; Mgbeoji, *Global Biopiracy*, *ibid* at 88.

<sup>71</sup> For an enquiry into some of the causes of under-development and the lack of access to medicines in SSA see: Mgbeoji, "TRIPS and TRIPS-Plus in Africa", *supra* note 8; Effeh, "Back to the Future", *supra* note 64. Roger Bate, "Protectionism Won't Heal Africa's Sick: Incompetence, Corruption and Opportunism are Denying Africans the Drugs they Need", *The Wall Street Journal* (28 September 2009), online: <<http://online.wsj.com/article/SB10001424052970204488304574426903620319302.html>> [Uganda's national procurement and distribution system recently admitted that 93 per cent of the drugs it purchased did not reach intended recipients].

the situation of the person will eventually get worse without access to medicines and other health care services. Therefore, the proposal to integrate human development considerations into global and national patent regimes can ameliorate human conditions across SSA, no matter the cultural differences and domestic conditions.

Before setting out the structure of this thesis, it is worth pausing momentarily to define some of the concepts employed in this study.

## **V. Defining Basic Concepts**

In a study such as this, the use of definitions could be fraught with the dangers associated with limiting the contextual meaning of words. In the field of law and elsewhere, relying on definitions creates a greater temptation for tampering with the contextual meaning of words. However, lexical fluidity necessitates that some guidance is established in this study to aid in the interpretation of words and sentences that constitute the building blocks of this work. Also, one could not agree more with Oguamanam's point that the "clarification of key terms is congruous to analytical integrity and guards against misleading assumptions."<sup>72</sup>

In consequence, this following section, in a modest way, seeks to define or explain some of the pivotal concepts employed in this text. The meaning of concepts such as globalization, patent regulation, pharmaceuticals, negotiations, deliberative democracy, marginalization and sustainable development as employed in this study are explained. None of these concepts is devoid of ambiguity. However, the clarification of some of the terms employed here will assist the reader to follow the arguments advanced in support of this study. Thus, for purposes of this study, and unless otherwise established:

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<sup>72</sup> Oguamanam, "Local Knowledge as Trapped Knowledge", *supra* note 59 at 35.

## A. Globalization

Globalization refers to “discernible policies and trends associated with the liberalization of markets and the process of functional integration between widely dispersed economic activities, which are characteristic of those markets.”<sup>73</sup> Globalization embraces issues of the balance of power dynamics and the integration of the world economy among humans, institutions and nations. It involves negotiations by global actors and institutions to remove obstacles to trade and development, and the closer integration of national economies. On his part, Goode describes globalization as “the increasing integration of national economic systems through growth in international trade, investment and capital flows.”<sup>74</sup> As such, globalization universalizes rules, practices and institutions that regulate human affairs, including cultural, political and social aspects of human life. The domestic implementation of TRIPS is an example of globalization whereby states harmonize their laws and policies on IP.<sup>75</sup> In this vein, the phrase ‘globalized patent regime’ refers to the international patent rules and norms that have been universalized as part of trade liberalization. However, globalization, in its progressive modus, ensures that there is diffusion and transfer of technology (such as access to medicines) among pharmaceutical producing and consuming nations. In some instances, the term globalization is used interchangeably with harmonization in this text, with the former encapsulating the latter.

## B. Patent Regulation

Patent regulation refers to the rules and principles that govern transactions involving pharmaceutical products and processes, both at the national and at the international

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<sup>73</sup> Mary E Footer, “Technical Assistance and Trade Law Reform Post-Doha: Brave New World” in John Hatchard & Amanda Perry-Kessaris, eds, *Law and Development: Facing Complexity in the 21<sup>st</sup> Century* (London: Cavendish, 2003) 108 at 113.

<sup>74</sup> Walter Goode, *Dictionary of Trade Policy Terms*, 4<sup>th</sup> ed (Cambridge: Cambridge University Press, 2003) <<http://wto.ncieCgov.vn/Collections/Dictionary%20of%20trade%20%20policy%20terms.pdf>>.

<sup>75</sup> Graham Dutfield & Uma Suthersanen, *Global Intellectual Property Law* (Cheltenham: Edward Elgar, 2008) at 3.

levels. Regulation in the context of this study is used to denote protection or the juridical control of pharmaceuticals in the global market place. It involves the grant of an exclusive right over knowledge goods, such as medicines. In effect, terminologies like, policies, regulation, and protection are thus employed interchangeably throughout this text. They refer to standard rules and principles that deal with the terms, scope and issues of enforceability of patents as regards pharmaceuticals.

### **C. Pharmaceuticals**

Pharmaceuticals are health related products and processes, such as medicines, vaccines and diagnostics. The annex to the amendment to TRIPS defines a ‘pharmaceutical product’ as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health.”<sup>76</sup> In this vein, I use the terms ‘drugs’, ‘medicines’, ‘vaccines’, and ‘pharmaceuticals’ interchangeably in this study.

### **D. Negotiations and Deliberative Democracy**

Negotiation, in this study, is to a large extent used interchangeably with bargaining or deliberations. For negotiations (bargaining) to reflect the true interests and concerns of all the interlocutors, it must be based on good argument rather than power, and must be cognizant of the principles of deliberative democracy.<sup>77</sup> Deliberative democracy “requires a dialogue among equal subjects in an open, transparent and participatory way.... Democratic deliberation is the exchange of information and arguments by advancing, supporting and criticizing different proposals and offering reasons for the position

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<sup>76</sup> See WTO General Council, *Amendment to the TRIPS Agreement* WT/L/641 (8 December 2005), online: [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm).

<sup>77</sup> See Habermas, *Theory of Communicative Action*, *supra* note 6.

taken.”<sup>78</sup> As will be discussed in chapter 3, the power politics employed by the West during negotiations that led to the design of the international patent regime undermined this requirement of deliberative democracy or democratic bargaining.

As discussed further in chapter 3 of this study, the lack of informed dialogue and participatory democracy in negotiations leading to the construction of the globalized pharmaceutical patent regulatory framework has partly contributed to the marginalization of countries in SSA and their citizens. Such marginalization undermines the legitimacy of both domestic and international patent regulatory and institutional set-ups. The point is that ensuring people’s participation in their legislative processes will enhance the legitimacy of their laws and enhance the prospects of compliance.

## **E. Marginalization**

By marginalization, I mean the exclusion of countries in SSA from both formal and informal processes and events of international patent law making. The exclusion or unequal incorporation of persons and states within the national and the global economies, respectively, takes place alongside globalization. As explained in chapter 3, this exclusion can be latent, in the sense that the incorporation of less developed countries in patent deliberations may be in the spheres of non-key committees that do not have the final say in international trade relations. Also, marginalization can be as a result of primary challenges that confront less developed countries in achieving effective participation within the WTO system. These challenges include: first, lack of capacity to access information concerning trade barriers and opportunities to challenge them; second, lack of internal legal expertise in international pharmaceutical patent-related laws; third, lack of financial wherewithal; fourth, fear of political and economic pressure from the

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<sup>78</sup> Markus Krajewski, “Democratic Legitimacy and Constitutional Perspectives of WTO” (2001) 35 J World Trade 186 at 172-173.

North; and, finally, constraints of internal governance.<sup>79</sup> Effective participation in the WTO system would require countries in SSA to surmount the above obstacles.

## F. Sustainable Development

The phrase ‘sustainable development’ is a fluid concept with an ancient root.<sup>80</sup> From ancient civilization to the present, the quest for sustainability has been the mantra for human survival. The concept however gained international prominence in 1987, when the Brundtland report provided the original clue as to what sustainability should depict. The report defined sustainable development as “development that meets the needs of the present without compromising the abilities of future generations to meet their own needs.”<sup>81</sup> The satisfaction of human needs and aspirations is the cardinal objective of development.<sup>82</sup>

Subsequent scholars and policy discourse have propagated the concept of sustainable development in several forms: as representing a ‘universal framework for development’;<sup>83</sup> as ‘the golden rule of our civilization in the 21<sup>st</sup> century’;<sup>84</sup> as a concept embodying ‘equitable opportunities for all’;<sup>85</sup> and, as a binding principle of customary international law.<sup>86</sup> In its precise sense – which this study adopts – sustainable development refers to “State efforts to achieve progress (development), qualified by the

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<sup>79</sup> Gregory Shaffer et al, “The Trials of Winning at the WTO: What Lies behind Brazil’s Success” (2008) 41 Cornell Int’l LJ 383 at 408.

<sup>80</sup> See Christina Voigt, *Sustainable Development as a Principle of International Law: Resolving Conflicts between Climate Measures and WTO Law* (Leiden: Martinus Nijhoff, 2009) 11 [Voigt, *Sustainable Development as a Principle*].

<sup>81</sup> Report of the World Commission on Environment and Development, *Our Common Future* (Oxford: Oxford University Press, 1987) at 43 [*Our Common Future*].

<sup>82</sup> *Our Common Future*, *ibid* at 54.

<sup>83</sup> 2007 UN Millennium Development Goals Report.

<sup>84</sup> M Decleris, *The Law of Sustainable Development: General Principles* (Luxembourg: EC, 2008) at 48.

<sup>85</sup> Voigt, *Sustainable Development as a Principle*, *supra* note 80 at 15.

<sup>86</sup> See opinion of Judge Weeramantry in the *Case Concerning the Gabčíkovo-Nagymaros Dam Project (Hungary v Slovakia)* (1997) ICJ Rep 7, cited in Philippe Sands, *Principles of International Environmental Law*, 2<sup>nd</sup> ed (Cambridge: Cambridge University Press, 2003) at 254.

condition that such efforts should be possible to maintain over the long term (sustainable).’’<sup>87</sup>

Although other studies have constrained its ambit or direct application to environmental regulation, progressive development scholars should read the above constitutive elements of sustainability broadly to encapsulate pharmaceutical patent-related issues. Lamy has, for instance, affirmed that sustainable development is the end-goal of the WTO.<sup>88</sup> And that global governance should help individuals and societies to achieve social aspects of human values.<sup>89</sup> In short, the concept of sustainable development is trade- and, for that matter, patent-related. This is especially important given that the phrase has received affirmation in the preamble to the Agreement establishing the WTO,<sup>90</sup> even though the extent of its usefulness has been constrained by western economism and market forces. Indeed, trade liberalization is subject to the objectives of sustainable development.<sup>91</sup>

In this light, this study recognizes that the concept of sustainable development can work as an effective link between the right of access to medicines, patents, human rights, and development. It is a promising concept for the realization of the recommendations contained in the WIPO Development Agenda.<sup>92</sup> Thus, linking the concept of sustainable development with this study is important because of its elasticity and ability to accommodate multiple approaches to the human development paradigms adopted in this study. It is an ideal concept comparable with universal ideals such as democracy,

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<sup>87</sup> Marie-Claire Cordonier Segger, “Sustainable Development in International Law” in Hans Christian Bugge & Christina Voigt, eds, *Sustainable Development in International and National Law* (Groningen: Europa Law, 2008) 87 at 88 [Segger, “Sustainable Development in IL”].

<sup>88</sup> Pascal Lamy, “Trade can be a Friend, not a Foe, of Conservation” Speech at WTO Symposium on Trade and Sustainable Development, Geneva, 10 October 2005).

<sup>89</sup> Pascal Lamy, “Humanizing Globalization” Santiago de Chile, 30 January 2006.

<sup>90</sup> The Preamble provides that trade relations should be conducted “with a view to raising standards of living...while allowing for optimal use of the world’s resources in accordance with the objective of *sustainable development*...to develop an integrated, more viable and durable multilateral trading system” [emphasis added].

<sup>91</sup> See Voigt, *Sustainable Development as a Principle*, *supra* note 80 at 143.

<sup>92</sup> See *WIPO Development Agenda* (2007), online: <<http://www.wipo.int/export/sites/www/ip-development/en/agenda/recommendations.pdf>>.

freedom and justice.<sup>93</sup> It has the capacity to rally otherwise fragmented notions of rights and development to improving human needs.<sup>94</sup>

## VI. Thesis Overview

This study is divided into eight chapters. Following this introductory chapter, the second chapter introduces the contentious debates between proponents and opponents of pharmaceutical patents at the WTO and in policy and academic discourse. This debate has elicited calls for steps to be taken to make the globalized patent legal regime more equitable in order to scale up access to medicines to treat pandemics in poor regions such as SSA. The debate evidences the re-directed focus of international patent discourse from trade to public health and development. By way of contribution, I suggest that discourses on patents should be viewed through the prism of laws, institutions, practices, and politics. The interaction between *laws, institutions, practices, and politics* offers an enriched understanding of the global pharmaceutical patent norm making endeavours. In consequence, this study employs this quadripartite framework as a methodological guide to elucidate the actual impact of the globalized patent regime on human lives in SSA and suggest realistic reforms.

Chapter 3 adopts a historical approach to investigate patent negotiations that institutionalized the globalized pharmaceutical legal order. It unravels developments prior to the adoption of TRIPS which marginalized countries in SSA and thus inhibited them from meaningfully participating in the trade-related negotiations within the General Agreement on Tariffs and Trade (GATT)/WTO system. It underscores the point that the ‘participation’ of SSA countries in the negotiations that led to the globalized patent framework failed to meet the basic tenets of democratic bargaining in global trade relations. This marginalization has not discouraged policy makers in SSA from

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<sup>93</sup> Voigt, *Sustainable Development as a Principle*, *supra* note 80 at 3.

<sup>94</sup> See Segger, “Sustainable Development in IL”, *supra* note 87 at 89.

implementing TRIPS obligations in national patent laws, however. Furthermore, pharmaceutical patent laws, policies and institutions have been established in African countries without true participation from the citizens. Supposed experts from the developed world provided ‘technical assistance’ by replicating the laws and institutions that they are familiar with in SSA countries; this is a phenomenon akin to the flexing of hegemonic-muscles that has characterized global economic relations. This approach contributes to the rich developing literature attempting to highlight, from a subaltern perspective, the historical inequities inherent in the prevailing globalized patent framework for pharmaceutical regulation.

In chapter 4, I focus on the assumptions upon which the prevailing international patent regime is based and show that those assumptions are not equally sustainable in both pharmaceutical producing and consuming nations. Essentially, this chapter establishes that the prevailing assumption that pharmaceutical patents work in the developed world and for that matter will work elsewhere is a ‘myth’, a dysfunction that can create and sustain economic dependency of SSA countries. The underlying assumptions for patent protection conform to the western conceptions of individuated rights. This defect in the globalized patent framework is synonymous with the promise of Enlightenment thinking that human reason is the unquestionable filtering criterion for authority.<sup>95</sup> Countries in SSA, as ardent consumers of pharmaceutical products and processes with no corresponding inventive and manufacturing capacities, are ill-prepared to swallow the globalized assumptions, which are predicated upon western epistemology and knowledge values. Also, the promises made to less developed countries to sign on to TRIPS in return for technology transfer and export subsidies have not been met. In highlighting the points of conflicts and the problems with those assumptions, chapter 4 suggests a need for WTO patent rules to reflect the impact-in-fact on socio-human conditions in SSA. The details

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<sup>95</sup> For a detailed discussion of the failure of the Enlightenment thinking which took humanity down the barbaric path of Nazism, see Max Horkheimer & Theodor W Adorno, *Dialectic of Enlightenment*, John Cumming, ed (New York: Continuum, 1995).

of this argument and how to ensure patent regulatory diversity are explored further in subsequent chapters.

Building on chapter 4, the fifth chapter details the substantive and relevant pharmaceutical patent regulatory frameworks in countries within SSA. Thus, it examines the existing patent regulatory and institutional frameworks in SSA *vis-à-vis* access to medicines to treat the HIV/AIDS, malaria, and TB epidemics. It briefly alludes to how domestic patent laws become established in SSA, by examining their sources and effects at the domestic level. It further underscores the lapses that exist in domestic patent systems, which erode any potential for access to essential medicines and thus constrain human development in SSA. These lapses include the lack of local (competent) institutions and mechanisms for ensuring that patent grants comply with formal requirements of patentability mandated by national laws. In using the South African experience as a reference point to make a case for patent regulatory reforms in other SSA countries, chapter 5 urges SSA countries to adopt evidenced-based approaches to patent lawmaking. An evidenced-based approach to the implementation of WTO patent rules will allow SSA countries to take account of their citizens' needs in patent law- and policy-making.

Chapter 6 shifts the discourse of pharmaceutical patents into the realms of constitutional law and the enforcement of socio-economic guarantees of human rights. It establishes that the grant of patent monopoly over pharmaceuticals may conflict with the enjoyment and protection of the fundamental right to health care and other socio-economic rights guaranteed under national constitutions in SSA. It urges the invocation of the human right to health care guaranteed in most national constitutions and international instruments as a foundation for creating exceptions in the recognition of private pharmaceutical patent rights. Thus, the resolution of conflicts between private rights and the public interest to have access to medicines to treat pandemics, such as HIV/AIDS, malaria, and TB, should be made in favour of the latter. The reasons why the vitality of a state should pre-

dominate over the globalized demands for higher levels of pharmaceutical patents are explored in this chapter. Here, I employ the South African constitutional jurisprudence/experience on the protection of the right to health to inform this discussion. Also, I employ the twin concepts of constitutional supremacy and the primacy of human rights to justify the trumping of the right to health over pharmaceutical patent rights in SSA countries.

Chapter 7 then explores the link between patent law and development. It critically examines the need for human development concepts to be incorporated into the development of patent policies to promote sustainable human survival in SSA. It also explores how patents, human rights and development concepts can work together to promote the public benefit goals of a sustainable pharmaceutical patent regulatory regime. As further explained, such an approach to integration implies creating additional human development-oriented exceptions/limitations to patents with the goal of scaling up access to medicines to treat epidemics in poor regions such as SSA. This approach of integrating human development needs into the design of pharmaceutical patent policies, if implemented, will help ensure sustainable patent regulatory frameworks in SSA. Perhaps, that is the key to rebuilding a fractured Africa region.

Chapter 8 presents the general conclusions of this study and considers what policy direction the globalized patent system should take in order to encourage access to medicines to treat pandemics in SSA.

To conclude, this general introductory chapter has set out in detail the framework for this study. As part of this study, I have argued that patents can play a seminal role in scaling up access to medicines to treat pandemics in SSA. Countries in SSA, therefore, require patent regulatory regimes that are equitable and are responsive to the needs of their citizens. So far, the globalized pharmaceutical patent framework has failed in this endeavour. The subsequent chapters recount the story of the globalized regulatory regime, the pitfalls and suggest ways to overcome these obstacles. In a subtle way, I

employ the concepts of laws, institutions, practices, and politics to inform the discussions in the remaining chapters of this study.

## Chapter 2

### **Exploring the Conceptual Domains for Patent Discourse in Global Trade Relations**

#### **I. Introduction**

As mentioned in chapter 1, the possibility of promoting social benefits through patents is highly debated by scholars and researchers. This debate has elicited calls for steps to be taken to make the globalized patent legal regime more equitable in order to scale up access to medicines to treat pandemics in poor regions such as SSA. The debate evidences the re-directed focus of international patent discourse from one concerned with ‘pure’ free trade to a discourse that also considers public health and development. This chapter revisits the discourse about pharmaceutical patents and also nuances that debate in the context of a quadripartite framework of patent laws, patent institutions, patent practices, and patent politics.

In consequence, Part II of this chapter introduces the contentious debates between proponents and opponents of pharmaceutical patents at the WTO and in policy and academic discourse. It concludes that the literature and policy discourse on patents would further be enriched if viewed through the prism of laws, institutions, practices, and politics, both at the domestic and at the international levels. Doing so would also provide a more reliable way to evaluate the globalized pharmaceutical patent system and its domestic prototypes in SSA. Part III then discusses in detail the conceptual and operational interconnections between patent laws, patent institutions, patent practices, and patent politics, and explains how they tie in with the other chapters of this thesis. The final Part IV concludes this discussion.

#### **II. On Patents and Conflicts**

Patents have become a new regulatory frontier in the quest for sustainable human development in SSA. Pharmaceutical patents in particular have evolved into a strongly protective mechanism for biotechnology innovators in the global economy; patents

involve the grant of a legal monopoly to patentees (which include many pharmaceutical companies), thereby preventing others from using, making, selling or importing the patented product or process (or their hybrid) for a set period of time within a jurisdiction. This grant of patent monopoly makes the cost of access to essential medicines, under the ubiquitous liberalized trade regime, prohibitively expensive for the most needy consumers of pharmaceuticals in parts of Africa. In consequence, scholars and commentators have had mixed reactions to the suitability of the globalized patent regulatory framework as it relates to SSA.<sup>1</sup>

On the one hand, critics have accused the patents regime of placing private property rights over public access goals, and have, as a result, failed to make life-saving medicines available to those who need them the most.<sup>2</sup> Heller for his part argues that patents contribute to the reduction in the capacity of the pharmaceutical industry to generate new products.<sup>3</sup> In support of this assertion is a 2006 Report by the US Government Accountability Office which has concluded that the “current patent law discouraged drug companies from developing new drugs by allowing them to make excessive profits through minor changes to existing pharmaceuticals.”<sup>4</sup> This prognosis is worrisome given

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<sup>1</sup> See generally: Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) [Hoen, *The Global Politics*]; Joseph E Stiglitz, “Economic Foundations of Intellectual Property Rights” (2008) 57 Duke LJ 1693 [Stiglitz, “Economic Foundations of IPRs”]; Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006); Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003) [Sell, *Private Power, Public Law*]; Robert L Ostergard, *The Development Dilemma: The Political Economy of Intellectual Property Rights in the International System*, Eric Rice, ed (New York: LFB Scholarly, 2003) [Ostergard, *The Development Dilemma*].

<sup>2</sup> See: Richard Gold et al, “Toward a New Era of Intellectual Property: From Confrontation to Negotiation” (2008) *A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property*, at 13, online: <[http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf)> [Gold et al, “Toward a New Era of IP”]; Marc-Andre Gagnon & Joel Lexchin, “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States” (2008) 5 PLoS Med 1.

<sup>3</sup> Michael Heller, *The Gridlock Economy: How too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* (New York: Basic Books, 2008) at 59.

<sup>4</sup> The US Government Accountability Office, “New Drug Development, Science, Business, Regulatory, and Intellectual Property Issues cited as Hampering Drug Development Efforts” in a *Report of the*

that millions of people die from diseases largely because they are unable to afford life-saving medicines in SSA.<sup>5</sup> For many in SSA, access to medicines to combat diseases such as HIV/AIDS, malaria, and TB can be the difference between life and death.<sup>6</sup> Cullet's conclusion is that "[patents] derogate from the principle of free trade by offering exclusive rights to an inventor to use the invention and to stop others from using it without his/her consent."<sup>7</sup> Therefore, for critics of pharmaceutical patents, the grant of an exclusive right of exploitation to a patent is *prima facie* incompatible with the public welfare ideals of the concept of free trade.<sup>8</sup>

In stark contrast to the above criticisms, proponents of private property rights concerns justify the grant of exclusive rights over pharmaceutical patents in the market-place. Their argument is that granting monopolistic rights over inventions incentivises innovative research and development (R&D) for the benefit of society.<sup>9</sup> For example, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) argues that "without patent protection, the world would have been deprived of the innovative medicines which have saved countless of lives."<sup>10</sup> This property rights justification has also been framed in terms of the international benefits to be derived from

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*United States Government Accountability Office* (November 2006), online: <<http://oversight.house.gov/Documents/20061219094529-73424.pdf>>.

<sup>5</sup> See generally ZUD Babar et al, "Evaluating Drug Prices, Availability, Affordability and Price Components: Implications for Access to Drugs in Malaysia" (2007) 4 PLoS Med 82. [Here, the authors cite the WHO-Health Action International survey, 2003 which has predicted that essential medicines will be very expensive and not universally available due to the prevailing patent regime. To reverse this trend, there is the need to promote generic medicines and improve availability of medicines in the public sector].

<sup>6</sup> See Stiglitz, "Economic Foundations of IPRs", *supra* note 1 at 1717.

<sup>7</sup> Philippe Cullet, "Patents and Health in Developing Countries" in John Hatchard & Amanda Perry-Kessaris, eds, *Law and Development: Facing Complexity in the 21<sup>st</sup> Century* (London: Cavendish, 2003) 78 at 79 [Cullet, "Patents and Health in DCs"].

<sup>8</sup> Free trade is a system of trade policy which abhors protectionism.

<sup>9</sup> This dominant economic justification is, however, marred in controversy. For a detailed critique of the assumptions of patent protection, see: E Richard Gold et al, "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" (2004) 18(4) Public Affairs Quarterly 299 [Gold et al, "The Unexamined Assumptions of IP"]; Sigrid Sterckx, "The Ethics of Patenting – Uneasy Justifications" in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 172.

<sup>10</sup> The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 2008, online: <<http://www.ifpma.org/index.php?id=418>>.

granting robust patent protection to pharmaceuticals. International documents such as TRIPS further assert that the grant of exclusive patent rights over pharmaceuticals will eliminate trade barriers and foster international trade.<sup>11</sup>

A more moderate position is that researching and developing a new product should draw inspiration from the social environment.<sup>12</sup> Therefore, claiming robust protection for inventions may create short term benefits for the patent holder, but in the longer term is likely to create social inequities and imbalances.<sup>13</sup> As Gold et al poignantly observe: “the recognition that innovation is a social, collaborative phenomenon changes the way that policy-makers, researchers, industry and technology consumers ought to view and appreciate IP: as something to be shared and built upon rather than as something to accumulate for its own sake.”<sup>14</sup> Herder & Gold further write that “even if we are willing to accept that IP rights (especially patents) provide a necessary incentive for biotechnology companies to engage in an R&D process, it is unmistakably clear that they are insufficient incentives to address the particular health and industrial needs of the world’s poor.”<sup>15</sup>

In this study, I adopt the perspective that this “extension of property rights to fruits of mental exertion has, in and of itself, the entire gamut of the characteristics of western liberal political ideology of freedom, individualism, capitalism, and free market economics.”<sup>16</sup> It is a neoliberal expression of property rights, which imposes western

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<sup>11</sup> See the Preamble to the World Trade Organization’s (WTO’s) *Agreement on Trade Related Aspects of Intellectual Property Rights* (adopted on 15 April 1994 and entered into force on 1 January 1995) 33 ILM 81.

<sup>12</sup> Gold et al, “Toward a New Era of IP”, *supra* note 2 at 15.

<sup>13</sup> Gold et al, “Toward a New Era of IP”, *ibid* at 16.

<sup>14</sup> Gold et al, “Toward a New Era of IP”, *ibid*

<sup>15</sup> Matthew Herder & E Richard Gold, “Intellectual Property Issues in Biotechnology: Health and Industry” (2008) at 11, online: <<http://www.oecd.org/dataoecd/16/9/40181372.pdf>>.

<sup>16</sup> Chidi Oguamanam, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (Toronto: University of Toronto Press, 2006) at 58 [Oguamanam, *International Law and Indigenous Knowledge*].

knowledge systems over southern countries' knowledge and cultural values.<sup>17</sup> The pursuit of western 'economism',<sup>18</sup> and the propertization of various forms of knowledge can thus be blamed for the plight of people in the global south.<sup>19</sup> In this respect, the grant of protection to IP rights, for instance, is criticized as a protectionist measure that neglects the fact that countries entering into the international trading system are at different stages of development.<sup>20</sup> Thus, unrestrained commoditization of IP rights is viewed as insensitive to the needs of people in third world countries. This continuous drift away from the *raison d'être* of patents (i.e., to promote social benefits) raises fundamental questions which challenge the legitimacy of the neoliberal approach<sup>21</sup> to pharmaceutical patent protection in the global economy.

Scholars and researchers have waded into the debate, and are equally divided over pharmaceutical patents and their implications for access to medicines in poor regions affected by epidemics. Discussions on patents, access to medicines, human rights and development continue to occur across a vast range of academic disciplines, including

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<sup>17</sup> Chidi Oguamanam, "Local Knowledge as Trapped Knowledge: Intellectual Property, Culture, Power and Politics" (2008) 11 *Journal of World Intellectual Property* 29 at 49.

<sup>18</sup> This is a term coined by Gyekye to represent the reduction of development into concepts of gross national products and theories of western epistemology and values. See Kwame Gyekye, "Taking Development Seriously" (1994) 11 *Journal of Applied Philosophy* 45 at 46.

<sup>19</sup> See Ray Bush, *Poverty & Neoliberalism: Persistence and Reproduction in the Global South* (London: Pluto Press, 2007). As Mgbeoji explains, the north and south, west and non-west denote rich and poor countries, respectively. The rich-north refers to the countries of North America, Europe, New Zealand, Japan and Australia. They form the membership-bloc of the Organization for Economic Cooperation and Development (OECD), namely: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. On the other, the poor-south generally refers to Africa, Asia (excluding Japan), Latin America, and Oceania. Specifically to this study, a reference to the south will be to SSA. Further, Mgbeoji rightly reminds us that "there is a 'north' in the 'south', as exemplified by the privileged and 'westernized' elites of the third world.... Considering the experiences of indigenous minorities of North America, Australia, and Europe, it cannot be denied that there is a 'south' in the north": Mgbeoji, *Global Biopiracy*, *supra* note 1 at 217.

<sup>20</sup> See Bhupinder Chimni, "WTO, Democracy, and Development: A View from the South" in Yong-Shik Lee, ed, *Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) 67 at 75 [Chimni, "WTO, Democracy, and Development"].

<sup>21</sup> Neoliberalism seeks to promote free market enterprise, which expands enormously the private rights of businesses. In the context of pharmaceutical regulation, the neo-liberal agenda correspondingly diminishes the controls that the poor, and usually consuming, states have on the hegemonic pharmaceutical industry in matters of drug pricing and delivery.

law.<sup>22</sup> Naturally, while some of the discourse on pharmaceutical patent regulation and development has been progressive, other aspects of the discourse have been slow-paced. It is, however, safe to say that this growing attention from scholars opens new vistas for fresh dialogue over the impact of the globalized legal order on human development needs in SSA, as well as a minefield on which one needs to tread cautiously. It is also worth emphasizing here that any perceived disconnectedness between pharmaceutical patents, development, human rights, and poverty-related issues has now decidedly abated.

Also, notwithstanding ideological differences and the lack of precision about the impacts of pharmaceutical patents on access to medicines in SSA, one thing is certain: that imposing barriers to access medicines to treat pandemics is detrimental to human development and progress. Patents are more than a de minimis contributor to the lack of sufficient access to medicines to alleviate human suffering in SSA.<sup>23</sup> As Fisher & Syed put it, there are strong links between improving the basic health of a country's people and improving its development prospects.<sup>24</sup> Thus, putting aside arguments for or against the grant of exclusive property rights over pharmaceutical products and processes, there is an increasing recognition of the nexus between patent rules and the role of access to medicines in promoting development. By virtue of their intimate relatedness, pharmaceutical patent regulation and progressive development principles are now

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<sup>22</sup> See generally: Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007); Johanna Gibson, ed, *Patenting Lives: Life Patents, Culture and Development* (England: Ashgate, 2008); Susan K Sell, *Powers and Ideas: North-South Politics of Intellectual Property and Anti-trust* (Albany: State University of New York Press, 1998); A Samuel Oddi, "The International Patent System and Third World Development: Reality or Myth?" (1987) 63 Duke LJ 831; Susan K Sell, "Post-TRIPS Development: The Tension between Commercial and Social Agendas in the Context of Intellectual Property" (2002) 14 Fla J Int'l L 193.

<sup>23</sup> This point is confirmed by the debates leading to the adoption of the WTO *Doha Ministerial Declaration*, WTO DoCWT/MIN(01)/DEC/1, 41 ILM 746 (2002) [Doha Ministerial Declaration]; WTO *Declaration on the TRIPS Agreement and Public Health* in 2001, WTO DoCWT/MIN(01)/DEC/2, 41 ILM 755 (2001) [Doha or Doha Declaration] and the subsequent Decision of the WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (30 August 2003) ['August 30' Decision].

<sup>24</sup> William W Fisher & Talha Syed, "Global Justice in Healthcare: Developing Drugs for the Developing World" (2007) 40 UC Davis L Rev 581 at 589.

considered as complementary pillars for human subsistence, warranting serious examination.

A major drawback to entering this discussion is that much of the pharmaceutical patent regulation and development discourses are enveloped in a complex conceptual and analytical quandary.<sup>25</sup> The literature and policy discourse on patents are not fully informed by the nuanced perspectives of laws, institutions, practices, and politics that help shape the direction of the globalized patent regime. Although a number of critiques have addressed the excesses of the globalized pharmaceutical legal order, they fail to suggest mechanisms as to how those excesses could be remedied.<sup>26</sup> Also, many of the theoretical conjectures contained in the literature lack concrete evidentiary support.<sup>27</sup> Additionally, much scholarship has focused on the developing world as a whole and does not examine regions specifically.<sup>28</sup> Thus, some of the real impacts of pharmaceutical patents on human lives in SSA, as the world's poorest region,<sup>29</sup> have been missed. This fact is even more concrete in countries in SSA that are technologically deficient. As one commentator crudely expresses it, "the saying goes that if one cannot invent, at least one

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<sup>25</sup> This quandary includes the lack of universally accepted justificatory framework for securing private interests in pharmaceuticals, among others. This lack of consensus has become a site for debate, if not a diversion from real issues, among scholars and commentators.

<sup>26</sup> See for example, Cullet, "Patents and Health in DCs", *supra* note 7. Compare with Mattias Ganslandt et al, "Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal" in Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005) 207.

<sup>27</sup> Gold et al, "The Unexamined Assumptions of IP", *supra* note 9 at 300. On the question of relying on anecdotal evidence see Robert Sheerwood, *Intellectual Property and Economic Development* (Boulder, CO: Westview Press, 1990).

<sup>28</sup> See generally: Shamnad Basheer & Annalisa Primi, "The WIPO Development Agenda: Factoring in the 'Technologically Proficient' Developing Countries" in Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization's Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009) 100; Yong-Shik Lee, ed, *Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008); Sumner La Croix & Ming Liu, "Patents and Access to Essential Medicines" in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 423.

<sup>29</sup> Not in terms of natural and biological resources, but rather in terms of the precarious state of human life-span as a result of the onslaught of HIV/AIDS, malaria and TB epidemics. Africa owns 54 per cent of the world's gold, 40 per cent of the world's diamond, and 75 per cent of the world's platinum.

can copy. For many sub Saharan countries, copying technologies for producing antiretroviral treatment (ARVs) remains a distant aspiration.”<sup>30</sup>

In light of these lacunae, this study urges the need to ground international patent discourse within the conceptual frameworks of laws, institutions, practices, and politics. It implies drawing from the nuanced perspectives of laws, institutions, practices, and politics to help comprehend fully the intricate domains for regulating pharmaceuticals in the marketplace. In consequence, this study employs the concepts of laws, institutions, practices, and politics as a methodological guide in evaluating the globalized pharmaceutical patent system and its domestic prototypes in SSA. As I explain in depth below, an examination of the regime of patents in light of this quadripartite framework gives a sound grounding to the discourse on patents within the world trading system. It also brings to the fore the various inequities inherent in the globalized patent system as regards the protection of pharmaceutical products and processes. By providing a holistic explanation as to why the globalized pharmaceutical patent regulatory framework is dysfunctional, one can conveniently suggest mechanisms to get out of that quagmire.

### **A. Toward an Informed Patent Discourse**

This section takes up the argument that drawing from the nuanced perspectives of laws, institutions, practices, and politics makes our understanding of pharmaceutical patent protection more precise and reasoned. The reason/justification for this assertion is that the regime of patents does not function in isolation; the workings of the regime of patents implicate a gamut of legal, institutional, practical, and political developments, both at the national and international levels. The quadripartite domains of laws, institutions, practices, and politics form the bedrock of the innovation system by dictating “the type of results that we want as against those that we do not want.”<sup>31</sup> Hence, the concepts of laws, institutions, practices, and politics provide formidable foundations for any research that

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<sup>30</sup> Rebecca Amollo, “Revisiting the TRIPS Regime: Rwanda-Canadian ARV Drug Deal ‘Tests’ the WTO General Council Decision” (2009) 17 RADIC 240 at 241.

<sup>31</sup> Gold et al, “Toward a New Era of IP”, *supra* note 2 at 15.

seeks to appraise the workings of the globalized patent system and its reflections in domestic jurisdictions. It follows that one cannot adequately evaluate the impacts of the regime of patents on societies without analyzing the legal, institutional, practical, and political dynamics involved in patent law- and policy-making. Similarly, the conceptual and operational dynamics of laws, institutions, practices, and politics should serve as foundations for making nuanced arguments for pharmaceutical patent reforms at the WTO and in policy and academic discourse. Although such nuanced perspectives may not completely eliminate controversies, they can provide an enriched understanding of patents.

This suggestion for a broad-based re-conceptualization of patents is further supported by the International Expert Group on Biotechnology, Innovation and Intellectual Property (IEGBIIP). According to the IEGBIIP, the conceptual and operational interconnections between laws, practices, institutions, and *politics*<sup>32</sup> provide

[a] comprehensive way to examine how IP affects knowledge production, sharing and use within biotechnology innovation system. It points to ways in which laws, practices, and institutions confirm one another, such as when patent offices do a good job of applying the legal criteria of what constitutes an invention. It also shows how these laws, practices, and institutions can complement one another, for example, when broad infringement by researchers is tolerated by patent holders in order to offset what would otherwise be a harsh rule.<sup>33</sup>

Further, the IEGBIIP avers that the use of such multi-disciplinary perspectives as foundations for pharmaceutical patent regulation helps to anticipate/pre-empt potential pitfalls. This is because laws, institutions, practices, and politics can “contradict one another, as when the high cost of litigation undermines the ability of a user to invalidate a patent that should never have been granted in the first place.”<sup>34</sup> It goes without saying

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<sup>32</sup> Even though the IEGBIIP’s work is silent on the role of politics, this study suggests a fourth trigger (i.e., politics) for understanding the workings of the globalized pharmaceutical patent system. Politics, as explained below, brings to the fore the myriad roles of actors in patent law making endeavours, both at the national and international levels.

<sup>33</sup> Gold et al, “Toward a New Era of IP”, *supra* note 2 at 22.

<sup>34</sup> Gold et al, “Toward a New Era of IP”, *ibid*.

that the influences of the various components of this quadripartite framework are mutually reinforcing; they provide a more reliable way for evaluating the globalized pharmaceutical patent system and its domestic prototypes in SSA. In consequence, viewing patent regulation through the prism of laws, institutions, practices, and politics offers a complete understanding of the global pharmaceutical patent norm making endeavours.

Specifically to this study, the use of the above quadripartite framework has several benefits. First, it provides a comprehensive foundation to analyze pharmaceutical patent regulation and development from the perspective of the world's poorest region which previous researchers and academics have not undertaken. It helps to unmask systemic developments that have created and perpetuated the prevailing regulatory system over a period of time, rather than viewing it as a single/autonomous phenomenon. Indeed, the current state of pharmaceutical patent protection reflects deep rooted actions of hegemonic states and their pharmaceutical corporations that have evolved over decades. Therefore, being cognizant of the processes of domination that have culminated in the globalized product/outcome is crucial to prescribing solutions for the present oligarchic maladies.

Second, the quadripartite framework allows for human rights and development-oriented concepts, which are scattered throughout the legal, political, economic and historical discourses, to be invoked to inform both domestic and international policies respecting pharmaceutical patent regulation. It provides an entry point for making a case for the integration of human development considerations into global and national patent law- and policy making. Also, drawing from such multidisciplinary sources portrays a holistic picture of the problems confronting people who lack access to basic health care in parts of Africa. In the particular case of this study, I draw from non-legal sources because studies about the negative repercussions of pandemics such as HIV/AIDS, malaria, and TB take place across a vast range of academic disciplines other than law.

Third, relying on the quadripartite framework exposes the reality that the international and domestic pharmaceutical patent regulatory arrangements are not devoid of politics and other western economic influences. There are established domestic and international actors who, in some cases, hold entrenched positions against the South on matters of global economic law making. Some speculate that ardent protectionists (disguised as trade liberalists) lurk behind the international scenes and pull the strings during deliberations which border on pharmaceutical patent policies; they frustrate efforts to make the globalized pharmaceutical legal order more equitable for people of the global south.<sup>35</sup> For his part, Chen notes that appeals for the complete elimination of inequities in the international order are blocked and confounded by western powers, which have sought to maintain established neo-colonial hegemony in international politics.<sup>36</sup> A divergent viewpoint, however, is that generally less developed countries accept global trade arrangements because they serve their interests.<sup>37</sup>

And fourth, employing the concepts of laws, institutions, practices, and politics provides an informed basis for making a case for pharmaceutical patent regulatory reforms, if there is any hope of achieving human development in SSA. Considering issues from multiple perspectives of laws, institutions, practices, and politics will allow for multi-pronged reform strategies to be devised in tackling patents and human development challenges in Africa. Additionally, it allows for the coordination of domestic and international strategies in order to ensure greater participation of countries in SSA in international patent law making. Suffice it to say that an in depth explanation (as done below) of the

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<sup>35</sup> See Joseph E Stiglitz, *Globalization and Its Discontents* (New York: W.W. Norton & Co., 2002); Joseph E Stiglitz & Andrew Charlton, *Fair Trade for All: How Trade Can Promote Development* (Oxford: Oxford University Press, 2005) at 74, 79.

<sup>36</sup> An Chen, "A Reflection on the South-South Coalition in the Last Half-Century from the Perspective of International Economic Law-Making" in Yong-Shik Lee, ed, *Economic Development Through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) 33 at 35.

<sup>37</sup> See generally Edmund W Kitch, "The Patent Policy of Developing Countries" (1994) 13 UCLA Pac Basin LJ 166 at 171 [Less developed countries signed on to TRIPS because it serves their interests to invent and commercialize technologies]; Alan O Sykes, "TRIPS, Pharmaceuticals, Developing Countries and the Doha 'Solution'" (2002) 3 Chicago J Int'l L 47.

domains of laws, institutions, practices, and politics will further highlight the benefits of using this quadripartite framework to inform any discourse on patents and development.

What then are the nuanced-components of this quadripartite framework? I turn now to discuss each of its four components and explain how they tie in with the other chapters of this thesis.

### **III. Explaining Laws, Institutions, Practices, and Politics as the Conceptual Domains for this Study**

#### **A. Law in a Global Economy**

Like most of the discourses on patents, this study seeks to understand the impact of law on society. It treats ‘international patent law’ as law properly so-called. In so doing, I am aware that the nature of the interaction between law and humans is ambiguous and unclear, especially as to how the former regulates the acts and omissions of persons in society. Suffice it to indicate that the discourses of the efficacy of law in solving human problems, and why people obey the dictates of law is an ongoing discussion.<sup>38</sup> How does law (i.e., international law, domestic law, regulation) that merges into different iterations of one norm in patent law affect humans? The salient point is that for a law to be effective, it must express societal standards accurately,<sup>39</sup> and the globalized pharmaceutical patent regime is no exception. It is for this reason that this section critiques the *TRIPS Agreement*, which has become an instrument for the globalization of patent norms in both developed and developing countries alike.

Further, the question as to whether international law is law properly so-called remains a site for debate among scholars and commentators. Austin, for instance, is renowned for

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<sup>38</sup> For analyses of the relationship between law, coercion, and morality, see: Lon L Fuller, *The Morality of Law* (New Haven: Yale University Press, 1964); Lon L Fuller, “The Case of the Speluncean Explorers” (1948) 62 Harv L Rev 616; HLA Hart, *The Concept of Law* (Oxford: Clarendon Press, 1961).

<sup>39</sup> Roscoe Pound, “Mechanical Jurisprudence” in Ray D Henson, ed, *Landmarks of Law* (Boston: Beacon Press, 1960) 101 at 107.

defining law as the command of the sovereign backed by threats of sanctions.<sup>40</sup> According to him, international law is no law because it does not emanate from a single sovereign. He observes that positive laws (as law properly so called) are unilaterally set by political superiors for political inferiors.<sup>41</sup> Bork makes a similar claim to the effect that international law is *only* politics.<sup>42</sup> As I discuss below, both the Austinian and the Borkian claims are highly contestable.

Notwithstanding its shortcomings, international law is both law and politics. Indeed, it is difficult to disagree with the counter-Austinian discourses which regard international law as law properly so-called.<sup>43</sup> After all, people comply with international law like most national laws. As Oppong ably demonstrates, the legal subjects of ‘community laws’ in Africa comply with the requirements of supranational law because of the benefits that compliance brings, rather than any inherent force of the law or sanctions attached to it.<sup>44</sup> What guarantees compliance with the dictates of law among persons in society is the faith that policy-makers vest in it.<sup>45</sup> Perhaps, more accurately, law’s imperatives are not triggered by any gunman’s situation writ large, as there are many instances where the law does not involve a command. But, “in this dialogue of patent laws, powerful states and important global actors, mainly from the United States, have [had] the capacity to influence the trajectory of patent laws in less powerful states.”<sup>46</sup>

Yet another basic understanding of law is Hart’s conclusion that the acceptance of a rule finds expression when viewed from an ‘internal perspective’, and not on the basis of any

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<sup>40</sup> John Austin, *The Province of Jurisprudence Determined*, HLA Hart ed (London: Weidenfield & Nicholson, 1955) [1832] at 1.

<sup>41</sup> Austin, *The Province of Jurisprudence Determined*, *ibid* at 9.

<sup>42</sup> Robert H Bork, *Coercing Virtue: The Worldwide Rule of Judges* (Washington D.C: AEI Press, 2003) at 21.

<sup>43</sup> See especially: Louis Henkin et al, *International Law*, 3<sup>rd</sup> ed (St Paul, MN: West, 1993); Lon L Fuller, “Human Interaction and the Law” (1969) 14 *Am J Juris* 1.

<sup>44</sup> Richard Frimpong Oppong, *Legal Aspects of Economic Integration in Africa* (Cambridge: Cambridge University Press, 2011) at 37-38.

<sup>45</sup> Desmond Manderson, “‘As If’: The Court of Shakespeare and the Relationships of Law and Literature” (2008) 4 *Law, Culture and the Humanities* 29 at 31 [Manderson, “Court of Shakespeare”].

<sup>46</sup> Mgbeoji, *Global Biopiracy*, *supra* note 1 at 32.

moral justification.<sup>47</sup> By contrast, Dworkin considers the application of a legal rule to specific facts as the foundation for unearthing its specific consequences.<sup>48</sup> And, the success or failure of any legal system (both domestic and international) is reliably measured by the future and not the present.<sup>49</sup>

The globalized pharmaceutical legal order is animated by similar complex ideals; the legal rules of domestic and international patent law define the formal relationships between players within the industry. As it is, the rules seek to promote legal and regulatory coherence among nations and institutions. Presently, the rules are being harmonized and/or globalized, even though such an approach is not needed. The globalized patent rules have thus circumscribed the ability of policy-makers to tailor patent protection to address social needs in the domestic context.<sup>50</sup> In consequence, the internationalization of law and its corresponding domestication renders discourses about whether international law is ‘law properly so-called’ to be a superfluous academic exercise. In a globalized world, national patent laws have become increasingly subservient to supranational law, including WTO rules, such that there is difficulty in distinguishing the two. International patent law now functions almost like domestic law. In that sense, international patent law is also law.

This blurring of the lines between international patent law and domestic patent law (traditionally recognized as law properly so-called) is emblemized by the *TRIPS Agreement* of the WTO. TRIPS, one of 28 agreements of the Uruguay Round’s Final Act, marked the beginning of the global property epoch;<sup>51</sup> it forms the bedrock of the globalized pharmaceutical patent regulatory regime. As Drahos succinctly expresses it this universalist conception of the one patent system has to some extent gained practical

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<sup>47</sup> Hart, *The Concept of Law*, *supra* note 38 at 56, 86-89.

<sup>48</sup> Ronald Dworkin, *Taking Rights Seriously* (Cambridge Mass.: Harvard University Press, 1971) at 22-24.

<sup>49</sup> Manderson, “Court of Shakespeare”, *supra* note 45 at 30.

<sup>50</sup> Graeme D. Dinwoodie & Rochelle C Dreyfuss, “Diversifying Without Discriminating: Complying With the Mandates of the TRIPS Agreement” (2007) 13 Mich. Telecomm. & Tech. L Rev 445 at 447.

<sup>51</sup> John Braithwaite & Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000) at 63.

expression in the project of patent harmonization under TRIPS.<sup>52</sup> As such, the contours of pharmaceutical patent protection under TRIPS in relation to those across WTO member-states are significantly uniform. The reason is that the international regulatory framework introduced by TRIPS drives the domestic systems.

TRIPS itself incorporates earlier pro-harmonization treaties such as the *Paris Convention*,<sup>53</sup> the *Berne Convention*,<sup>54</sup> the *Rome Convention*,<sup>55</sup> and the *IPIC Treaty*,<sup>56</sup> all of which protect diverse IP rights. These property right treaties have substantially lifted IP matters out of the province of domestic law and subjected them to the control of international law.<sup>57</sup> And, through TRIPS, SSA states have further been insulated from exercising their national prerogatives over matters of pharmaceutical patent protection and policies. In addition, recent bilateral and regional trade agreements have imposed further obligations on countries in SSA to protect pharmaceutical products and processes.<sup>58</sup>

Presently, the TRIPS provisions relating to patents are laid down in Articles 27 to 34. These provisions oblige states to provide effective and adequate protection and enforcement procedures against the infringement of patent rights.<sup>59</sup> TRIPS also requires that states comply with standardized administrative rules and procedures. Also, far-

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<sup>52</sup> Peter Drahos, “Death of Patent System – Introduction” in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 1 at 4.

<sup>53</sup> *Paris Convention for the Protection of Industrial Property*, 1883, 21 UST 1538, 828 UNTS 305 (last revision: 14 July 1967).

<sup>54</sup> *Berne Convention for the Protection of Literary and Artistic Works*, 1886, 828 UNTS 221 (last revision: 24 July 1971).

<sup>55</sup> *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations*, 1961.

<sup>56</sup> *Treaty on Intellectual Property in Respect of Integrated Circuits*, 1989, 28 ILM 1477.

<sup>57</sup> See M Sornarajah, “Economic Neo-Liberalism and the International Law on Foreign Investment” in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (The Netherlands: Martinus Nijhoff, 2003) 173.

<sup>58</sup> An example of such regional agreements is the European Partnership Agreements (EPAs) with African, Caribbean and Pacific (ACP) countries. For a discussion of the implications of bilateral agreements with TRIPS-plus requirements, see Jean-Frederic Morin, “Tripping up TRIPS Debates: IP and Health in Bilateral Agreements” (2006) 1 *International Journal of Intellectual Property Management* 37.

<sup>59</sup> See Peter Drahos, “When the Weak Bargain with the Strong: Negotiations in the World Trade Organization” (2003) 8(1) *International Negotiation* 79.

reaching are provisions that required compliance with the national treatment and most-favoured-nation principles.<sup>60</sup> These provisions, as will be shown, grant exclusive protection to pharmaceutical products and processes by putting private interests before the public good. Thus, exclusive patent protection measures mean that there would be increased demands for royalty payments by private rights holders in return for access to essential medicines.

In addition, TRIPS allows states to grant protection for medicinal test data, thereby creating an additional form of monopoly for data needed to obtain marketing approval for medicines.<sup>61</sup> To this end, all new health related products and processes, such as medicines, vaccines and diagnostics, are enclosed by the ‘fence’ of protection of the TRIPS-based patent framework.<sup>62</sup> The grant of such pharmaceutical patents confers exclusive rights on the owner to make, use, sell and/or import protected medicines.<sup>63</sup> This harmonization has thus curtailed the powers of national governments over IP rights protection and regulation. And to ensure compliance with all of these, deadlines were imposed on states as part of their trade obligations. Also, by associating IP with trade, the *TRIPS Agreement* effectively globalised the principles contained therein and compelled WTO members to comply with the treaty.<sup>64</sup> In consequence, TRIPS fails to properly promote the interests of the world’s poor as a means to promote innovative and

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<sup>60</sup> Both principles primarily deal with formal equality and non-discrimination among WTO member-states. On the national treatment principle, Article 3 of the *TRIPS Agreement* (Part 1) provides that each WTO member shall accord to nationals of other member states treatment no less favourable than it accords to its own nationals with regard to protection. On the most favoured nation principle, Article 4 of the *TRIPS Agreement* (Part 1) stipulates that any advantage, favour, privilege or immunity granted by a WTO member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other member states.

<sup>61</sup> Article 39.3 of the *TRIPS Agreement*. See Karin Timmermans, “Intertwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals” (2005) 8 *Journal of World Intellectual Property* 67 [The protection of data further disables generic producers from entering the market until the end of the exclusivity period].

<sup>62</sup> Hoen, *The Global Politics*, *supra* note 1 at 2.

<sup>63</sup> Article 28 of the *TRIPS Agreement*, 1994.

<sup>64</sup> Peter Drahos & John Braithwaite, “Who Owns the Knowledge Economy: Political Organizing Behind TRIPS” (2004) *Corner House Briefing* 32, 1, online: <<http://www.thecornerhouse.org.uk>>.

sustainable societies.<sup>65</sup> It circumscribes the quest for regulatory diversity, by insisting on compliance with high western standards of patent protection, while at the same time ignoring matters of traditional knowledge.<sup>66</sup>

Although one cannot strictly talk about ‘international patent law’, as if there is a single legal order that regulates every action and omission of states and humans, harmonization has inched the world closer to such a phenomenon. TRIPS’ macro-management of national patent systems has rendered the principle of territoriality in patent law virtually otiose. The harmonized rules give assurance as to the rights available to the patent right-holder and also inform the right-holder about the procedures to follow to vindicate those rights when infringed. And, “as a legal matter, the failure to comply with international IP standards is punishable through the international trade enforcement mechanisms inherited from the GATT and amplified in the World Trade Organization (WTO).”<sup>67</sup>

In the province of pharmaceutical patent protection and related institutional arrangements, more than a decade and a half has passed since the WTO’s *TRIPS Agreement* entered into force, and states have consequently ‘embraced’ the international normative order as part of their laws. Given that the *TRIPS Agreement* constitutes a framework treaty which regulates matters appurtenant to international and domestic patent law, this study subjects the Agreement to a critical review to ascertain its functionality in human development discourse. The salient point to add here is that the globalization, if not imposition, of the TRIPS-based patent concepts has aroused controversies with regard to the impact on social agendas in less developed countries.

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<sup>65</sup> Simon Walker, “The TRIPS Agreement, Sustainable Development and the Public Interest” (2001) 41 *IUCN Environmental Policy and Law Paper* at 4.

<sup>66</sup> Oguamanam, “Local Knowledge as Trapped Knowledge”, *supra* note 17 at 32.

<sup>67</sup> Jonathan Putman, “The Law and Economics of International Intellectual Property: A Primer” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 19 at 22.

## 1. TRIPS' North-South Dichotomization

There is a north-south dichotomy over the impact of the globalized patent rules under the *TRIPS Agreement*. Since entry into force, the *TRIPS Agreement* has generated contentious debates between developed and less developed countries at the WTO. This division has convinced Mgbeoji to conclude that TRIPS-engineered patent rules have split the world into two camps.<sup>68</sup> As if such polarization is not enough, there is also an ongoing attempt to *further* harmonize patent law by WIPO in what will be referred to as 'Substantive Patent Law Treaty (SPLT).<sup>69</sup> The proposed SPLT seeks to harmonize the substantive requirements of patent law, including having the same definition/standards for novelty, inventive step and non-obviousness, industrial applicability and utility. Dutfield opines that, if successful, such a substantive harmonization will mean that "patent standards will be exactly the same to the extent, for example, of having identical definitions of novelty, inventive step and industrial application."<sup>70</sup> This proposed patent law treaty also contains relatively fewer exceptions to patentability than those contained in the *TRIPS Agreement*. Predictably, this so-called 'WIPO substantive harmonization' will generate vociferous opposition and counter-narratives. According to Dutfield, such harmonization would move the world towards a unitary patent system, which the world is not prepared for.<sup>71</sup>

More importantly, while many view the harmonization of IP rights as economically benign, others consider it socially malignant. In the extreme cases, calls have been made, and to some extent justifiably so, for the TRIPS regime to be suspended in favour of developing countries, not to mention LDCs.<sup>72</sup> However, any suggestions for the

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<sup>68</sup> Mgbeoji, *Global Biopiracy*, *supra* note 1 at 32.

<sup>69</sup> WIPO, *Draft Substantive Patent Law Treaty*, SCP/10/2, online: <[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_10/scp\\_10\\_2.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_2.pdf)>.

<sup>70</sup> Graham Dutfield, "Is the World Ready for Substantive Patent Law Harmonization? A Lesson from History" in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 228 at 229 [Dutfield, "Is the World Ready for SPLH?"].

<sup>71</sup> For a discussion of the undesirability of the so-called 'WIPO-supported Substantive Patent Law Treaty' see Dutfield, "Is the World Ready for SPLH?", *ibid*

<sup>72</sup> Yong-Shik Lee, "Development and the World Trade Organization: Proposal for the Agreement on Development and the Council for Trade and Development in the WTO" in Yong-Shik Lee, ed,

suspension of TRIPS is not likely to receive support within the WTO system because of the potential for such acts/omissions to distort global trade governance; it is thus safe to say that the globalized patent rules under TRIPS have come to stay. Admittedly, globalization aids homogenization, but the converse is that globalization should also facilitate the flourishing of diversity.<sup>73</sup> It is through such diversity that contradictions and conflicts can be resolved to promote harmonious north-south interdependence and co-operation in the field of pharmaceutical patent regulation and development.

Nonetheless, the depth of harmonization under TRIPS “marked a paradigmatic shift from the status quo when IP issues which hitherto were the subject matter of national laws and instruments of national and social policy were located at the World Trade Organization (WTO)-supervised international trade regime.”<sup>74</sup> TRIPS succeeded in universalizing the scope of patent protection, enforcement mechanisms and institutional frameworks. The UN agency – WIPO, which until 1995 was principally tasked to oversee IP issues, lost its mandate over IP/trade-related issues to the WTO. The supervisory power of WIPO was viewed as too frail to demand compliance with rigorous IP standards. This phenomenon of moving international norm setting activities and treaty negotiations from one international venue (i.e., WIPO) to another (i.e., GATT/WTO<sup>75</sup>) is what Helfer refers to as ‘regime shifting.’<sup>76</sup> The shift in the negotiations of trade-related aspects of IP norms from WIPO to the GATT/WTO was intended to enhance the powers of the US and EU and to bolster the economic fortunes of their multinational corporations.<sup>77</sup>

Besides those controversies generated as a result of the globalized patent regime, the US and the EU continue to push less developed countries to the brink of accepting higher

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*Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) 3 at 26.

<sup>73</sup> Oguamanam, *International Law and Indigenous Knowledge*, *supra* note 16 at 203.

<sup>74</sup> Oguamanam, “Local Knowledge as Trapped Knowledge”, *supra* note 17 at 31.

<sup>75</sup> General Agreement on Tariffs and Trade, October 30, 1947, 55 UNTS 194. The GATT 1947 was incorporated into the WTO as GATT 1994 in Annex 1A to the Agreement Establishing the WTO.

<sup>76</sup> Laurence R Helfer, “Regime Shifting: the TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29 *Yale J Int’l L* 1 at 6 [Helfer, “Regime Shifting”].

<sup>77</sup> Helfer, “Regime Shifting”, *ibid* at 19-20.

standards of protection for pharmaceuticals (otherwise known as TRIPS-plus obligations) through ‘freer’ bilateral and investment deals. Maskus argues that the TRIPS-plus agenda eliminates discretion on the part of public-health authorities in matters of compulsory licensing, parallel imports, and generic competition.<sup>78</sup> The question as to whether TRIPS’ globalization measures and its latter-day ‘freer’ trade deals have promoted social benefits in SSA will further be explored in this study. Suffice it to say that the TRIPS’s global benchmark of patent protection of pharmaceutical products and processes is evidence of globalization. On the flip side, forced globalization has serious implications for the pursuit of domestic social agendas in SSA. This is especially pronounced in SSA since the WTO’s globalized patent rules have not worked for the citizens of SSA countries.

## 2. Globalization and the Pursuit of Social Agendas

The prevailing pharmaceutical patent regime – emblemized by TRIPS – is the product of such a neoliberal agenda.<sup>79</sup> The TRIPS legal framework has played a monumental role in removing national barriers and policies as regards pharmaceutical patents. This deconstruction of territorial control over pharmaceuticals was meant to “reduce distortions and impediments to international trade...and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”<sup>80</sup> As shown below, governments and national institutions therefore serve as the agents to dismantle such national barriers.

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<sup>78</sup> Keith E Maskus, “Incorporating a Globalized Intellectual Property Rights Regime into an Economic Development Strategy” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 497 at 498.

<sup>79</sup> For example, the *TRIPS Agreement* sets global minimum standards for protecting biotechnology products and processes in both developed and developing countries alike: Article 27.1. These minimum standards should not be misconstrued as low standards. In the context of SSA, they are very high standards. However, defenders of the international patent system point to the ‘flexibilities’ in the *TRIPS Agreement*. These ‘flexibilities’, they argue, leave room to Member states to formulate domestic patent policies. On this debate see Stiglitz, “Economic Foundations of IPRs”, *supra* note 1 at 1716-1719.

<sup>80</sup> See Preamble to the *TRIPS Agreement*.

Economic globalization, however, has its ardent followers and vociferous critics.<sup>81</sup> In the field of patents, it is implicated in furthering inequalities in the global south while promoting the economic interests of big pharma in the north. Mgbeoji's conclusion is that globalizing "strong patent regimes result in a net economic loss for the south and a net economic gain for the north."<sup>82</sup> While Stiglitz perspicaciously recounts "the devastating effect that globalization can have on developing countries, and especially the poor within those countries,"<sup>83</sup> Bhagwati grandiosely contends that globalization's perils are based on "'gotcha' examples...with fears masquerading as evidence."<sup>84</sup> According to Stiglitz, the level of pain in less developed countries as a result of globalization is far greater than necessary. He avers further that poverty levels have increased despite the promises of human benefits from globalization; the result is that some of the poorest countries in Africa have plunged deeper into misery.<sup>85</sup> In the field of patents, Stiglitz concludes that the TRIPS regime overwhelmingly reflects the interests and perspectives of pharmaceutical companies as opposed to the users.<sup>86</sup> Therefore, the cries of the voiceless and the sick in Africa for greater social justice and equity have fallen on deaf ears.

In a subtle but blistering response to Stiglitz, Bhagwati posits that those who consider globalization as lacking a human face are mistaken.<sup>87</sup> For him, globalization is part of the solution to human problems, not the problem; therefore, emphasis should be on policies to enhance, supplement, complement and accentuate globalization's good outcomes.<sup>88</sup> For globalization's negative outcomes, Bhagwati does not follow up fully. Nonetheless, Bhagwati admits that IP was not a proper subject matter for the GATT/WTO to consider.

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<sup>81</sup> For unending references on pro- and anti-globalists see generally: Thomas Friedman, *The Lexus and the Olive Tree* (New York: Farrar, Straus & Giroux, 2000); Noam Chomsky, *Profit Over People: Neo-liberalism and the Global Order* (New York: Seven Stories Press, 1999); Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (Cambridge: Cambridge University Press, 2005); Jagdish Bhagwati, *In Defense of Globalization* (New York: Oxford University Press, 2004).

<sup>82</sup> Mgbeoji, *Global Biopiracy*, *supra* note 1 at 35.

<sup>83</sup> Stiglitz, *Globalization and Its Discontents*, *supra* note 35 at ix.

<sup>84</sup> Bhagwati, *In Defense of Globalization*, *supra* note 81 at ix.

<sup>85</sup> Stiglitz, *Globalization and Its Discontents*, *supra* note 35 at 5.

<sup>86</sup> Stiglitz, *Globalization and Its Discontents*, *ibid* at 8.

<sup>87</sup> Bhagwati, *In Defense of Globalization*, *supra* note 81 at 30.

<sup>88</sup> Bhagwati, *In Defense of Globalization*, *ibid* at 31.

For him, making IP part of the WTO was like introducing cancer cells into a healthy body: while GATT (trade in goods) and GATS (General Agreement on Trade in Services) certainly belonged in a trade body TRIPS did not.<sup>89</sup> IP rights are not a ‘trade issue’ as they inhibit or stifle a competitive environment.<sup>90</sup> In explaining why TRIPS then became ‘trade-related’, Bhagwati further writes that “the corporate lobbies in pharmaceutical and software...distorted and deformed an important multilateral institution [WTO]), turning it away from its trade mission and rationale and transforming it into a royalty collection agency.”<sup>91</sup>

In light of these disagreements and the specific focus of this study on SSA, I argue that critics’ concern about the international patent regime is not a false alarm. The patent system plays a significant role in the pricing of essential medicines and thus affects the right to access medicines in SSA. For example, Novartis’ patented-medicine such as Coartem® (artemether 20 mg/lumefantrine 120 mg), which has proven effective for treating the malaria parasites in SSA, costs almost US\$10 per every treatment cycle. The generic versions of the same medication (Artefan 20/120) manufactured by Ajanta pharma limited in India costs US\$1 in SSA per every treatment cycle. The point here is that patented drugs are significantly more expensive than generic drugs. And this trend affects the attainment of the three basic dimensions of human livelihood, notably, a long and healthy life, knowledge, and a decent standard of living.<sup>92</sup>

In sum, within the world trading system, a case has been made that globalization from above favours the North and its pharmaceutical industries, and this trend severely limits

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<sup>89</sup> Bhagwati, *In Defense of Globalization*, *ibid* at 183.

<sup>90</sup> See Ruth Rikowski, “Tripping over TRIPS?: An Assessment of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights, Focusing in Particular on Trade, Moral and Information Issues” (2003) 20:3 Business Information Review 149.

<sup>91</sup> Bhagwati, *In Defense of Globalization*, *supra* note 81 at 183.

<sup>92</sup> See Marie-Claire Cordonier Segger, “Sustainable Development in International Law” in Hans Christian Bugge & Christina Voigt, eds, *Sustainable Development in International and National Law* (Groningen: Europa Law, 2008) 87 at 90.

the powers of countries in SSA to effectively help their citizens.<sup>93</sup> The views of other scholars are far from sanguine; they dismiss as unfounded the claim that the top-down approach to globalization within the WTO has diminished the autonomy and authority of southern states.<sup>94</sup> Lai has also expressed the view that the TRIPS minimum standards are far from being classified as global harmonization.<sup>95</sup> He further observes that, even if that is the case, harmonizing patent protection is necessary for global economic efficiency.<sup>96</sup>

Whichever spectacles one may wear, recent developments confirm that globalization under the WTO system poses enormous challenges for the citizens in poor regions such as SSA. With efforts underway to reverse unjust paths, via the Doha Round of trade negotiations and the WIPO Development Agenda, globalists should be aware of the possible harms of globalization. Preliminary indications of such reversals are beginning to emerge and are alluded to below.

### 3. Mitigation Measures: The Doha Round?

This section articulates the point that supposed mitigation steps under the Doha Declaration, the Doha Ministerial Declaration and the WTO General Council's 'August 30' Decision have yet to roll back the enormous challenges that confront policy-makers in tackling the pandemic situations in SSA. Since the 2001 Doha Round of trade negotiations, dubbed 'the Development Round', efforts have been made to give development agendas a more humane face in order to rectify some of the imbalances of the past. The Doha Declaration symbolizes the first global acknowledgement of the existence of serious health problems faced by less developed nations and their link to

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<sup>93</sup> Shedrack Agbakwa, "A Line in the Sand: International (Dis)Order and the Impunity of the Non-State Corporate Actors in the Developing World" in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (The Netherlands: Martinus Nijhoff, 2003) 1 at 13.

<sup>94</sup> See Jeffrey L Dunoff, "Does Globalization Advance Human Rights?" (1999) 25 *Brook J Int'l L* 125 at 129-132.

<sup>95</sup> See Edwin L-C Lai, "The Theory of International Policy Coordination in the Protection of Ideas" in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 357 at 360.

<sup>96</sup> Lai, "The Theory of International Policy", *ibid.*

increased levels of patent protection.<sup>97</sup> Most importantly, at the launch of Doha, the less developed countries succeeded in negotiating a mandate that had the promise of delivering a development outcome.<sup>98</sup> This attempt at rectification of the past imbalance is partly echoed by the Doha Declaration that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>99</sup> Indeed, there was recognition of the gravity of public health problems afflicting many developing nations and LDCs, with particular emphasis on HIV/AIDS, malaria, and TB epidemics.

Also, as part of the shift at Doha, the trade ministers of the WTO member-states reaffirmed their commitment to the concept of sustainable human development.<sup>100</sup> These declarations, however, could not roll back the adverse effects of TRIPS on public health and development programs in SSA. There are still fundamental limitations on the ‘humanitarian’ objectives of the Doha Declaration and its subsequent implementing WTO General Council Decision on August 30, 2003.<sup>101</sup> In practice, domestic policy-makers in many SSA countries do not also understand their international patent obligations and have, as a result, assumed more obligations than legally required. As shown in chapter 5 of this text, the provisions on compulsory licensing and parallel imports under the patent laws of Ghana, Uganda, and Botswana are not consistent with the post TRIPS mitigation measures agreed to under the WTO system.

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<sup>97</sup> Scott Lucyk, “Patents, Politics and Public Health Access to Essential Medicines under the *TRIPS Agreement*” (2007) 38 *Ottawa L Rev* 191 at 215.

<sup>98</sup> Faizel Ismail, “One Year since the WTO Hong Kong Ministerial Conference: Developing Countries Reclaim the Development Content of the WTO Doha Round” in Yong-Shik Lee, ed, *Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) 121 at 138 [Ismail’s position is that developing countries achieved this feat because of their active participation in the negotiations].

<sup>99</sup> Paragraph 4 of the Doha Declaration. Also paragraph 17 of the Doha Ministerial Declaration states that TRIPS should be interpreted “in a manner supportive of public health, by promoting access to existing medicines and research and development into new medicines.”

<sup>100</sup> See paragraph 6 of the Doha Ministerial Declaration.

<sup>101</sup> See George Tsai, “Canada’s Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration” (2009) 39 *Va J Int’l L* 1063 at 1065 [Tsai, “Canada’s Access to Medicines Regime”].

Further, intractable disagreements between developed and less developed countries over key issues of development in general and access to medicines in particular has stalled the progress of patent negotiations, among others. As will be further elaborated in chapters 3 and 4, the imposition of increased levels of IP protection in recent bilateral agreements has asphyxiated the already fragile ‘flexibilities’ under TRIPS and Doha.

In light of the above, this study will examine laws through the prism of a globalized or harmonized patent regime, implemented via TRIPS, the WIPO Development Agenda and Doha type accommodations, and assess their impact/manifestation in SSA. It will also urge the point that more needs to be done to bridge the north-south gulf if there is any prospect of achieving sustainable human development in SSA through the instrumentality of pharmaceutical patent regulatory frameworks. Though the primary focus of previous and dominant development agendas has been on neoliberal prescriptions for economic development,<sup>102</sup> it must suffice here to emphasize that development, in the context of this study, is about improving human lives and enabling people to have access to medicines and other life-saving health care services. The fact that the globalized patent regulatory regime operates within institutional arrangements takes us to the next trigger for comprehending the domains of patent law – institutions.

## **B. Institutions**

The second aspect of the quadripartite framework employed to study the globalized pharmaceutical patent system is institutions. Like the globalized legal regime, patent institutions play a crucial role in sustaining a particular normative world order. Patent regulatory institutions play a critical role not only in shaping the law but also in defining

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<sup>102</sup> See: *Marrakesh Agreement Establishing the WTO*, 1994, online: <[www.wto.org/english/docs\\_e/legal\\_e/04-wto.pdf](http://www.wto.org/english/docs_e/legal_e/04-wto.pdf)>; Yong-Shik Lee, *Reclaiming Development in the World Trading System* (New York: Cambridge University Press, 2006) [this discusses the impact of WTO regulatory framework on economic development]; Yong-Shik Lee, ed, *Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) [discussing the impact of global trade negotiations on economic development from the perspectives of developing countries]; Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth*, 2<sup>nd</sup> ed (Geneva: WIPO, 2003) [affirming that IP is a power tool for economic growth notwithstanding a state’s level of development].

the behaviour of players in the patent industry.<sup>103</sup> Patent institutions are the political instruments that specific players employ to bring about their desired changes. According to North, institutions are formed to reduce supposed uncertainties in human exchange.<sup>104</sup> They are therefore key determinants of the efficiency of markets.<sup>105</sup> These institutional apparatuses and regulatory structures are nevertheless emblematic of how western conceptions of globalization have shaped domestic and international bodies.

In this study, I adopt the perspective of Oguamanam that a key feature of the globalized patent regulatory institutions is that they are sustained by the western epistemic system.<sup>106</sup> The institutions, by process and outcome, work as a transcendental force, and their rules and organization are shaped by powerful states.<sup>107</sup> According to Poulantzas, international institutions crystallize class powers, and therefore negotiations and international law making processes within these institutions lack deliberative democracy.<sup>108</sup> As a consequence, scholars like Chimni urges ‘active peaceful resistance’ against the WTO by social movements.<sup>109</sup> My view is that dysfunctional patent institutions can be transformed or reconstructed to solve human development problems in SSA. Patent institutions can, and should, evolve to respond to changing circumstances and human development needs.

Generally speaking, the World Trade Organization (WTO), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), the United Nations Development Programme (UNDP), the Food and Agricultural Organization of

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<sup>103</sup> Gold et al, “Toward a New Era of IP”, *supra* note 2 at 22.

<sup>104</sup> See Douglass C North, “The New Institutional Economics and Development” online: <http://www.Econistate.edu/tesfatsi/NewInstE.North.pdf>.

<sup>105</sup> Sivaramjani Thambisetty, “Patents as Credence Goods” (2007) 27(4) Oxford J Legal Stud 707 at 740.

<sup>106</sup> Oguamanam, *International Law and Indigenous Knowledge*, *supra* note 16 at 176.

<sup>107</sup> Chimni, “WTO, Democracy, and Development”, *supra* note 20 at 68. Chimni’s position is that resistance should become an integral part of the narration of international law. This far-leftism is countered by other scholars from the south who argue against diagnoses of global inequality in terms of false binaries. On this point see John S. Saul, “Globalization, Imperialism, Development: False Binaries and Radical Resolutions” (2004) Socialist Register 223.

<sup>108</sup> See Nico Poulantzas, *Classes in Contemporary Capitalism* (London: New Left Books, 1975) at 70.

<sup>109</sup> Chimni, “WTO, Democracy, and Development”, *supra* note 20 at 69.

the United Nations' (FAO), the United Nations Commission on International Trade Law (UNCITRAL), the United Nations Conference on Trade and Development (UNCTAD), the World Bank, the International Monetary Fund (IMF) and other United Nations (UN) bodies all have complementary roles to play in the formulation and implementation of pharmaceutical patent and development policies. These institutions were established after the Second World War (WWII) mainly to respond to particular social, economic, legal and cultural demands in international relations. These international bodies have ensured not only the legalization of trade relations among states but also of domestic protection of the rights of western pharmaceutical corporations. They thus provide a forum for continued negotiations on the liberalization of trade-related matters within the international patent system and global development. While some of the above institutions have become proponents of the most protectionist IP norms, others have framed the international patent discourse as unfavourable to access-to-medicine-goals in less developed countries.<sup>110</sup>

For example, an UNCTAD report had concluded that: "overwhelming majority (84 per cent) of the patents in developing countries are owned by foreigners, mainly multinational corporations of five developed market-economy countries."<sup>111</sup> This report further avers that: "The nationals of developing countries hold in their own countries no more than 1 per cent of the world's stock of patents, and in other countries no more than about two thirds of 1 per cent of foreign-owned patents. These countries have plainly been on the periphery of the patent system."<sup>112</sup> As a pro-access-to-medicine institution, UNCTAD encourages developing countries to establish competition laws and

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<sup>110</sup> See Sell, *Private Power, Public Law*, *supra* note 1 at 20.

<sup>111</sup> See UN Department of Economic & Social Affairs, UNCTAD Secretariat and International Bureau of the WIPO, *The Role of the Patent System in the Transfer of Technology to Developing Countries* (1974) UN Doc TD/B/AC11/19 at 92 [UN/UNCTAD/WIPO].

<sup>112</sup> UN/UNCTAD/WIPO, *ibid.*

frameworks best suited to their development, and complemented by capacity-building that recognizes national policy objectives and capacity constraints.<sup>113</sup>

Also, a 2003 UNDP report on TRIPS concluded that the “relevance of TRIPs is highly questionable for large parts of the developing world.”<sup>114</sup> This report further urged developing countries to adopt a flexible approach to interpreting and implementing TRIPS while negotiating to replace the Agreement.<sup>115</sup> A similar conclusion was reached by the UK Commission on Intellectual Property Rights, which questioned the rationale for adopting equal minimum standards of IP protection irrespective of a State’s economic circumstances or level of development.<sup>116</sup> The UNDP’s approach to development, which takes into account different levels of development among states and their priorities, influenced the design of the WIPO Development Agenda.<sup>117</sup> More importantly, chapter 7 of this study will set out in detail the institutional roles of the WIPO and WTO in the quest to promote an equitable and human-development oriented patent paradigm in global trade relations

Further, there is a greater role for traditional and non-traditional actors in international patent law making. In the domestic arena, the traditional branches of government – the executive, the judiciary and the legislature – play important roles in the reception of international patent rules and negotiating, signing, ratifying, implementing and enforcing treaties across countries. Regional patent organizations such as ARIPO/OAPI and national patent offices also play critical roles in bringing supranational laws closer to domestic jurisdictions in SSA. Their objective is to promote the harmonization and development of a patent regime among members. Also, the key role of transnational corporate actors such as big pharma cannot be glossed over. Sometimes medicine

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<sup>113</sup> UNCTAD Mission online at <<http://www.unctad.org/Templates/Page.asp?intItemID=4031&lang=1>>.

<sup>114</sup> UNDP, *Making Global Trade Work for People* (2003) 221 at 222, online: <<http://www.undp.org/dpa/publications/globaltrade.pdf>>.

<sup>115</sup> UNDP, *Making Global Trade Work for People*, *ibid*.

<sup>116</sup> UK, *Commission on Intellectual Property Rights: Integrating Intellectual Property Rights and Development Policy* (September 2002) at 5-6, online: <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)>.

<sup>117</sup> See recommendation 15 of the WIPO Development Agenda, 2007.

research-outcomes and pricing policies are macro-managed by big pharmaceutical corporations to sustain their dominant market positions.<sup>118</sup>

Moreover, agitations from international non-governmental organizations in post-TRIPS trade negotiations in Seattle, Doha, Cancun, and Hong Kong have become the new face of resistance in international economic law making. These international non-governmental bodies also participate (sometimes via *amicus curiae* briefs) in dispute settlements within the WTO. International NGOs are also recognized as key players in the implementation of WIPO's IP-development norm-setting activities.<sup>119</sup> This increase in NGOs' participation could check some of the participatory-disparities in international economic law making within the WTO and other international organizations; it could bolster the positions of less developed countries in global trade relations.

Thus, the notion of the state as the traditionally recognizable global entity with pre-eminent standing in the international arena is changing. There is also intensification of non-traditional actors' participation in international economic law making. Non-traditional actors in international legal processes such as transnational corporations are increasingly assuming prominent roles within different UN bodies. The trend is that these private institutions have begun lending financial assistance to the international institutions; the danger is that these UN bodies may sing to the tune of powerful transnational corporate actors, especially big pharma.<sup>120</sup> There is also a movement that is expanding the status of individuals as subjects of international law.<sup>121</sup> This is because

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<sup>118</sup> See Sergio Sismondo, "Ghost Management: How Much of the Medical Literature is shaped behind the Scenes by the Pharmaceutical Industry?" (2007) 4 PLoS Med 1429.

<sup>119</sup> See recommendations 5, 6, 15, 21, 42 & 44 of WIPO Development Agenda (2007), online: <<http://www.wipo.int/export/sites/www/ip-development/en/agenda/recommendations.pdf>>.

<sup>120</sup> See BS Chimni, "Third World Approaches to International Law: A Manifesto" in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003) 47 at 59.

<sup>121</sup> See Kate Parlett, *The Individual in the International Legal System: Continuity and Change in International Law* (Cambridge: Cambridge University Press, 2011) 37; Wesley A Cann, "On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism" (2004) 25 U Pa J Int'l Econ L 755 at 760.

individuals influence the choices of states, and their actions can ultimately affect global economic relations. Therefore, understanding how TRIPS functions today requires an examination of the nature of the formal and informal actors in the WTO system and the changing ways in which they interact with one another.

In short, the roles of private and public institutions from both the domestic and international settings shape the directions of the globalized pharmaceutical patent regulatory regime. For instance, Shaffer et al have rightly touted the effectiveness of pluralistic interactions between the private sector, civil society, and the government on trade matters, by studying Brazil's leading role in international trade dispute settlements.<sup>122</sup> As a consequence, the complementary roles of private and public institutions in the pharmaceutical sector must influence the design of pharmaceutical patent policies to ensure sustainable human development in SSA. In relation to the overall thesis, chapters 3 to 7 will highlight the influence of the above mentioned institutions, especially the WIPO and WTO, in the formulation of patent policies at the domestic and international levels. I now turn to examine the third aspect of the proposed quadripartite framework – practices.

### **C. Practices**

As noted earlier, the international patent regulatory regime can have a significant impact on national economies and regulatory practices. Likewise, the practices of states and that of their citizens shed light on the effectiveness of the international and domestic legal orders. Practices by states and domestic actors alter the state of international legal norms.<sup>123</sup> In consequence, the influence of pharmaceutical patent regulatory practices on both domestic and international patent regimes cannot be under-estimated. As Gold et al adumbrate, “how people behave – in other words, their practices – and the effect of

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<sup>122</sup> Gregory Shaffer et al, “The Trials of Winning at the WTO: What Lies behind Brazil's Success” (2008) 41 Cornell Int'l LJ 383.

<sup>123</sup> William K Agyebeng, “Theory in Search of Practice: The Right of Innocent Passage in the Territorial Sea” (2006) 39 Cornell Int'l LJ 371 at 373.

practices on innovation is critical”<sup>124</sup> in understanding the workings of the globalized patent regime. Thus, the behaviour of players in the patent industry can be a more reliable indicator for measuring the extent of compliance with the formal law; patent practices can also re-shape the frontiers of the globalized regulatory framework. Worth emphasizing is that patent practices may occur through the passage of domestic legislation to implement international obligations or through the use of domestic access guidelines, advocacy and litigation. In some cases, practices arising from flawed patent administration may result in granting bad patents which do not meet the true test of patentability mandated by formal law. Taking one such ‘practice’ as an example, chapter 5 of this study will show that a vast majority of SSA states with the exception of South Africa lack the capacity and local know-how to examine pharmaceutical patent applications. Most pharmaceutical patents filed in SSA are examined via the PCT/ARIPO/OAPI systems, without significant national inputs as to their suitability to the country in question. This practice of non-examination of patent applications in national patent offices may undermine the efficacy of existing formal norms in SSA.

Another case in point whereby a State’s practice posed a fundamental challenge to the legitimacy of a rigid globalized patent regime occurred in South Africa in 1997. Here, Nelson Mandela’s government passed the *Medicines and Related Substances Control (Amendment) Act, 1997*<sup>125</sup> to allow the Health Minister to use compulsory licensing for the manufacture of generic versions of antiretroviral drugs. The Act also permits the parallel importation of cheaper generic versions of vaccines from other countries so as to reduce medical costs. This generated immense anger from lobbyist, capitalists and maximalists in the pharmaceutical industry. As a result, the South African government was sued by 39 pharmaceutical companies<sup>126</sup> and mounting pressure was exerted by the US government for repeal of the law. When the government failed to succumb to the

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<sup>124</sup> Gold et al, “Toward a New Era of IP”, *supra* note 2 at 9.

<sup>125</sup> Republic of South Africa Government Gazette No 18505, Act No 90, 1997 (entered into force on 12 December 1997).

<sup>126</sup> See *Pharmaceutical Manufacturers’ Association of South Africa et al v President of the Republic of South Africa*, Case No.4183/98, filed 18 February 1998.

incessant pressure, the US put South Africa on its Special 301 watch list for possible trade sanctions. In effect, South Africa was blacklisted. The pressure, however, did not succeed because the South African government stood by its policy. Eventually, the US government removed South Africa from its Special 301 watch list. The suit was also shelved, as negative public opinion swelled against the drug companies.

This South African experience has been hailed as one of the major turning points in the pursuit of anti-globalization agendas on matters of global public health.<sup>127</sup> It is acknowledged as a trail-blazing move which triggered efforts by countries such as Brazil and India to agitate for equitable and fair trade rules.<sup>128</sup> Subsequently, Brazil passed its *Intellectual Property Law*, which permitted compulsory licensing where there is a lack of local manufacturing of patented medicines.<sup>129</sup> The law also allowed parallel import by others if the patent holder failed to fulfil the ‘local working’ requirement of manufacturing the patented product in Brazil within three years from when the patent was granted. This caused the US government to commence proceedings against Brazil before the WTO Dispute Settlement Body.<sup>130</sup> The US argued that the Brazilian law violated Articles 27.1 and 28.1 of TRIPS. Eventually, the complaint was withdrawn by the US due to political pressure from international NGOs which had then joined in the global movement to moderate rules relating to IP rights. The then US Trade Representative, Robert Zoellick, subsequently “explained the move in the media by calling it another step

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<sup>127</sup> See: Andreas Rahmatian, “Neo-Colonial Aspects of Global Intellectual Property Protection” (2009) 12 *Journal of World Intellectual Property* 40 at 54-55; Sell, *Private Power, Public Law*, *supra* note 1 at 157; Gold et al, “Toward a New Era of IP”, *supra* note 2.; Patrick Bond, “Globalisation, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians” (1999) 29:4 *International Journal of Health Services* 765 at 771, 775.

<sup>128</sup> See: Hoen, *The Global Politics*, *supra* note 1 at 23; Ostergard, *The Development Dilemma*, *supra* note 1 at c 6.

<sup>129</sup> Article 68, Brazilian *Intellectual Property Law*, 1997, online at <<http://www.araripe.com.br/law9279eng.htm#patente>>.

<sup>130</sup> See: *Brazil – Measures Affecting Patent Protection, Complaint by the US* (WT/DS199/3) in 2001; Tsai, “Canada’s Access to Medicines Regime”, *supra* note 101 at 1069.

forward in the Bush administration's 'flexible approach' to health and intellectual property issues."<sup>131</sup>

In 1999 (and subsequently in 2003 at Cancún), the agitation reached a crescendo when international non-governmental bodies, such as Médecins Sans Frontières, Public Citizen, Greenpeace, Health Action International, and Health GAP, successfully frustrated the WTO's Seattle Ministerial Meeting. This was followed by a softening of IP rules and led to some success at the 4<sup>th</sup> WTO Ministerial Conference in Doha; a move that gave birth to a Declaration re-enforcing the interconnectedness between patent rules, access to medicines and public health issues in poor countries.<sup>132</sup> But the question remains: how many fragile states in SSA have the wherewithal to take such bold steps as those previously taken by South Africa and Brazil? What lessons should countries in SSA learn from the South African experience in light of the threats posed by HIV/AIDS, malaria, and TB to their citizens? The influence of these state policy-decisions or patent practices will be discussed in subsequent chapters of this study. Suffice it to say that practices provide an interesting avenue for studying the impact of law on society and the development of patent law in general.

This takes us to the final quadripartite context within which international economic relations and the analysis of the globalized patent regime is grounded in this study – politics.

#### **D. Politics**

Politics is another important context within which to appreciate the workings of an IP system; political clout in global economic relations is the epitome of power dynamics through which actors influence pharmaceutical policy outcomes. Politics is about power and the language of law, institutions and practices is a social scientific gloss that doesn't always capture the effect of power. Also, practices differ from politics in that the latter

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<sup>131</sup> Hoen, *The Global Politics*, *supra* note 1 at 23.

<sup>132</sup> See Paragraph 4 of the Doha Declaration & Paragraph 17 of the Doha Ministerial Declaration.

signifies how competing interests are weighed in international and domestic relations. It involves how divisions of power are brought to bear on questions bordering on safeguarding private pharmaceutical patent rights *vis-à-vis* public goals to have access to medicines. The questions I will address are: where does the balance of domestic and international powers lie in fashioning pharmaceutical patent regulatory policies? Do international and domestic actors play balanced roles in formulating patent regulatory policies? How do political and economic pressures affect the implementation of domestic policies on access to life-saving medicines in SSA? This study attempts to answer these questions in chapters 3, 4 and 5.

It must suffice here to indicate that the evolutionary trajectory of pharmaceutical patent-related negotiations and subsequent events attest to the fact that the design of international regulatory frameworks is no stranger to political machinations. These political manoeuvrings are just more than a set of actions taken in the formal arenas. They encompass power struggles, which are enacted in the private, social, economic and cultural arenas, in both formal and informal settings.<sup>133</sup> International law as politics reflects this world's power dynamics. Therefore, the dominant patent-related institutions, such as the WTO, WIPO, and WHO, are all international political institutions. These institutions have become a site for power politics on matters of international patent law making.

As will become clear in chapter 3, the prevailing patent regulatory framework for the protection of pharmaceuticals is born out of politics. Indeed, patent law cannot be insulated from politics. The use of political pressure by a hegemonic economic North, led by the US, against southern states has ensured that there is significant compliance with TRIPS, whether it is in the latter's interest or not. In essence, for fear of global alienation, countries, especially those in SSA, do not have the wherewithal to opt out of

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<sup>133</sup> Balakrishnan Rajagopal, "International Law, and the Third World Resistance: A Theoretical Inquiry" in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003) 145 at 158.

these established arrangements. Threats of trade sanctions have been an ‘effective’ weapon against perceived obstinate states. Besides deadlines for compliance with the provisions of TRIPS, IP-trade-related arrangements under TRIPS are fortified with dispute settlement mechanisms and the possibility of trade sanctions against a non-compliant WTO Member state. The fact that newly recognized economic powers such as India and China have succumbed to the international regulatory order are sufficient evidence of the uneven politics in the international trading system.<sup>134</sup>

Further, those who steer the international institutions are also political. Decisions are often made based on ideological and political predilections.<sup>135</sup> The use of bilateral bargain and private meetings among economic powers over deliberative democracy and openness in trade negotiations result in a system of governance flawed by lack of transparency and accountability.<sup>136</sup> Recently, a case has been made for the need to enhance participation by third world voices in debates about international law.<sup>137</sup> Politics is crucial to any pharmaceutical patent negotiations, policies, decisions, and practices in today’s global world. Therefore, understanding the politics of the globalized pharmaceutical patent regime will significantly illuminate the various positions taken by players in the industry. It will also assist in devising strategies to counter Northern domination.

#### IV. Conclusion

In conclusion, the foregoing discussion has urged the need to employ a quadripartite framework of laws, institutions, practices, and politics to inform/enrich the debate on patents and development at the WTO and in policy and academic discourse. The use of

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<sup>134</sup> See Anitha Ramanna, “Shifts in India’s Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests” in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 150 at 173

<sup>135</sup> Stiglitz, *Globalization and Its Discontents*, *supra* note 35 at x.

<sup>136</sup> Diana Tussie “Trade Diplomacy and Development Clubs: the Interaction in the Americas” in Yong-Shik Lee, ed, *Economic Development through World Trade: A Developing World Perspective* (The Netherlands: Kluwer Law International, 2008) 149 at 151.

<sup>137</sup> See e.g. Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (The Netherlands: Martinus Nijhoff, 2003).

such a multidisciplinary approach holds the key to addressing some of the complex conceptual and analytical issues surrounding pharmaceutical patent regulation and development discourses. The use of this quadripartite framework provides a promising avenue for evaluating the impacts of the regime of patents on societies in SSA; such a holistic approach will also make the debate on patents, access to medicines and development relevant in today's global trade relations.

## Chapter 3

### **Evolutionary Trajectories of Patents and the Politics of Exclusion in Sub-Saharan Africa**

#### **I. Introduction**

As I have noted in the preceding chapters, countries in SSA and their citizens have been marginalized in both international and domestic patent polity, respectively. These marginalizations challenge the legitimacy of both the domestic and the international patent regulatory frameworks. They also produce juridical outcomes that fail to recognize different levels of development among nations/regions. In order to substantiate these claims, this chapter investigates the evolutionary trajectories of the concept of patents and tests whether the ‘participation’ of SSA countries in TRIPS negotiations met the basic conditions of the theory of democratic bargaining in global trade relations. Do the undemocratic outcomes, if any, affect the implementation of TRIPS in SSA countries?

Against this backdrop, I divide this chapter into seven parts including this introduction. The second part discusses the European character of the origin and development of the concept of patent law. It surmises that although modern patent concepts began as national policies/legislation in Europe, non-western knowledge control systems that predate the Europeanization of the concept of patent law have been suppressed. The European character of the concept of patent law has squelched the story of knowledge control forms in other civilizations. Also, most commentaries on the origins of patent law fail to account for the historical racialization of patent rules that denied ownership rights to ‘certain categories of persons’. In addition, the historical literature has failed to provide an explanation for the chasm between the notion of patent law and indigenous knowledge. This tale of patent imperialism is epitomized by the globalized patent regulatory and institutional standards that protect pharmaceuticals in both developed and less developed countries alike. Under this part, I also discuss the first formal multilateral patent law treaty – the *Paris Convention* of 1883.

Part III analyzes the second phase in the pursuit of patent/economic harmonization under the GATT system of 1947. It makes allusions to the socio-economic, cultural and political contexts within which these developments and processes occurred to better inform us about the future. It recounts the tales of the exercise of western hegemony in developing multilateral treaties relating to patents, among others, under the GATT 1947 system. In addition, this part discusses the *Patent Cooperation Treaty* (PCT) of 1970, which introduced additional mechanisms for harmonizing the procedures involved in securing the rights of inventors across nations. The PCT's harmonization of patent filing-procedures influenced the design and the subsequent adoption of similar African regional instruments that established ARIPO and OAPI in SSA.

Part IV traverses the history of developments and negotiations that led to the linkage of IP to trade as part of the founding of the WTO. The *TRIPS Agreement* of the WTO is the result of the multilateral negotiations that began in the late twentieth century in Uruguay. In consequence, this part examines the history and negotiations that shaped the *TRIPS Agreement*, a treaty which marks a shift from 'soft' law (as epitomized by the *Paris Convention* and the *Patent Cooperation Treaty*) to 'hard' law, by providing strict obligations backed by a binding WTO complaint system and associated retaliatory sanctions. By tracing the routes of these negotiations that culminated in the adoption of TRIPS, I argue that countries in SSA were marginalized in the formulation of the globalized patent regime. This exclusion adversely affects how both the domestic and the international patent regimes work and contributes to impoverishing countries in SSA and their citizens. Theoretically, it also undermines the legitimacy of the globalized patent regime. The question as to whether those undemocratic outcomes affect the implementation of TRIPS in SSA countries remains a site for debate.

Part V alludes to post-TRIPS developments and narratives that suggest a new era of IP is emerging.<sup>1</sup> This post-TRIPS paradigm has witnessed a heightened awareness about the negative impacts of globalized patent norms on domestic social policies in poor countries. Consequently, steps are being taken to mitigate the negative and adverse effects of the globalized normative order on human lives by shifting the international patent discourse from one concerned with ‘pure’ free trade to a discourse that also considers public health and development. Significant examples of such transformations in the post-TRIPS epoch are epitomized by the adoption of the Doha Declaration, the ‘August 30’ Decision of the General Council of the WTO, and the WIPO Development Agenda. These mitigation measures respond to demands by less developed countries to have access to medicines to address public health and development challenges that affect their citizens. Whether those ‘humanitarian’ steps are adequate to overcome the politics of exclusion discussed in the preceding parts remains a matter for investigation. Here, I also assess the implications of the recent surge in bilateralism which imposes TRIPS-plus obligations on countries in SSA.

In Part VI, I examine a number of domestic stories, which confirm that the politics of exclusion at the international level is replicated in the design of national patent laws in SSA. I also confirm that the marginalization of SSA in the Uruguay Round negotiations has not affected the formal implementation of TRIPS in SSA countries, however. Through technical assistance initiatives, ‘experts’, with the support of the domestic elites, have transplanted western patent legislative models, concepts and western institutional apparatuses into countries in SSA. The question as to whether those legal and institutional transplants have worked to promote access to medicines for the suffering

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<sup>1</sup> See generally Daniel J Gervais, “TRIPS and Development” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 3 [Gervais, “TRIPS and Development”]; Richard Gold et al, “Toward a New Era of Intellectual Property: From Confrontation to Negotiation” (2008) *A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property*, online: <[http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf)>.

masses remain a site for debate. Suffice it to say that such transplants constitute “no more than the reiteration and adaptation of developed country approaches to the implementation of substantive international obligations, which are borne of different traditions and experiences, and cannot fully take care of the specific developing country requirements and levels of social and economic development.”<sup>2</sup> Legal standardization, according to Vaver, requires major reconsideration to avoid imposing defective laws on the developing world.<sup>3</sup> Also, it bears emphasizing that any regulatory and institutional transplants must be attuned to the real socio-economic conditions of the citizens of SSA. Part VII concludes the discussion under this chapter.

## II. Origin of Patent Law and Historical Inequities

### A. Origin of Patent Law

The history of the development of the concept of patent law confirms its European origins. The concept of patent law, as we understand it today, began in the early fifteenth century (i.e., 1421) when Filippo Brunelleschi invented the *Badalone* (a sea-vessel) in Florence, Italy for which no formal protection was available.<sup>4</sup> As a consequence, Brunelleschi refused to disclose his invention unless the city of Florence granted him a limited right to exploit the sea-craft.<sup>5</sup> Eventually, the city yielded to his demands on June 19 1421, thereby granting him a public letter to exploit his invention commercially.<sup>6</sup> The city conferred an exclusive privilege on Brunelleschi for a method of loading and transporting heavy merchandise on the *Badalone* across the Arno River in Florence for a period of three years. This grant thus sowed the seed for a movement to secure the rights

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<sup>2</sup> Mary E Footer, “Technical Assistance and Trade Law Reform Post-Doha: Brave New World” in John Hatchard & Amanda Perry-Kessaris, eds, *Law and Development: Facing Complexity in the 21<sup>st</sup> Century* (London: Cavendish, 2003) 108 at 125 [Footer, “Technical Assistance and Trade Law”].

<sup>3</sup> David Vaver, “Need Intellectual Property Be Everywhere? Against Ubiquity and Uniformity” (2002) 25 Dal LJ 1 at 5.

<sup>4</sup> Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006) at 16.

<sup>5</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 16.

<sup>6</sup> Mgbeoji, *Global Biopiracy*, *ibid*.

of inventors under some kind of formal or governmental arrangements. This formal arrangement crystallized in the form of patent law across Europe.

In 1474, the first substantive patent statute (*Parte Veneziana*) was passed in Venice, Italy. The preamble of the statute justified the grant of patents on grounds that it would induce people to invent devices for the common good of society.<sup>7</sup> The original Venetian patent statute offered protection for a period of ten years to all inventions that qualified for protection under the Act.<sup>8</sup> Between 1475 and 1550, an estimated one hundred patent privileges were granted or applied for in respect of industrial inventions.<sup>9</sup> In addition, this grant of a patent privilege was fortified with enforcement mechanisms to ward off potential infringers. This trend of granting patents for inventions diffused from the peripheries of Italy to Central and Western Europe, and subsequently to the rest of the world.<sup>10</sup>

Historically, patents began as monarchical ‘open letters’ to confer special titles, privileges, or status on people.<sup>11</sup> For example, German Prince August of Saxony granted privileges to inventors of novel and useful things, including methods of improving mine drainage in the sixteenth century.<sup>12</sup> Crown privileges were thus strategically employed to encourage the importation of foreign or new technology from abroad.<sup>13</sup> Similarly, Britain employed patent privileges to further its domestic trade policy on grounds that if a person brings in a new invention or a new trade to the UK, s/he deserves a monopoly grant to

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<sup>7</sup> Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 22 [Hestermeyer, *Human Rights and the WTO*].

<sup>8</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 16.

<sup>9</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Westport, Connecticut: Greenwood Press, 1951) at 2.

<sup>10</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 27; Robert P Merges & John F Duffy, *Patent Law and Policy*, 3<sup>rd</sup> ed (Newark: LexisNexis, 2002) at 4.

<sup>11</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 16.

<sup>12</sup> Penrose, *Economics of the International Patent System*, *supra* note 9 at 3.

<sup>13</sup> Bitu Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (England: Ashgate, 2009) at 41 [Amani, *State Agency and the Patenting of Life*].

use it for a specified period of time.<sup>14</sup> This desire to encourage the introduction of new arts remained an important reason for the grant of monopoly by the Crown in the UK. For these reasons, Baxter has concluded that the early patent system was based largely on a regime of “invention by importation.”<sup>15</sup>

However, over the years, the patent system has changed in form and substance. Presently, the consent of the right holder is required to import/export the patented product or process, unless the right is exhausted. Patents also now cover a broad spectrum of subject matters, including pharmaceutical products and processes; and, the terms of patent protection have also increased. While a full survey of the history of patent law, which spans five centuries, is beyond the scope of this chapter, this brief historical narrative demonstrates that the character of patents has expanded with respect to objects of protection, scope/reach of protection, and period of protection.

Specifically to this study, the frontiers of patents in the pharmaceutical industry have expanded in recent years. Patentable inventions were traditionally limited to machines or processes involving new art, manufacture, compositions of matter, and design.<sup>16</sup> Pharmaceutical products in particular and pharmaceutical processes in general were traditionally non-patentable subject matter. Today, the requirements of patentability have changed in tandem with the demands of the pharmaceutical and biotechnology industry, and the terms of patent protection have increased from 10 years or less to 20 years in most jurisdictions.<sup>17</sup> This transformation has brought pharmaceutical products and processes into the ambit of patent law. At present, despite the controversies surrounding judicial decisions in the US, patent protection extends to cover business methods and

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<sup>14</sup> See *The Clothesworkers of Ipswich Case*, 78 ER 147; *Statute of Monopolies*, 1623.

<sup>15</sup> JW Baxter, *World Patent Law and Practice*, vol. 2 (London: Sweet and Maxwell, 1976) at 7.

<sup>16</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 122.

<sup>17</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 122.

financial service products,<sup>18</sup> including a method of swinging from side to side (US patent no: 6368277), peanut butter and jelly sandwiches (US patent no: 6329919), and a method for drafting patent claims (US patent no: 6574645).<sup>19</sup>

Also, the privileged nature of patent grants has metamorphosed into near absolute rights,<sup>20</sup> such that the grant of property rights over patents now empowers persons to withhold (in near absolute terms) from others the exercise of the right to make, use, sell, and/or import the invention across jurisdictions.<sup>21</sup> In addition, corporate entities, as non-natural persons, were traditionally not allowed to own patents.<sup>22</sup> Presently, corporate entities (including many pharmaceutical corporations) have become the preeminent owners of patents, a remarkable shift from the situation that hitherto prevailed. It is estimated that 90 per cent of all patents are granted to businesses.<sup>23</sup> Governments have also come on board to confer on patentees the exclusive right to prevent others from using, making, selling, and/or importing the patented product or process for a set period of time within a jurisdiction. Today, patent concepts have been harmonized and mainstreamed as part of global trade governance.

According to Mgbeoji, this radical shift of patents from monarchical grants into governmental grants and subsequently into near global grants occurred as a result of four factors.<sup>24</sup> First, this transformation occurred as a result of migration. For example, the migration of British settlers to North America and Oceania contributed significantly to

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<sup>18</sup> See *State Street Bank & Trust Co. v Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed Cir, 1998) *cf* *In Re Bernard L Bilski & Rand A Warsaw* (2007-1130) (Serial No. 08/833,892) [as of writing in 2011, this case was on appeal at the US Supreme Court].

<sup>19</sup> See Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 58.

<sup>20</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 30.

<sup>21</sup> See Article 28 of the *TRIPS Agreement*, which provides that a patent shall confer on its owner the exclusive rights to use, make, import, or sell the patented products or processes.

<sup>22</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 29.

<sup>23</sup> See Mgbeoji, *Global Biopiracy*, *ibid* at 24.

<sup>24</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 28.

the dissemination of British technology into those parts of the world.<sup>25</sup> Accordingly, the British *Statute of Monopolies*, 1623<sup>26</sup> which introduced the idea of granting a patent to the first to invent including the first person to introduce a new art from abroad, became the direct ancestor of the US and Australian/New Zealand patent laws.<sup>27</sup> Under the *Statute of Monopolies*, 14 years protection was granted to the inventor.

Second, the change came about as a result of colonization. When a state is colonized, its laws and institutions are not left unscathed.<sup>28</sup> Most states in SSA were thrust into the Eurocentric patent system because at all material times they were subject to colonial control. Indeed, the first political independence in a black African country south of the Sahara occurred in Ghana in 1957. Third, the change in the character of patent law in most jurisdictions occurred through direct/volitional borrowing. Modeling laws in line with what has happened elsewhere has become a common phenomenon among policy-makers and legislators in the global economy. Indeed, apart from Japan which developed its own patent system with little regard to European patent tradition, all other states have followed the European approach to patent regulation.<sup>29</sup>

The fourth transformative factor in the character of patents occurred as a result of external pressure to create and enforce patents within domestic jurisdictions. Economic and political pressures on less developed countries have established what can be termed ‘patent imperialism’— a phenomenon that imposes western systems of propertization of knowledge on poor countries and preys on the cultural and knowledge values of countries

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<sup>25</sup> Ituku Elangi Botoy, “From the Paris Convention to the TRIPS Agreement: A One-Hundred-and-Twelve-Year Transition for the Industrialized Countries” *Journal of World Intellectual Property* 115 at 118.

<sup>26</sup> *An Act Concerning Monopolies and Dispensations with Penal Laws, and the Forfeiture thereof* 1623 (UK) 21 Jac 1, cap 3.

<sup>27</sup> See Penrose, *Economics of the International Patent System*, *supra* note 9 at 7.

<sup>28</sup> Chidi Oguamanam, “Local Knowledge as Trapped Knowledge: Intellectual Property, Culture, Power and Politics” (2008) 11 *Journal of World Intellectual Property* 29 at 33; Samuel O Manteaw, “Patents and Development in Ghana: Proposals for Change” (2008-2010) 24 *UGLJ* 111 at 114.

<sup>29</sup> Mgbogji, *Global Biopiracy*, *supra* note 4 at 37-38.

in the south. Patent imperialism also encapsulates the influence of big pharma in the design of the international regulatory framework for protecting pharmaceuticals in utter disregard for the social consequences in poor countries. For Rahmatian, patent imperialism contributes to maintaining trans-colonial empires for purposes of enforcing western interests in the legal and political systems of poor sovereign states.<sup>30</sup> The globalized patent regime has fulfilled this imperial role of securing and entrenching the interests of pharmaceutical patent holders in SSA with minimal checks-and-balances in force. This lack of effective counter-mechanisms to moderate relatively high patent protection standards has partly contributed to the anemic scope of access to medicines policies in SSA.

Meanwhile, the effects of the first two evolutionary factors (i.e., migration and colonization) have significantly diminished as compared to the last two factors (i.e., legal transplants and economic pressure). Hence, the issue of colonialism will not receive detailed attention here as other scholars have trodden that path already.<sup>31</sup> Rather, I focus on the latter two factors (i.e., legal transplants and economic pressure) which predominate in modern international economic relations. In particular, the use of economic pressure in the name of economic globalization is emblematic of patent imperialism, of which TRIPS is the most potent multilateral expression. In this vein, IP-

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<sup>30</sup> See e.g. Andreas Rahmatian, “Neo-colonial Aspects of Global Intellectual Property Protection (2009) 12 *Journal of World Intellectual Property* 40 [Rahmatian, “Neo-colonial Aspects of Global IP Protection”]; Marci A Hamilton, “The TRIPS Agreement: Imperialistic, Outdated, and Overprotective” (1996) 29 *Vand J Transnat’l Law* 613 [TRIPS may become one of the most effective vehicles of western imperialism in history].

<sup>31</sup> See Ruth L Okediji, “The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual System” (2003) 7 *Sing. JICL* 315 at 320-341 [Okediji, “The International Relations of IP”] [Historical accounts identify the early 15<sup>th</sup> century as the beginning of European contact and interaction with SSA These interactions continued on several fronts including trade and maritime travels until the 19<sup>th</sup> century when European countries concluded the Paris Convention in 1883 and the Berne Convention in 1886. The IP system became a central part of the commercial relations in and outside Europe. To this end, African countries were brought under the aegis of the international IP system through the agency of colonial rule. The modus operandi of the struggle towards independence also made African countries beneficiaries of standard IP laws; it was as though IP protection was an incidence of statehood itself]; Oguamanam, “Local Knowledge as Trapped Knowledge”, *supra* note 28.

trade-related arrangements under TRIPS are fortified with dispute settlement mechanisms and trade sanctions to procure compliance. A state, therefore, cannot deviate from these established arrangements without the threat of trade sanctions from the dominant economic powers, such as the US and the EU. As discussed in chapter 2, the South African experience with its *Medicines and Related Substances Control (Amendment) Act*, 1997 is an apt illustration of this point. The effect is that poor countries show little resistance in complying with WTO patent rules.

Given that states are at different levels of development, rigid norms transplant and strict compliance with TRIPS would not do. Countries in SSA need to recalibrate WTO patent rules and fine-tune TRIPS implementation in domestic jurisdictions to facilitate access to medicines to treat epidemics that threaten human lives. Further, in exploring avenues to determine how patents can serve human development goals in SSA, it is imperative to appreciate some of the historical inequities and distortions in the evolution of the concept of patent law. Hence, this following section will bring to the fore some of these distortions and patent inequities that have historically militated against less developed countries and their knowledge control values.

## **B. Historical Distortions and Patenting Inequities**

The origin and development of the concept of patent law is not so much as to what patent law includes; but rather what it excludes. Most accounts omit, for example, that historical evidence of exclusion of slaves from owning patents allowed for black inventors to be exploited, mostly in the US and in parts of Europe.<sup>32</sup> The slave trade and the resultant colonization of black people south of the Sahara also derailed many efforts to imitate, via reverse engineering, and, probably, develop the capacity to innovate in SSA.<sup>33</sup> Also, the fact that blacks in the early American patent system were denied patents on grounds that

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<sup>32</sup> Keith Aoki, “Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)” (2007) UC Davis L Rev 717 at 741.

<sup>33</sup> See Aoki, “Distributive Syncretic Motives in IP Law”, *ibid* at 741.

they lacked the requisite inventive agency to generate or possess patentable ideas created obstacles for black inventors to develop innovative ideas.<sup>34</sup> For instance, Aoki's account on the invention of the cotton gin shows that Eli Whitney (a slave owner) was granted patents in the cotton gin even though a slave identified only by the name 'Sam' may have invented it.<sup>35</sup> This disdain for original black inventors disabled them from progressing into the patent aristocracy in the 'primitive' or antebellum era.

In essence, western cultures and knowledge systems have obfuscated the knowledge systems of African people. As Oguamanam observes, 'cultural cosmopolitanism' caused the colonial and post-colonial hierarchies of western power to view African knowledge systems and values with disdain and denigration.<sup>36</sup> Accordingly, the literature on the origin of patents traces the phenomenon to Europe, without mentioning the knowledge protection regimes in other civilizations which perhaps predate European economic systems.<sup>37</sup> This lacuna, probably, explains why folklore is a non-patentable subject matter.<sup>38</sup> Dutfield offers a different insight into the non-patentability of indigenous knowledge on grounds that the exclusion is "really a matter of social injustice rather than one of economic inefficiency."<sup>39</sup>

However, research has shown that prior to the introduction, if not imposition, of a western-conception of patent ownership on non-western societies, there were in existence sophisticated communal regimes of ownership and control of invention in the latter

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<sup>34</sup> Aoki, "Distributive Syncretic Motives in IP Law", *ibid* at 743.

<sup>35</sup> Aoki, "Distributive Syncretic Motives in IP Law", *ibid* at 722, 745-747 [The cotton gin was cutting edge technology in the 1790s which perpetuated the antebellum chattel slavery regime for several decades].

<sup>36</sup> Chidi Oguamanam, "Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions and the Dialectics of Knowledge Transformation" (2008) 15 Ind J Global Legal Stud 489.

<sup>37</sup> Oguamanam, "Local Knowledge as Trapped Knowledge", *supra* note 28 at 33.

<sup>38</sup> See Paul Kuruk, "Protecting Folklore under Modern Intellectual Property Regimes: A Reappraisal of the Tensions between Individual and Communal Rights in Africa and the United States" (1999) 46 Am UL Rev 769.

<sup>39</sup> Graham Dutfield, "Sharing the Benefit of Biodiversity: Is there a Role for the Patent System?" (2002) 5 Journal of World Intellectual Property 899 at 905.

societies.<sup>40</sup> For example, Arab and Pharaonic civilizations recorded technological progress without the aid of the patent system.<sup>41</sup> The existence of non-western knowledge systems, by logical implication, confirms the existence of inventive activities in pre-colonial times among the people of the global South. Indeed, what accounts for the deafening silence on the contributions of non-western states to the knowledge control systems is a site for debate. The convergence of asymmetrical power relations, cultural domination, colonization, and the pursuit of neoliberal politics has squelched the other side of the story.

As fallout from this exclusion, ancient civilizations/inventions of Egypt and other countries which predate the epoch of writing are left out of many accounts. Similarly, “the requirement of writing meant that indigenous peoples’ knowledge, often [un]recorded or transmitted orally, fell outside the ambit of protected information.”<sup>42</sup> In other words, non-written means of transmitting information remain unaccounted for in modern patenting endeavours. However, it bears noting that non-recorded communal rights also exist in places such as SSA. The Eurocentric character of the development of patent concepts raises questions about efforts to promote the requirements of contemporary patent law as universal verities.<sup>43</sup>

In addition, the western concept of ownership and the scientific notion of the inventive process, as the mantra for protecting knowledge forms, have been enacted as part of the international law on patents, beginning with the *Paris Convention*, to the present day. Contemporary patent law thus fails to accept the reality that the property right regimes in the south seem at odds with the individualistic conception of ownership and knowledge

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<sup>40</sup> See *Draft Report of the World Intellectual Property Organization Fact-Finding Missions on Intellectual Property and Traditional Knowledge* (Geneva: WIPO, 1998-1999).

<sup>41</sup> Mgbefi, *Global Biopiracy*, *supra* note 4 at 23.

<sup>42</sup> Mgbefi, *Global Biopiracy*, *ibid* at 29.

<sup>43</sup> Ikechi Mgbefi, “TRIPS and TRIPS-Plus Impacts in Africa” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 259 at 263.

systems of the western worldview.<sup>44</sup> According to Mgbeoji, this failure of the concept of patent law to reflect the worldviews of indigenous people has provided the basis for the appropriation of traditional knowledge from the primitive era to the present.<sup>45</sup> This alleged appropriation of indigenous knowledge values was not salvaged by the first international legal instrument on industrial property – the *Paris Convention*, which I discuss below.

### C. *Paris Convention, 1883*

The *Paris Convention* was the first formal multilateral patent treaty to be adopted at the international level; it made the first international attempt to harmonize patent rules, among others. The primary aim of the *Paris Convention* is to secure the rights of industrial property holders. Such industrial property rights include patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.<sup>46</sup> Specifically to patents, the *Paris Convention* (Paris) rules now include various kinds of industrial patents such as patents of importation, patents of improvement, patents and certification of addition, among others.<sup>47</sup>

The *Paris Convention* was drafted at a diplomatic conference in Paris in 1880 and was ratified by eleven states in 1884.<sup>48</sup> The original eleven member-states of the Paris Union comprised: Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain, and Switzerland. What is apparent from this Convention is not only who the founding nations were but the lack of participation by any African country in formulating the Paris rules. African interests were subsumed under western control. It also confirms the European dominance in the formal articulation of patent rules in an

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<sup>44</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 38.

<sup>45</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 29.

<sup>46</sup> See Article 1(3), *Paris Convention*, 1883.

<sup>47</sup> See Article 1(4), *Paris Convention*, 1883.

<sup>48</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 39.

international treaty. In consequence, the *Paris Convention* laid the foundation for marginalizing African countries in international patent law making. Presently, the membership of the Paris Union includes SSA countries among the 171 member-state parties of the Convention.

The *Paris Convention* articulates four categories of rules.<sup>49</sup> The first category deals with rules of public international law that regulate the rights and obligations of member-states, organs of the organization, and the constitutional character of the organization.<sup>50</sup> Secondly, there are rules that require or permit member-states to legislate in the field of industrial property.<sup>51</sup> As pointed out in chapter 2, this territorial regulatory discretion was removed by the norms of the *TRIPS Agreement*. Thirdly, there are substantive provisions in the field of industrial property regarding the rights and obligations of private parties.<sup>52</sup> These provisions, which afford primacy to private property rights, have gained currency under the *TRIPS Agreement* up to now. The fourth and final category of rules under the *Paris Convention* deals with substantive law regarding the rights and obligations of states-parties.<sup>53</sup>

Most importantly, the *Paris Convention*, in its quest to harmonize patent law, introduced the principles of ‘national treatment’ and ‘right of priority.’<sup>54</sup> By the national treatment principle, foreigners receive the same privileges under national patent laws as do nationals of the home country of a member state.<sup>55</sup> The right of priority rule also provides that if a patent application is filed in any Union state within one year of filing in a home country or other first Union filing, the subsequent application is effectively back-dated to

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<sup>49</sup> Mgbeoji, *Global Biopiracy*, *ibid* at 40.

<sup>50</sup> See Articles 13-15 of the *Paris Convention*, 1883.

<sup>51</sup> See Article 20 of the *Paris Convention*, 1883.

<sup>52</sup> See Article 4 to 5bis of the *Paris Convention*, 1883.

<sup>53</sup> See Article 22 of the *Paris Convention*, 1883.

<sup>54</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 40.

<sup>55</sup> Article 2, *Paris Convention*, 1883.

the first filing date.<sup>56</sup> This priority rule makes it possible to designate countries where protection will be sought so that copies of the first filing are remitted for consideration in those countries. This rule has in turn mitigated the hardships that innovators had to endure to meet a twelve-month deadline to file for patent protection throughout the world, failing which the invention receives no protection in a particular state. To a degree, the above principles standardized how patent rules worked or operated across jurisdictions.

The Paris rules have had substantively unequal effects even though they may on the surface act neutrally. According to Oddi, the low levels of inventiveness in developing countries mean that the Paris rules, including the national treatment principle and the right of priority rule, do not benefit these countries.<sup>57</sup> The rules thus fail to provide poor countries with assurances that the grant of patents predominantly to foreigners will lead to national development.<sup>58</sup> Mgbeoji on his part notes that the Paris rules are “akin to saying that an Olympian athlete and a cripple are all potential gold medalists in a compulsory 100-metre dash.”<sup>59</sup> This analogy fundamentally underscores the failure of the international standards to reflect domestic realities in places such as Africa where there are relatively low levels of inventiveness.

It is, however, significant to point out that, in spite of the *Paris Convention's* pro-harmonization stance, it left issues of compulsory licensing to individual countries to legislate.<sup>60</sup> Also the *Paris Convention* did not obligate its members to provide patent

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<sup>56</sup> See Article 4 of the *Paris Convention*, 1883.

<sup>57</sup> A Samuel Oddi, “The International Patent System and Third World Development: Reality or Myth?” (1987) 63 Duke LJ 831 at 856, 859.

<sup>58</sup> Oddi, “The International Patent System”, *ibid* at 865; According to UNCTAD, 84 per cent of patents in developing countries are owned by foreigners.

<sup>59</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 223. Arguably, Mgbeoji’s analogy fails to account for the moratorium granted to developing and LDCs in implementing the TRIPS Agreement. This moratorium is nonetheless threatened by recent bilateral and regional agreements which impose stringent patent regulatory standards on countries in SSA

<sup>60</sup> See Article 5(2) of the *Paris Convention*. This issue becomes manifest if a state fails to legislate to permit compulsory licensing.

protection to pharmaceutical products. As Oddi observes, the Convention allowed member states to: limit the classes of patentable subject matter, adopt high standards of patentability, limit the duration of patent grants, set the conditions for patent renewals, or impose high filing and maintenance fees.<sup>61</sup> These domestic flexibilities allowed a number of Paris Union-members to exclude pharmaceutical products and processes from patent protection in accordance with their public policy objectives to promote innovation and development. Specifically, until the 1970s and 1980s, a number of western countries including Switzerland, Japan, Canada, Italy, Germany, and Sweden did not grant protection to pharmaceutical products, albeit some protected pharmaceutical processes.<sup>62</sup> Spain and Portugal declined to grant patents to pharmaceutical products until 1992. A WIPO study in 1988 confirmed that out of the 98 Paris Union-members, 49 then excluded pharmaceutical products from patent protection.<sup>63</sup>

In the context of SSA, the scenario is, however, different: patent laws were re-enacted in African countries without regard to local sensibilities and realities.<sup>64</sup> A number of SSA countries were ill-advised by ‘experts’ from the West to adopt patent protection mechanisms for pharmaceutical products.<sup>65</sup> Although this study does not assess the impacts of colonization on the legal systems of SSA countries, one thing is certain: since France and Britain colonized most countries in SSA and were among the early countries to adopt pharmaceutical product patents, SSA countries were socialized, if not forced, to follow suit. Accordingly, “OAPI members have provided for pharmaceutical product patents since the Bangui Agreement of 1977 and ARIPO members (except Ghana and

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<sup>61</sup> Oddi, “The International Patent System”, *supra* note 57 at 869.

<sup>62</sup> Sumner La Croix & Ming Liu, “Patents and Access to Essential Medicines” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 423 at 437.

<sup>63</sup> WIPO, “Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, WO/INF/29 September 1988, GATT document MTN.GNG/NG11/W/24/Rev1.

<sup>64</sup> Mgbeoji, “TRIPS and TRIPS-Plus in Africa”, *supra* note 43 at 266.

<sup>65</sup> Oddi, “The International Patent System”, *supra* note 57 at 854.

Malawi) have done the same since 1984.”<sup>66</sup> Also, the instruments that establish OAPI and ARIPO vest both institutions with powers to grant regional patents. Such regional grants are enforceable across all member states irrespective of domestic regulatory and institutional lapses. In addition, SSA countries use the examination processes established by both ARIPO and OAPI in granting domestic patents.

These European influences (i.e., legal transplants) partly laid the foundation for the present patent regulatory and institutional obstacles that impede access to medicines to treat epidemics in SSA. Also, this story of marginalization of SSA countries continued during the Rounds<sup>67</sup> of the GATT 1947 trade debate.

### III. Patents in Multilateral Global Relations

Since the end of WWII, various processes and events have coalesced to lay the foundation for the development of the present globalized patent system. The disruption of free trade during the First and Second World Wars, the collapse of the capital market as a result of the Great Depression, and the upsurge of communism, which obstructed inflows of capital, became a lightning rod in the quest to establish a ‘pure’ free trade regime in 1947.<sup>68</sup> Also, the failure of Enlightenment thinking<sup>69</sup> supported the case for change in global trade relations.<sup>70</sup> A new free trade paradigm, based on the General Agreement on

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<sup>66</sup> Croix & Liu, “Patents and Access to Medicines”, *supra* note 62 at 438.

<sup>67</sup> The Rounds include: 1949 in Geneva, England in 1950-51, Geneva in: 1955-56, 1960-61 (Dillon Round), 1964-67 (Kennedy Round), 1973-79 (Tokyo Round), and 1986-94 (Uruguay Round).

<sup>68</sup> Mark R Brawley, *Power, Money, & Trade: Decisions that Shape Global Economic Relations* (Ontario, Canada: Broadview Press, 2005) at 157-158.

<sup>69</sup> The promise of the Enlightenment thinking was that human reason was the primary source and legitimacy for authority. This promise turned out to be a ‘myth’, a dysfunction. The promise imposed the political ideals and institutions of the powerful states on less powerful countries, by perpetuating discourse that tends to create and extend domination and dependency. The Enlightenment thinking also fostered the Second World War. For a detailed discussion of the failure of the Enlightenment thinking which took humanity down the barbaric path of Nazism, see Max Horkheimer & Theodor W Adorno, *Dialectic of Enlightenment*, John Cumming, ed (New York: Continuum, 1995).

<sup>70</sup> Joseph E Stiglitz, *Globalization and Its Discontents* (New York: W.W. Norton & Co., 2002) at 282.

Tariffs and Trade (GATT) 1947, was therefore constructed to respond to these failures of the early twentieth century.

The GATT 1947 trade system championed the cause for negotiating multilateral treaties relating to tariff and non-tariff barriers. The GATT arrangements also contained some IP rules, notably, Articles I(1), III(10), IV, XII(3), XVIII(10) and XX(d) that made limited reference to actions taken in connection with national enforcement of IP rights. These limited provisions relating to IP rights included: most-favoured-nation (MFN) treatment; national treatment relating to cinematograph films; compliance with patent, trade mark and copyright procedures; and, the enforcement of monopolies relating to patents, trade mark, and copyright. Although the link between trade and IP was manifestly weak under the GATT 1947 system, the GATT rules together with the Paris rules were presumably adequate, and were thus employed to secure the rights of inventors for a greater part of the twentieth century.

It bears mentioning that the GATT 1947 arrangements were less intrusive of domestic sovereignty as it focused on border barriers. GATT 1947 offered less developed countries some formal ‘differential treatment’<sup>71</sup> in order to implement domestic programs and policies to raise the general standard of living of their citizens and to protect infant industries.<sup>72</sup> Although the formal differential treatment arrangement was *prima facie* laudable, economists contend that the exclusion of less developed countries from the GATT Rounds meant that the world trading system was tailored to favour the West. According to Stiglitz & Charlton, this exclusion of countries under GATT’s Article XVIII (which deals with governmental assistance for economic development) caused less developed countries to be marginalized on matters of substantive trade negotiations.<sup>73</sup> A

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<sup>71</sup> This is a formal exclusion of developing countries from the GATT requirements in order to shove up the standard of living of their people.

<sup>72</sup> Article XVIII of GATT 1947.

<sup>73</sup> Joseph E Stiglitz & Andrew Charlton, *Fair Trade for All: How Trade Can Promote Development* (Oxford: Oxford University Press, 2005) at 43 [Stiglitz & Charlton, *Fair Trade For All*].

contrary viewpoint is that the GATT arrangement rather showed deference to the economic development concerns of less developed countries.<sup>74</sup>

However, in light of the fact that the *Paris Convention*'s national treatment principle and the GATT's MFN principle were still in force, less developed countries could not discriminate against foreign owned patents. As a consequence, the GATT's differential treatment provision was rendered ineffective in developing local innovative capacities and promoting technology transfer to SSA. In addition, the PCT was concluded outside the GATT system to further harmonize and facilitate patent applications across nations. The PCT has influenced the design and the subsequent adoption of ARIPO and OAPI regional instruments in SSA.

#### **A. *Patent Cooperation Treaty, 1970***

The *Patent Cooperation Treaty* (PCT) represents another major milestone towards a truly procedural harmonization of the concept of patent law after the *Paris Convention*.<sup>75</sup> The PCT was concluded in 1970 as an international instrument to streamline the administrative processes involved in filing a patent application in different jurisdictions. The PCT's founding history shows the influence of Europe in its agenda-setting activities.<sup>76</sup> The primary purpose of this treaty is to lower the cost of securing international protection to patents by allowing innovators to acquire patent protection in all PCT signatory-countries on the basis of a single application and examination.<sup>77</sup> The PCT, therefore, introduced procedural mechanisms for making international patent application possible. In April 2011, WIPO confirmed that the two millionth international patent application under the PCT was filed by a US-based mobile technology company,

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<sup>74</sup> See e.g. Okediji, "The International Relations of IP", *supra* note 31 at 328

<sup>75</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 40.

<sup>76</sup> Mgbeoji, *Global Biopiracy*, *ibid.*

<sup>77</sup> See Rochelle Dreyfuss et al, eds, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford: Oxford University Press, 2004) at xi.

Qualcomm.<sup>78</sup> Today, plans are underway to institutionalize electronic filing in order to further facilitate international patent applications.

Article 27(1) of the PCT prohibits member-states from invoking domestic law as requirements for non-compliance with the form and content of the international application system. To some extent, this obligation introduced certainty in the global patent application processes. It also limited the issue of exclusive territoriality of states over procedures for securing intangible property rights. In addition, the PCT establishes a Union to supplement the workings of the Paris Convention. Presently, the PCT has a total of 142 member-states. This increase in membership is remarkably different from the situation in the early 1970s when the treaty had 20-members with no African country as a member.

Like the *Paris Convention*, SSA countries did not participate in the design of the PCT. Yet, the PCT has become a blueprint for the design of the ARIPO and OAPI regional instruments in SSA. Both instruments seek to harmonize the filing of patent applications and to develop a common view on patent matters in SSA.<sup>79</sup> Given that the bulk of pharmaceutical patents in SSA are owned by non-Africans, regional harmonization of patents, via the ARIPO and OAPI instruments, raises legitimate questions for access to medicine issues in SSA.

Aside from the PCT (which was concluded outside the GATT system), patent matters did not receive particular attention in twentieth-century multilateral trade relations until 1979, when attempts were made to pass an international code against trading in counterfeit goods.<sup>80</sup> This attempt to adopt an anti-counterfeiting code failed to materialize, but it was

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<sup>78</sup> See WIPO, “International Patent System Marks Two Millionth Filing – U.S. Mobile Technology Innovator, Qualcomm, files Landmark Application” PR/2011/687 (2011).

<sup>79</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 41.

<sup>80</sup> See Marco CEJ Bronckers, “The Impact of TRIPS: Intellectual Property Protection in Developing Countries” (1994) 31 CML Rev 1245.

resuscitated in the 1980s as part of the Uruguay Round of trade negotiations. The salient point to emphasize here is that under the GATT 1947 system countries still operated under a palimpsest of patent rules. As shown below, a new trend emerged in the 1980s when robust standards for IP protection were established in the developed world, especially in the US, and subsequently, those standards were globalized across the board through a multilateral treaty in the form of TRIPS.

#### **IV. Evolution of the Uruguay Round of Trade Negotiations<sup>81</sup>**

##### **A. Prelude to a Globalized Patent Framework**

The early 1980s witnessed major legal and political victories in relation to patent protection for the pharmaceutical, software and entertainment industries in the US and in other western economies. These industries made a case to the effect that globalizing US/western IP standards would fuel creativity and innovation, generate higher rents, attract foreign investment, and encourage a more rapid transfer of technology.<sup>82</sup> Industry also portrayed less developed countries as ‘pirates’ and ‘thieves’ when it comes to the use of biotechnology protected materials.<sup>83</sup> The industries supplemented this anti-piracy stance by portraying themselves as embattled innovators who faced an uncertain future in a world where mercenary southerners were unwilling to engage in fair business practices.<sup>84</sup> In particular, the resurgence of China as a technologically proficient state

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<sup>81</sup> The discussion under this part will be based on the jurisprudence of the US, since the prevailing globalized patent regime is the outcome of the policies and influence of the US and its industries.

<sup>82</sup> Laurence R Helfer, “Regime Shifting: the TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29 Yale J Int’l L 1 at 2; Gervais, “TRIPS and Development”, *supra* note 1 at 13.

<sup>83</sup> Robert Weissman, “A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries” (1996) 17:4 U Pa J Int’l Econ L 1069.

<sup>84</sup> Peter Drahos & John Braithwaite, “Who Owns the Knowledge Economy: Political Organizing Behind TRIPS” (2004) *Corner House Briefing* 32, 9, online: <<http://www.thecornerhouse.org.uk>> [Drahos & Braithwaite, “Who Owns the Knowledge Economy”].

involved in ‘piracy’ was considered as a threat to American innovators.<sup>85</sup> Also, the internet/information revolution was depicted as a potential threat to securing the traditional rights of innovators in the global economy.<sup>86</sup> The pharmaceutical, software and entertainment industries in the US, therefore, lobbied for the acceptance of an international regime that recognized the western standards of pharmaceutical patent protection, among others.

The arguments of Mossinghoff, the then President of Pharmaceutical Research and Manufacturers of America (PhRMA), vividly depict the rhetoric of the US industries.<sup>87</sup> First, he posits that effective patent protection in the US and abroad is vitally important to the pharmaceutical industry. Second, that America’s research-based pharmaceutical companies pour millions of dollars into the research and development of new technology every year.<sup>88</sup> In consequence, whether this commitment can continue depends greatly upon the extent to which foreign governments allow innovators to be rewarded for their inventiveness, monetary investment, and intellectual labour. Third, Mossinghoff argues that for the private sector pharmaceutical industry, which has been the primary source of new therapies for the past four decades, there is little incentive to provide an ever-increasing commitment to research unless there are reasonable expectations of financial return.<sup>89</sup> He consequently concludes that only effective patent protection provides the incentives necessary to enable pharmaceutical companies to commit the required resources for innovation.<sup>90</sup>

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<sup>85</sup> See Rahmatian, “Neo-colonial Aspects of Global IP Protection”, *supra* note 30 at 47-48; Okediji, “The International Relations of IP”, *supra* note 31 at 336.

<sup>86</sup> See e.g. Graham Dutfield & Uma Suthersanen, *Global Intellectual Property Law* (Cheltenham: Edward Elgar, 2008) at 236; Poku Adusei, “Cyberspace and the Dilemma of Traditional Copyright Law: An Assessment of the Impact on the Legal Community” (2002-2004) 22 UGLJ 202.

<sup>87</sup> Gerald J Mossinghoff, “Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide” (1987) 2 JL & Tech 307.

<sup>88</sup> Mossinghoff, “Research-Based Pharmaceutical Companies”, *ibid.*

<sup>89</sup> Mossinghoff, “Research-Based Pharmaceutical Companies”, *ibid.*

<sup>90</sup> Mossinghoff, “Research-Based Pharmaceutical Companies”, *ibid.*

Halle explains industry's claim for increased global IP protection differently, however. He notes that for the trade world, IP rights are one of the pillars on which the entire trade edifice is built.<sup>91</sup> As such, it would be difficult to muster the confidence necessary for international commerce without widespread recognition of property rights, without a considerable degree of harmony in how these rights are recognized, and without an assurance that these rights will be respected and – where necessary – enforced.<sup>92</sup> Put another way, the growth and success of the US and other western companies would not be possible without the strong protection of IP materials around the world.

This pro-industry maximalist agenda for increased pharmaceutical protection standards convinced policy-makers in the US to begin a search for 'effective' and 'adequate' patent protection mechanisms across the globe in the early 1980s. Gervais refers to this early 1980-period as *addition narratives* era; it is an era in which a persuasive, if not coercive, case was made to the effect that if IP rights protection is good, then more protection for IP rights is better to jump-start economic growth in both rich and poor countries alike.<sup>93</sup> At the rent-seeking insistence of industry, policy-makers in the US and other western countries pushed for an upward expansion of the scope and levels of patent protection across the globe by bringing them to the levels in force in developed economies.

In this regard, the US courts, the US Congress, and the Executive branch of the US government joined industry's anti-piracy/economic-dominance bandwagon for enhanced patent protection. For example, the US Supreme Court decided to extend patent protection to "anything under the sun that is made by man" including an oil-splitting bacterium.<sup>94</sup> This grant of patent to a genetically modified bacterium is said to have

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<sup>91</sup> Mark Hale, "Foreword" in Graham Dutfield, *Intellectual Property Rights, Trade and Biotechnology: Seeds and Plant Varieties* (London: Earthscan, 2000) at xii.

<sup>92</sup> Hale, "Foreword", *ibid.*

<sup>93</sup> Daniel J Gervais, "Introduction" in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) xv at xv.

<sup>94</sup> *Diamond v Chakrabarty*, 447 US 303(1980).

fueled a growing biotech industry in the US.<sup>95</sup> Further, in 1981 the US Supreme Court extended patent rights to software beyond the traditional focus on “physical elements or process steps.”<sup>96</sup> Also, in 1985 patent protection in the US was extended to higher life forms such as man-made sexually reproducing plants.<sup>97</sup> In tandem with the resurgence in patent rights in the 1980s was a relaxation of perceived stringent anti-trust policies by the Reagan Administration.<sup>98</sup>

Another related event was the passage of the *Bayh-Dole Act*, 1980.<sup>99</sup> This Act encouraged universities and other federal-public funded institutions to patent discoveries arising from their research and to commercialize such technologies by transferring them to the private sector. The new *Bayh-Dole Act* property regime increased patent filings and private biotechnology investment.<sup>100</sup> Other scholars, however, discount the claim that the *Bayh-Dole Act* fuelled the rise of technology transfer in the biotechnology industry.<sup>101</sup> Nonetheless, research has shown that between 1991 and 2004 patent applications by US universities rose from 1,584 to 10,517.<sup>102</sup> This exponential rise in university patent applications also increased license income from \$218 million to \$1.4 billion, amounting

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<sup>95</sup> See Stacey Berg et al, “PTO Biotechnology Patent Protection Hearing” (1994) 6:11 J Proprietary Rts 33.

<sup>96</sup> *Diamond v Diehr*, 450 US 175 (1981) [granting protection to computer monitoring of a rubber molding process, because of the physical transformation of the rubber ‘into a different state or thing’].

<sup>97</sup> See *Ex Parte Hibberd*, 227 US Patents Quarterly 443 (Board of Appeals and Interferences, 1985).

<sup>98</sup> Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003) at 72; Ellen FM ’t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) at 10.

<sup>99</sup> *Bayh-Dole University and Small Business Patent Procedures Act* of 1980, Pub L No. 96-517, 35 USC 200-212. The original intent of this Act was to encourage technology transfer from the federally-funded universities in the US.

<sup>100</sup> Michael Heller, *The Gridlock Economy: How too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* (New York: Basic Books, 2008) at 58.

<sup>101</sup> E Richard Gold & Michel Trommetter, “The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030” OECD Paper 8 (2007), online: <<http://www.oecd.org/dataoecd/11/58/40925999.pdf>>.

<sup>102</sup> Sharon Belenzon & Mark Schankerman, “University Knowledge Transfer: Private Ownership, Incentives, and Local Development Objectives” (2009) 52 J L & Econ 111 at 112.

to 6 per cent of federal research and development financing for universities.<sup>103</sup> The reason for the reported increases in university-licensing is that the *Bayh-Dole Act* encouraged universities to focus on areas where licensing is more effective.<sup>104</sup>

The US also amended its section 301<sup>105</sup> of the *Trade Act* of 1974 to allow for the US Trade Representative to take action against nations which fail to protect IP.<sup>106</sup> The ‘Special 301’ regime empowered the US Trade Representative to review IP standards and practices in foreign countries in order to ascertain their levels of compliance with the US-standards of adequate and effective protection of IP rights. Through such ‘section 301’ annual reviews, immense pressure was brought to bear on less developed countries to enforce IP rights.<sup>107</sup> For example, the review caused Brazil, China, India, and Thailand to be named under the ‘Special 301’ regime in 1991.<sup>108</sup> Subsequently, threats to use this ‘Special 301’ retaliatory provision of the US *Trade Act* against countries that deny adequate and effective patent protection caused those countries to agree to the US demands during the Uruguay Round.<sup>109</sup> In short, this unilateral retaliation mechanism became a strong weapon in the hands of the US during TRIPS negotiations.<sup>110</sup>

Also, decisions of the US court system influenced the international patent agenda-setting activities of the 1980s. A special court – the Court of Appeals for the Federal Circuit (CAFC) – was set up to adjudicate over patent matters in the US.<sup>111</sup> The aim for

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<sup>103</sup> Belenzon & Schankerman, “University Knowledge Transfer”, *ibid* at 112.

<sup>104</sup> Jerry Thursby & Marie Thursby, “Knowledge Creation and Diffusion of Public Science with Intellectual Property Rights” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (Amsterdam: Elsevier, 2008) 200 at 207.

<sup>105</sup> This section 301 mechanism is a trade enforcement tool that permits the US to withdraw the benefits trade agreements or impose duties on goods from foreign countries. It also includes entering into new agreements to eliminate the alleged offending action.

<sup>106</sup> Hoen, *The Global Politics*, *supra* note 98 at 11.

<sup>107</sup> Sell, *Private Power, Public Law*, *supra* note 98 at 122-123.

<sup>108</sup> See Rahmatian, “Neo-colonial Aspects of Global IP Protection”, *supra* note 30 at 48.

<sup>109</sup> See Hoen, *The Global Politics*, *supra* note 98 at 10; Rahmatian, “Neo-colonial Aspects of Global IP Protection”, *ibid*

<sup>110</sup> Hoen, *The Global Politics*, *ibid* at 11.

<sup>111</sup> See *Federal Courts Improvement Act* of 1982, Pub L No. 97-164, 96 Stat. 25.

establishing the CAFC was to make patent litigation more uniform.<sup>112</sup> This Court has, since its establishment, been liberal in its approach towards granting patents to products and processes in the US. According to Sell, the CAFC's decisions have reflected a more pro-patent approach and have supported higher award of damages against patent infringers.<sup>113</sup> On his part, Merges notes that CAFC has "increased the stability and predictability of patent doctrine, to the benefit of innovative private firms."<sup>114</sup> Studies confirm that the number of cases in which patents was found to be valid and infringed increased from 62 per cent in the early 1980s to 90 per cent in the early 1990s under the CAFC.<sup>115</sup>

The CAFC, for instance, ruled that it was an infringement where, before patents expire, the patented product was made and used in research to obtain data needed for receiving approval for generic medicines.<sup>116</sup> Thus, the use of patented medicines for clinical tests conducted by generic manufacturers before patent expiration was held to be infringing even if the test was meant to fulfill the US Food and Drug Administration approval requirements. In *Arrhythmia Research Tech., Inc. v Corazonix Corp.*, the CAFC followed the earlier noted *Diehr* decision, by holding that an invention is patentable if it involved a mathematical algorithm that was "applied to, or limited by, physical elements or process steps."<sup>117</sup> The CAFC's pro-patent stance has triggered enthusiasm among patentees to

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<sup>112</sup> Ashish Arora et al, "Patents and the Market for Technology" in Keith E Maskus, *Intellectual Property, Growth and Trade* (Amsterdam: Elsevier, 2008) 123 at 126.

<sup>113</sup> Sell, *Private Power, Public Law*, *supra* note 98 at 69.

<sup>114</sup> Robert P Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation" (1988) 76 Cal L Rev 803 at 806.

<sup>115</sup> Keith E Maskus, *Reforming US Patent Policy: Getting the Incentives Right* (CSR No. 19, November 2006) at 13.

<sup>116</sup> See *Roche Products Inc v Bolar Pharmaceutical Co* (733 F 2d 858, Fed Cir, 1984). The effect of this ruling has now been minimized. Presently, generic manufacturers can use such test data before the expiry of the patent for purposes of meeting regulatory requirements for approval of generic medicines in the US after 5 years. See, the *US Drug Price Competition and Patent Term Restoration Act*, 1984, Pub L No. 98-417, 98 Stat. 1585 (1984) (this Act is also called "Hatch-Waxman Act").

<sup>117</sup> 958 F2d 1053, at 1058 (Fed Cir, 1992).

seek judicial remedies for alleged patent infringements.<sup>118</sup> This patent-friendly forum also makes it difficult to challenge patent grants, even if they ever get litigated.

The extraordinary influence of the US and its industry catapulted US patent standards to global benchmarks in international patent law making. Mgbeoji aptly sums up this point as follows:

Article 27 of...TRIPS, constituting the global minimum threshold of patentability, is an approximation of US jurisprudence and ideology...TRIPS is a product of the immense clout of the American pharmaceutical and biotechnology industries...the US patent system accounts for almost half of all patents issued in the world...the United States has the most appropriative regime on patents...the pronouncements and decisions of US courts on matters of patent law have immense international influence.<sup>119</sup>

Around the same time, other western countries, such as Japan, Canada and those in Europe felt the need to benefit from the biotechnology and information technology boom, and thus brought their IP laws into conformity with those of the US.<sup>120</sup> They thus joined the crusade to make all countries compete on the same patent regulatory terms and conditions as part of global trade governance. For instance, the European Community (EC)/EU, in line with the US approach, introduced its own proposal for negotiations on trade-related aspects of IP rights.<sup>121</sup> The US also succeeded in enshrining IP rights protection in the North American Free Trade Agreement between itself, Canada and Mexico.<sup>122</sup> By joining this crusade, the EU, Japan and Canada gave the US the needed impetus and imprimatur to push for the adoption of strong standards of patent protection

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<sup>118</sup> Sell, *Private Power, Public Law*, *supra* note 98 at 67-69.

<sup>119</sup> Mgbeoji, *Global Biopiracy*, *supra* note 4 at 14.

<sup>120</sup> E Richard Gold & Alain Gallochat, "The European Biotech Directive: Past as Prologue" (2007) 7 Eur LJ 331.

<sup>121</sup> See EC, *Guidelines Proposed by the European Community for the Negotiations on Trade-Related Aspects of Intellectual Property Rights*, GATT DoC MTN.GNG/NG11/W/16.

<sup>122</sup> See *North American Free Trade Agreement*, United States-Canada-Mexico, 17 December 1992, 32 ILM 289.

in 1994. Today, the US administration has also linked counterfeiting and piracy of IP-protected materials with terrorism to serve its instrumentalist agenda.<sup>123</sup>

History, however, tells us that today's ardent defenders of western-style patent standards were yesterday's 'pirates' of other people's knowledge-based products and processes. The same developed states that today push for stronger IP protection did not observe strict IP standards until they had reached a high level of development and economic maturity facilitated by the exchange of ideas and transfer of technology.<sup>124</sup> For example, between 1790 and 1836 the US imported British technology by restricting the grant of domestic patents.<sup>125</sup> This fact is confirmed by a 1986 study for the US Congress, which indicates that "when the United States was a relatively young and developing country it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development."<sup>126</sup> The British *Statute of Monopolies* also excluded from patentability inventions that were mischievous to the state by raising prices of domestic commodities, or hurt trade, or were generally inconvenient.<sup>127</sup> In addition, China's enhanced capacity to innovate is another example of what 'piracy' may offer in terms of industrial development.<sup>128</sup> Countries' ability to imitate and import foreign technologies prior to the introduction of stringent global patent protection standards likely greatly benefited them and propelled their domestic technological capacities.

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<sup>123</sup> See Duncan Matthews & Viviana Munoz-Tellez, "Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective" (2006) 9 *Journal of World Intellectual Property* 629 at 635 [Matthews & Munoz-Tellez, "Bilateral Technical Assistance and TRIPS"].

<sup>124</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 2.

<sup>125</sup> Mgbeoji, "TRIPS and TRIPS-Plus in Africa", *supra* note 43 at 264.

<sup>126</sup> US Congress, Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronics and Information* (1987) at 230.

<sup>127</sup> See Section 6 of the *Statute of Monopolies*.

<sup>128</sup> See Frederick M Abbott, "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" (2005) 8 *J Int'l Econ L* 77 at 81 [Abbott, "Toward a New Era of Objective Assessment"].

To conclude, three important events occurred that laid the foundation for patent-promotion efforts in the late 1980s. First, the pharmaceutical and software industries in the US succeeded in influencing government agencies and transforming domestic legislation in the US as part of a drive for a global IP renaissance. This influence of industry has further consolidated its control over pharmaceuticals, and provided avenues for rent-seeking activities in the global market-place. The influence of industry has established what Amani calls the ‘Corporate Republic’ in which public participation in important domestic policy decisions is diminished.<sup>129</sup>

The second trigger for the 1980s maximalist patent agenda is based on a flawed ideology that the resurgence of China, as a technologically proficient state, if unchecked, could threaten the interests of American innovators. A case was, therefore, made for countries to model their IP rules in line with the US standards of IP rights protection to secure the interests of innovators. But, this much we also know: that, in an increasingly interdependent world, a state cannot sustain its growth and development if that state free-rides on the weakness of another. As Landes aptly puts it:

Failure to extend the benefits of technology and science to large parts of the world is not only morally wrong, but in the long run it denies to the total system its ultimate fulfillment. Prosperity like peace is indivisible. The accelerated pace of the West’s own economic progress could be nullified by the failure of the rise in the standard of living of the largest part of the world.<sup>130</sup>

The third trigger relates to the computer-driven or information revolution of the late twentieth century. The internet/information revolution has facilitated the generation, processing, diffusion, manipulation and application of sensitive information across borders.<sup>131</sup> This information volatility was depicted as a potential threat to securing the

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<sup>129</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 13.

<sup>130</sup> Stephen Landas, “Existing Uniformity of Industrial Property Laws and Revised Patent of Introduction: Means for Transfer of Technical Information to Less Industrialized Countries” (1968) 12 IDEA 163 at 163.

<sup>131</sup> Oguamanam, “Local Knowledge as Trapped Knowledge”, *supra* note 28 at 31.

traditional rights of innovators in the global economy. As a result, frantic efforts were made to forestall this threat of possible global knowledge piracy. These triggers explain why US innovators framed the debate as a fight against piracy; the triggers also became a lightning rod to revamp the global knowledge control system by including IP matters in the Uruguay Round of multilateral trade negotiations, which began in 1986.

## **B. Birth of the Uruguay Round of Negotiations**

The Uruguay Round of multilateral trade negotiations ensued between 1986 and 1994. When the Round commenced in 1986, at the Uruguay resort city of Punta del Este, the aim was to clarify GATT provisions and elaborate upon new rules and subject-areas.<sup>132</sup> At the inception of the Uruguay Round, these new rules and areas did not then include IP matters as part of the negotiations. IP matters would later become a necessary subject for the Uruguay Round, however.<sup>133</sup>

IP matters were included in the Uruguay Round because the US government continued the crusade, began by the US pharmaceutical and biotechnology industries, for adequate and effective protection of the IP rights of innovators. As Sell explains,

[P]rivate actors pursued their interests through multiple channels and struck bargains with multiple actors: domestic interindustry counterparts, domestic governments, foreign governments, foreign private sector counterparts, domestic and foreign industry associations, and international organizations. They vigorously pursued their IP objectives at all possible levels and in multiple venues, successfully redefining intellectual property as a trade issue. However, it was not merely their relative economic power that led to their ultimate success, but their command of IP expertise, their

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<sup>132</sup> It must be noted at the outset that most of the accounts of the Uruguay trade deliberations are based on anecdotes and claims rather than concrete evidence, as there were no recordings of the oral arguments. The good news is that the credibility of some of the accounts has not been disputed by key players who participated in the Uruguay negotiations. On this point see Lars Anell, “Foreword” in Daniel Gervais, ed, *The TRIPS Agreement: Drafting History and Analysis*, 3<sup>rd</sup> ed (London: Sweet & Maxwell, 2008) viii. Anell chaired the Negotiating Group on TRIPS, including Trade in Counterfeit Goods.

<sup>133</sup> Anell, “Foreword”, *ibid* at vii.

ideas, their information, and their framing skills (translating complex issues into political discourse).<sup>134</sup>

In other words, at the behest of industry, the US and other western governments moved to rectify flawed IP laws, via a multilateral treaty, in less developed countries so as to check piracy. Others contend that the US and EC/EU opened the TRIPS negotiations with a desire to limit compulsory licensing in domestic regimes.<sup>135</sup> Be that as it may, it is beyond doubt that the Uruguay Round altered the status quo by incorporating IP matters into multilateral trading system for the first time.<sup>136</sup> On his part, Ostergard notes that the Uruguay process elevated the IP rights issue from “an obscure, esoteric legal field to a critical economic and political issue that brought states to the brink of trade wars.”<sup>137</sup>

Scholars also recount that the Uruguay Round of trade negotiations was dominated by the Quad: the US, EU, Japan and Canada.<sup>138</sup> The Quad states supported the US industry agenda. In addition, western negotiators adopted what is termed ‘green room’<sup>139</sup> consultations by reaching key decisions in informal settings and leaving out negotiators

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<sup>134</sup> Sell, *Private Power, Public Law*, *supra* note 98 at 8.

<sup>135</sup> E Richard Gold & Daniel K Lam, “Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing” (2003) 6 *Journal of World Intellectual Property* 5 at 15.

<sup>136</sup> See Dilip K. Das, “Intellectual Property Rights and the Doha Round” (2005) 8 *Journal of World Intellectual Property* 33 at 35.

<sup>137</sup> Robert L Ostergard, “Economic Growth and Intellectual Property Rights Protection: A Reassessment of the Conventional Wisdom” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 115 at 116.

<sup>138</sup> See Donald P Harris, “Carrying a Joke Too Far: TRIPS and Treaties of Adhesion” (2006) 27 *U Pa J Int’l Econ L* 681 at 730 [Harris, “Carrying a Joke Too Far”]; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3<sup>rd</sup> ed (London: Sweet & Maxwell, 2008); Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002) [Drahos & Braithwaite, *Information Feudalism*].

<sup>139</sup> This refers to informal inner circle group meetings used by the Quad: the US, EC, Japan, and Canada to seek consensus and finalize decisions that should have been taken in the formal multilateral setting, where less developed countries can contribute. Occasionally, a number of developing countries were invited to join in such consensus seeking endeavours in order to build a seemingly broad coalition and give the decision a semblance of legitimacy.

from the Third World.<sup>140</sup> During the Uruguay Round, the green room meetings became so intense that the delegates from less developed countries cynically referred to such meetings as ‘black room’ consultations.<sup>141</sup> The point is that less developed countries, especially those in SSA, were largely absent from the negotiations and consensus-building activities in the green room meetings.

Also, western negotiators in conjunction with the pharmaceutical industry, among others, wanted to change the forum for trade-related IP law making. The position of Pfizer was that WIPO had failed to secure the higher patent standards that the large pharmaceuticals players wanted.<sup>142</sup> The WTO was seen as better suited to implementing the *TRIPS Agreement* and to enforcing it through its dispute settlement mechanisms. This regime shift caused WIPO to lose its over-sight role as the UN Agency in charge of IP-related matters.

Meanwhile, less developed countries ‘opposed’ the West’s efforts to plug the gap in the regimes of knowledge protection via the GATT/WTO system. As Drahos & Braithwaite note, countries such as India and Brazil argued that WIPO was the appropriate forum for the development of IP standards and that the GATT/WTO’s involvement with IP issues was inappropriate.<sup>143</sup> Accordingly, a common ground had to be found to pave the way for the Uruguay Round to continue. Consequently, developed countries promised less developed counterparts relatively easy access to western markets for agricultural products and textiles as a *quid pro quo* for the latter to accept IP rights protection as part of global

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<sup>140</sup> BS Chimni, “Third World Approaches to International Law: A Manifesto” in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (Leiden, Martinus Nijhoff, 2003) 47 at 53.

<sup>141</sup> Peter Drahos, “When the Weak Bargain with the Strong: Negotiation in the World Trade Organization” (2003) 8:1 *International Negotiation* 79 at 87 [Drahos, “When the Weak Bargain with the Strong”].

<sup>142</sup> See Peter Drahos, “Developing Countries and International Intellectual Property Standard-Setting” (2002) 5 *Journal of World Intellectual Property* 765 at 769 [Drahos, “DC and International IP Standard-Setting”].

<sup>143</sup> Drahos & Braithwaite, “Who Owns the Knowledge Economy”, *supra* note 84 at 19.

trade governance.<sup>144</sup> Developed countries also promised to refrain from using unilateral and bilateral trade pressures against less developed nations if the latter signed on to TRIPS.<sup>145</sup> Eventually, less developed countries agreed to the west's demands for the negotiations to proceed with IP matters firmly on the agenda.

Conversely, the frontline of less developed countries was utterly divided. Like the Tower of Babel,<sup>146</sup> from which everyone speaks but with a different voice, less developed countries failed to pursue a common anti-liberalization agenda. According to Drahos & Braithwaite, as southern opposition began to solidify, western negotiators sowed a seed of confusion among the developing country group led by India and Brazil.<sup>147</sup> Shukla, then Indian Ambassador to the GATT, aptly notes that:

The impression went round that the show of firmness that the [southern] negotiators were making...was only a facade not backed by a firm political support at [country] capital. No negotiators can hope to muster support from other countries on difficult issues involving disagreement and even confrontation with major powers, if those [powerful] countries suspect the inherent strength of the stand or even the sincerity of its propounders.<sup>148</sup>

More importantly, SSA countries became political inferiors who played no meaningful role in the Uruguay Round of negotiations that led to the passage of the *TRIPS Agreement*. The African Group, which consists mainly of SSA countries, was largely absent from the Uruguay Round of trade negotiations.<sup>149</sup> As some commentators have lamented, African countries had negligible or no input into the negotiations that resulted

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<sup>144</sup> See Helfer, "Regime Shifting", *supra* note 82 at 3.

<sup>145</sup> M El-Said, "The road from TRIPS-minus, to TRIPS, to TRIPS-plus: implications of intellectual property rights for the Arab world" (2005) 8 *Journal of World Intellectual Property* 53 at 55 [El-Said, "From TRIPS-minus, to TRIPS, to TRIPS-plus"]; Helfer, "Regime Shifting", *ibid* at 22.

<sup>146</sup> The Tower of Babel offers a metaphorical reminder of what happens when a shared 'context' is completely shattered as a result of divergent opinions. This point is taken from See Katharine T Bartlett, "Only Girls Wear Barrettes: Dress and Appearance Standards, Community Norms, and Workplace Equality" (1994) *Mich L Rev* 2541 at 2550.

<sup>147</sup> Drahos & Braithwaite, "Who Owns the Knowledge Economy", *supra* note 84 at 25.

<sup>148</sup> SP Shukla, cited in *Agriculture in Dunkel's Draft of GATT – A Critical Analysis* (New Delhi: TWN, 1993) at 6.

<sup>149</sup> Drahos, "When the Weak Bargain with the Strong", *supra* note 141 at 91.

in the design of the WTO rules on patents.<sup>150</sup> Out of the 48 countries in SSA, it was not until 1989 that Nigeria and Tanzania joined the Group of 10 Developing countries to object to the inclusion of IP protection as part of the WTO arrangements.<sup>151</sup>

On his part, Ogunkola observes that less than three per cent of the overall written proposals and comments circulated during the Uruguay Round were submitted by countries in SSA.<sup>152</sup> By 1989, when Nigeria and Tanzania came on board, the ‘world’ had decided. It had become too late to save a sinking ship. Even a more skeptical view is that the Uruguay Round of trade negotiations had concluded by 1989.<sup>153</sup> The political superiors were the West (led by the US) and its multinational corporations who lobbied and pushed for the passage of TRIPS, a multinational treaty which sets western benchmarks for patent protection in SSA.

The reasons for the anemic participation of countries in SSA include, first, the failure of African countries to forge links with Geneva-based delegations (even where they existed), and secondly, the failure of policy makers to involve relevant domestic ministries and agencies with issues of international economic law making.<sup>154</sup> Negotiators from SSA did not also have significant expertise in international negotiations involving IP matters. Further, other scholars posit that the costs involved in maintaining any meaningful participation in the Uruguay Round, and the WTO processes had blocked SSA countries.<sup>155</sup> As Drahos & Braithwaite explain, “South African trade negotiators simply did not understand that they were signing an agreement that would contribute to a

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<sup>150</sup> See Michelle Gravelle & John Whalley, “Africa and the Uruguay Round” (1996) *Transnat’l L & Contemp Probs* 123.

<sup>151</sup> Hoen, *The Global Politics*, *supra* note 98 at 10.

<sup>152</sup> EO Ogunkola, “African Capacity for Compliance and Defence of WTO Rights” Paper for African Economic Research Consortium (AERC)-Sponsored Conference on Africa and the World Trading System, Yaounde, Cameroon (17-18 April 1999) at 3.

<sup>153</sup> See Drahos & Braithwaite, “Who Owns the Knowledge Economy”, *supra* note 84 at 28.

<sup>154</sup> Footer, “Technical Assistance and Trade Law”, *supra* note 2 at 114.

<sup>155</sup> See e.g. Richard Blackhurst et al, “Options for Improving Africa’s Participation in the WTO” in Bernard Hoekman et al, eds, *Developing Countries and the WTO: a Pro-active Agenda* (Oxford: Blackwell, 2001) 95.

situation by 2001 where...a 15-year-old would have greater than a 50 per cent chance of dying of HIV-related causes.”<sup>156</sup> In essence, African states that signed on to TRIPS did not fully understand its impact on their citizens’ health.

In 1994, TRIPS was adopted as part of the establishment of the WTO to “reduce distortions and impediments to international trade...promote *effective* and *adequate* protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”<sup>157</sup> On January 1, 1995 the Agreement entered into force as a global benchmark for patent protection, among other IP rights. Industry was rewarded on grounds that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>158</sup> The downside is that the grant of product patents gives the owner exclusive rights over the composition of the drug itself regardless of how it is produced, and the process patents give the owner exclusive rights over the scientific method of producing the drug.<sup>159</sup> Further, the enjoyment of patent rights is without discrimination as to whether the products are imported or manufactured locally.<sup>160</sup> Moreover, TRIPS requires each signatory country to provide an effective enforcement mechanism for patents.<sup>161</sup> To cap it all, the grant of patents is backed by a dispute settlement mechanism that can hold states liable for any infringement.

Since the standards embodied in the *TRIPS Agreement* were high western standards, transition periods were offered to developing and LDCs to configure their legislation in

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<sup>156</sup> Drahos & Braithwaite, *Information Feudalism*, *supra* note 138 at 191. See also Peter K Yu, “TRIPS and Its Discontents” (2006) 10 Marq Intell Prop L Rev 369 at 375 [less developed countries were ignorant of the extensive nature of the obligations they adopted].

<sup>157</sup> Preamble to the *TRIPS Agreement*.

<sup>158</sup> Article 27.1 of TRIPS.

<sup>159</sup> See Margaret B Kwoka, “Vindicating the Rights of People Living with AIDS Under the Alien Tort Claims Act” (2008-2009) 40 Loy U Chi LJ 643 at 655.

<sup>160</sup> See Article 27.1 of TRIPS.

<sup>161</sup> See Articles 41-43 of TRIPS.

order for them to become TRIPS-compliant. Developing countries had a deadline of January 1, 2005 to protect and enforce pharmaceutical patents; LDCs have until 2016 to protect and enforce pharmaceutical product patents.<sup>162</sup> This extension of the transition period for LDCs is further evidence that the globalized patent regime is not serving the needs of such countries yet. According to Yu, “had the level of intellectual property protection been adjusted to reflect the countries’ needs, interests, and conditions, those transitional provisions in the TRIPS Agreement might not have been needed.”<sup>163</sup> On the other hand, developed countries such as the US and those in Europe, did not require any significant configuration of existing IP laws. After all, the *TRIPS Agreement* was modeled in line with their existing laws.

Aside from the above formal moratorium for poor countries, a new concept of ‘single undertaking’<sup>164</sup> was introduced to compel countries to accede to universal standards of patent protection, among others, irrespective of any diversity they may have. This single undertaking approach thus operated as a claw-back mechanism for the realization of any benefits under the transitional arrangements put in place. Countries that seek to use the transition period must institute mechanisms for granting exclusive marketing rights for

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<sup>162</sup> These two new deadlines are based on an extension. The initial deadline for developing countries was 1 January 2000, and that of LDCs was 1 January 2006. See Decision by the Council for TRIPS of June 27, 2002, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for LDC Members for Certain Obligations with respect to Pharmaceutical Products*, WTO Doc IP/C/25, 1 July 2005. Besides, pharmaceuticals, LDCs have until 1 July 2013 to comply with TRIPS. As earlier indicated, the transition periods for developing and LDCs did not affect the national treatment and most favoured nations treatment obligations under Articles 3 and 4 of TRIPS, respectively.

<sup>163</sup> Peter Yu, “Four Common Misconceptions about Copyright Piracy” (2003) 26 *Loy La Int’l & Comp L Rev* 127 at 135.

<sup>164</sup> This single undertaking rule obliges member countries to agree on an entire set of rules that have been multilaterally negotiated as part of the GATT/WTO. This approach was adopted in concluding the Uruguay Round such that the Final Act was presented as a package deal for which no pick and choose policy were permitted. According to Chimni, this single undertaking practice undermines the legitimacy of the Uruguay Round agreements: Chimni, “Third World Approaches to International Law”, *supra* note 140 at 53.

pharmaceuticals during the transition period.<sup>165</sup> Also, TRIPS did not insulate less developed countries from adhering to substantive matters including compliance with the requirements of national treatment and most favoured nation treatment. As Harris explains, “TRIPS was presented to developing countries on a take-it-or-leave-it basis...developing countries had no meaningful choice but complete adherence to TRIPS.”<sup>166</sup> Since most SSA countries lack the capacity to manufacture drugs, coupled with the fact that there are strong patent systems in places where they may receive support, the formal transitional arrangements would not yield significant technology transfer to such places.

The reality is that the promise to accepting TRIPS conditionalities as a concession for access to subsidies from developed countries has not been fulfilled.<sup>167</sup> As Stiglitz crudely puts it: “as they signed, the trade ministers were so pleased that they had finally reached an agreement that they didn’t notice they were signing a death warrant for thousands of people in the poorest countries around the world.”<sup>168</sup> The prices of patented medicines are far beyond the means of the masses in SSA, and efforts to obtain generic substitutes are hampered by claimants of patent rights over pharmaceuticals. For critics, this skepticism towards pharmaceutical patents is a wake-up call for IP matters to be excised from the WTO due to their negative impacts on domestic social welfare policies in poor countries.<sup>169</sup>

Not all scholars agree with these claims, however. Counter narratives have emerged that the protection of IP rights is an essential component of economic strategy regardless of

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<sup>165</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 7 at 74 [mandating members to provide what is called a ‘mailbox’ system for exclusive marketing of pharmaceuticals for five years in consonance with Article 70.8 & 70.9 of TRIPS].

<sup>166</sup> Harris, “Carrying a Joke Too Far”, *supra* note 138 at 727.

<sup>167</sup> Joseph Stiglitz, *Making Globalization Work* (New York: Norton, 2006) at 311.

<sup>168</sup> Stiglitz, *Making Globalization Work*, *ibid* 105.

<sup>169</sup> Stiglitz & Charlton, *Fair Trade For All*, *supra* note 73 at 11-46.

whether the country is developed or developing.<sup>170</sup> Kitch explains the need for patent protection in less developed countries differently, however. According to Kitch, less developed countries signed on to TRIPS because it serves their interests to invent and commercialize technologies.<sup>171</sup> It is, however, difficult to deny that SSA countries signed on to TRIPS because of assurances of technology transfer and export subsidies from the developed world. Those assurances were backed by threats of alienation from the community of trading nations if a country failed to comply with the multilateral framework.

In sum, for almost ten years the developed world united to convince the less developed world to accept that IP issues are trade-related. The private sector was also instrumental in drafting most of the documents which became the broadly successful position advocated by the US and other developed countries.<sup>172</sup> Throughout the negotiations, the interplay of power and politics subjugated the interests of developing countries to those of the West. Arewa posits that “hierarchies of power reinforced the exclusion of [less developed countries] from the global intellectual property framework, partly by replicating and continuing the exclusion of representatives of the vast majority of the world’s population from the negotiating table.”<sup>173</sup> This marginalization has led a scholar to conclude that TRIPS is a treaty of adhesion,<sup>174</sup> which undermines the legitimacy of

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<sup>170</sup> Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth*, 2<sup>nd</sup> ed (Geneva: WIPO, 2003) at 133; Edmund W Kitch, “The Patent Policy of Developing Countries” (1994) 13 UCLA Pac Basin LJ 166 at 171 [the incentive to invent and market technologies will only exist if there are patents available to protect innovators in those markets]; Alan O. Sykes, “TRIPS, Pharmaceuticals, Developing Countries and the Doha ‘Solution’” (2002) 3 Chicago J Int’l L 47.

<sup>171</sup> See generally Kitch, “The Patent Policy of Developing Countries”, *ibid*; Sykes, “TRIPS, Pharmaceuticals”, *ibid*

<sup>172</sup> Christopher May, “Capacity Building and the (Re)production of Intellectual Property Rights” (2004) 25:5 Third World Quarterly 821 at 822 [May, “Capacity Building”].

<sup>173</sup> Olufunmilayo B Arewa, “Piracy, Biopiracy and Borrowing: Culture, Cultural Heritage and the Globalization of Intellectual Property”, online: <[http://works.bepress.com/o\\_arewa/4/](http://works.bepress.com/o_arewa/4/)> at 45.

<sup>174</sup> Harris defines a treaty of adhesion as a treaty procured through coercion as a result of unequal bargaining power, resulting in an unfair surprise and grossly unfair burdens for the weaker party. For him, embracing the treaty of adhesion doctrine will provide the WTO a basis for interpreting TRIPS more favorably to developing and least developed countries: see Harris, “Carrying a Joke Too Far”,

global trade governance.<sup>175</sup> The implication is that TRIPS may not be efficient or command compliance at the domestic levels of states that were marginalized.<sup>176</sup> That said the question of TRIPS' legitimacy deserves further theoretical probing, which I undertake below.

### C. Grounding TRIPS Negotiations on a Theory of Democratic Bargaining

Stemming from the historical period until 1995 when TRIPS entered into force, the 'participation' of SSA countries in global trade relations has left a sour taste in the mouths of proponents of human development and public health policies in poor countries. Suppose SSA countries did not 'participate' in the Uruguay Round (as noted above), did the negotiations still meet the basic tenets of democratic bargaining? Do the undemocratic outcomes, if any, affect the implementation of TRIPS in SSA countries? The following discussion probes these questions.

To start with, the discourse on the political economy of IP rights is replete with intimations as to the existence of asymmetrical power relations between developed and less developed countries in the international economic law making arena.<sup>177</sup> Critics contend that the use of economic hegemony by developed countries in international economic law making has tilted the scale of globalization in favour of the North and its pharmaceutical industries, and this trend severely limits the powers of countries in SSA

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*supra* note 138; Donald P Harris, "TRIPS and Treaties of Adhesion Part II: Back to the Past or a Small Step Forward?" (2007) 2007 Mich St L Rev 185.

<sup>175</sup> See e.g. Harris, "Carrying a Joke Too Far", *ibid*.

<sup>176</sup> See generally Gravelle & Whalley, "Africa and the Uruguay Round", *supra* note 150; Jerome Reichman, "The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries" (2000) 32 Case W Res J Int'l L 441; Peter Gerhart, "Reflections: Beyond Compliance Theory: TRIPs as a Substantive Issues" (2000) 32 Case W Res J Int'l L 357.

<sup>177</sup> See Christopher May, *The Political Economy of Intellectual Property Rights*, vol 1 (Cheltenham: Edward Elgar, 2011); Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (The Netherlands: Martinus Nijhoff, 2003); Arewa, "Piracy, Biopiracy and Borrowing", *supra* note 173.

to effectively help their citizens.<sup>178</sup> For his part, Fuentes has used the term ‘democratic deficit’ to depict the lack of meaningful participation in international decision-making processes, which lead to the adoption of policies that affect a state and its citizenry.<sup>179</sup> Similarly, scholars in IP law have questioned the legitimacy of TRIPS on grounds that the Uruguay Round was undemocratic.<sup>180</sup> To respond to these concerns we need to test the ‘participation’ of SSA countries in TRIPS negotiations against the tenets of a theory of democratic bargaining.

The economic theory of democratic bargaining posits that an open discussion among self-interested and rational actors can produce efficient outcomes by allowing resources to go to those who value them the most.<sup>181</sup> It surmises that deliberation and open discussion of ideas give the interlocutors a better chance of finding good solutions to societal problems. It follows that domination by one party over another in any negotiations is less likely to promote an efficient outcome. Based on this reasoning, Drahos & Braithwaite contend that we could develop an efficient set of IP rules if there is equal representation of producer and consumer interests in the production of information, and with both competing interests having roughly equal powers of influence.<sup>182</sup> For them, this rationale of a theory of democratic bargaining applies to both domestic and international law making endeavours.

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<sup>178</sup> Shedrack Agbakwa, “A Line in the Sand: International (Dis)Order and the Impunity of the Non-State Corporate Actors in the Developing World” in Antony Anghie et al, eds, *The Third World and International Order: Law, Politics and Globalization* (The Netherlands: Martinus Nijhoff, 2003) 1 at 13; Chidi Oguamanam, “IP in Global Governance: A Venture in Critical Reflection” (2011) 2 WIPO Journal 196 at 198; Stiglitz, *Globalization and Its Discontents*, *supra* note 70 at ix.

<sup>179</sup> Ximena Fuentes, “International Law-Making in the Field of Sustainable Development: The Unequal Competition between Development and the Environment” in Nico Schrijver and Friedl Weiss, eds, *International Law and Sustainable Development* (Leiden: Martinus Nijhoff, 2004) 1 at 12-14.

<sup>180</sup> Drahos & Braithwaite, *Information Feudalism*, *supra* note 138 at 12; J See also Michael Finger et al, “Implementation of Uruguay Round Commitments: the Development Challenge” in Bernard Hoekman et al, eds, *Developing Countries and the WTO: a Pro-active Agenda* (Oxford: Blackwell, 2001) 115.

<sup>181</sup> See Drahos & Braithwaite, *Information Feudalism*, *ibid* at 13, citing R Cooter & T Ulen, *Law and Economics* (MA: Addison-Wesley, 1997).

<sup>182</sup> Drahos & Braithwaite, *Information Feudalism*, *ibid* at 13-14.

By application to the processes of international law making, Drahos & Braithwaite explain that in order for democratic bargaining to take place among sovereign states, at least three conditions must be met: first, all relevant interests have to be represented in the negotiation process (the condition of representation); second, all those involved in the negotiations must have full information about the consequences of the various possible outcomes (the condition of full information); and third, one party must not coerce the others (the condition of non-domination).<sup>183</sup> It follows that the absence of any of the basic conditions of a theory of democratic bargaining in TRIPS negotiations could affect the Agreement's efficiency as well as legitimacy.

Putting theory into context, first, the conditions of representation and full information required SSA countries to take part in the TRIPS negotiations with full access to the Uruguay Round information. However, as the above narrative shows, the Uruguay Round of negotiations did not meaningfully involve countries in SSA. It was not until 1989 when negotiators from Nigeria and Tanzania joined the Uruguay Round of trade negotiations, by which time the negotiations had nearly concluded. Further, negotiators from SSA were constrained by insufficient access to proposals and comments circulated during the Uruguay Round of trade negotiations; they also lacked expertise in international IP norms.<sup>184</sup> Indeed, the use of green room meetings alienated many countries in SSA. Even negotiators from other developing countries such as Brazil and India, who 'participated' in the Uruguay Round, were constrained by insufficient access to Uruguay Round information that was at the disposal of western negotiators.<sup>185</sup> As Gervais points out, this resource asymmetry put developing countries' experts at a disadvantage when discussing detailed and arcane drafting points that were linked to

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<sup>183</sup> Drahos, "DC and International IP Standard-Setting", *supra* note 142 at 770; Drahos & Braithwaite, *Information Feudalism*, *supra* note 138 at 14; 190-192.

<sup>184</sup> Gervais, "TRIPS and Development", *supra* note 1 at 10.

<sup>185</sup> Gervais, "TRIPS and Development", *ibid* at 10.

existing treaties such as the Berne and Paris Conventions.<sup>186</sup> The result is that SSA countries embraced high western standards of IP protection as part of their domestic laws without a strong appreciation of the ramifications.

Second, in regard to the condition of non-domination, the above narrative of TRIPS negotiations confirms that there were glimpses of coercion by the West to procure the consent of less developed countries to cede their autonomy on IP matters. This coercion is evidenced by threats of retaliatory sanctions under the US Trade Act and a possible forfeiture of GATT/WTO status. The coercion story portrays the United States as systematically threatening to close its borders to countries that would not agree to minimum IP standards.<sup>187</sup> Brazil and India came in for special trade pressure under the US' Priority Watch List. In addition, developed countries used their superior bargaining power to ensure compliance by less developed countries. The point is that the trajectories of TRIPS negotiations failed to measure up to the benchmarks of a theory of democratic bargaining. Yet, less developed countries in SSA accepted TRIPS to ease trade pressures and avoid being left out of the then emerging WTO trading system.<sup>188</sup> As it turned out, the promise to avoid retaliatory sanctions against less developed states provided they signed on to TRIPS has not been met. Rather, the TRIPS-based patent regulatory framework is fortified with mechanisms to sanction a non-compliant WTO Member state.<sup>189</sup> The oft-cited South African experience that brought the country to the brink of trade wars with the US and 39 pharmaceutical corporations speaks volumes. Also, a recent upsurge in bilateral trade and investment agreements which impose higher TRIPS-plus obligations shows the troubling dimensions of the west's broken promises.<sup>190</sup>

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<sup>186</sup> Gervais, "TRIPS and Development", *ibid.*

<sup>187</sup> Gerhart, "Reflections: Beyond Compliance Theory", *supra* note 176 at 368.

<sup>188</sup> Scott Lucyk, "Patents, Politics and Public Health Access to Essential Medicines under the *TRIPS Agreement*" (2007) 38 *Ottawa L Rev* 191 at 212.

<sup>189</sup> Drahos & Braithwaite, *Information Feudalism*, *supra* note 138 at 106-107 [the threat of retaliatory sanctions has attained a machine-like efficiency in the post-TRIPS period].

<sup>190</sup> El-Said, "From TRIPS-minus, to TRIPS, to TRIPS-plus", *supra* note 145 at 59-61.

By summary, the anemic participation of SSA countries in TRIPS negotiations shows all too well that the three conditions of democratic bargaining were not met. The democratic deficits of the TRIPS negotiations cast doubt on the supposed beneficence of the globalized patent regulatory and institutional framework.<sup>191</sup> Yet, TRIPS obligations and global institutional benchmarks have influenced the design of domestic patent regulatory frameworks in SSA. Thus, even though the question of legitimacy of TRIPS may be an issue for theoretical discourse, chapter 5 will show that SSA countries significantly comply with the formal requirements of the treaty in domestic IP laws. For fear of global alienation and threats of trade sanctions, SSA countries do not have the wherewithal to opt out of these established normative arrangements, even though TRIPS negotiations defied basic tenets of democratic bargaining.

This faith-based approach to TRIPS implementation in SSA is further bolstered by technical assistance initiatives from the developed world. As discussed in Part VI below, much of the technical assistance initiatives from developed countries and WIPO have also focused on socializing SSA countries to protect and enforce international patent standards and to create awareness among their publics.<sup>192</sup> To reverse these trends, public health considerations should become the new foundation to recalibrate TRIPS implementation to serve human development needs in SSA. Also increasing the democratic governance of national involvement in international trade relations provides promising avenues to improving the accountability and democratic legitimacy of the globalized system in the post TRIPS era.<sup>193</sup> Suffice it to say that such recalibration efforts are underway in global trade governance, and the African Group has become much more

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<sup>191</sup> For a similar discussion of this point see John O McGinnis & Ilya Somin, “Democracy and International Human Rights Law (2009) 84 Notre Dame L Rev 1739 at 1778-1779.

<sup>192</sup> See e.g. Drahos, “DC and International IP Standard-Setting”, *supra* note 142 at 789; Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *supra* note 123.

<sup>193</sup> James Bacchus, “A Few Thoughts on Legitimacy, Democracy, and the WTO” (2004) 7(3) J Int’l Econ L 667. See also Gregory Shaffer, “Parliamentary Oversight of WTO Rule-Making: The Political, Normative, and Practical Contexts” (2004) 7(3) J Int’l Econ L 629.

influential in international negotiations bordering on patents, access to medicines and development in the post-TRIPS era.

## **V. Post-TRIPS Patent Paradigm**

The fourth phase in the evolution of the concept of patent law is the post-TRIPS era. This era denotes the subtraction and calibration narratives phases in which less developed countries have come on board to test and challenge a number of assumptions that were employed to ground and sustain the addition narratives paradigm of the 1980s. Thus, the post-TRIPS patent paradigm has achieved important milestones for rectifying the imbalances of the addition narratives of the 1980s. Indeed, the works of intergovernmental institutions, perceived as sympathetic to the cause of less developed countries, have served as checks-and-balances to the pursuit of neoliberal agendas under the GATT/WTO system. And one such example of the influence of patent institutions will be adequate for now.

In 1996, the WHO in conjunction with Brazil, South Africa, Zimbabwe and other international NGOs such as Médecins Sans Frontières (MSF), Health Action International (HAI), and Oxfam began a critical evaluation of the impact of TRIPS on public health.<sup>194</sup> This critical review recommended that states make use of TRIPS flexibilities and thus minimize the effects of pharmaceutical patents on access to essential medicines.<sup>195</sup> This report was relied upon by the World Health Assembly to pass a resolution that highlighted “the negative impact of new world trade agreements on...access to and prices of pharmaceuticals in developing countries.”<sup>196</sup> The resolution further urged states “to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies.” This resolution influenced the decision by the government of South Africa to pass a statute to empower its Minister of Health to grant compulsory licenses

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<sup>194</sup> See Helfer, “Regime Shifting”, *supra* note 82 at 42.

<sup>195</sup> Helfer, “Regime Shifting”, *ibid* at 43.

<sup>196</sup> This Resolution of the World Health Assembly is quoted in Helfer, “Regime Shifting”, *ibid*

and to promote parallel imports of medicines to treat HIV/AIDS epidemics. The analysis of *patent institutions* under chapter 2 also indicates that the UNDP and UNCTAD have made similar recommendations with the goal of scaling up access to medicines to treat epidemics in SSA.

The salient point is that, efforts by less developed countries and intergovernmental institutions in the post-TRIPS era have redirected the focus of international patent discourse from trade to public health and development. Further, post-TRIPS efforts by SSA states and intergovernmental institutions have established and solidified the connections between patents, access to medicines, and development. Countries and intergovernmental institutions have also supported efforts for more flexibility to be infused into the design of international and domestic patent agendas. But for the interventions of some of these institutions, which are seen as sympathetic to the cause of less developed countries, the global patent and development norm-making activities might have evolved much more disappointingly for poor countries. The question, however, remains whether the impact of the post-TRIPS recalibration efforts had any effect in SSA. As will be discussed in chapter 5, patent regulatory and institutional lapses are still prevalent in SSA, and, therefore, these mitigation measures have not yielded substantive fruits yet. Worse still, SSA countries are increasingly assuming TRIPS-plus obligations with their attendant consequences, a matter which I address next.

#### **A. TRIPS-Plus Agenda**

A brief definition of the phrase ‘TRIPS-plus’ is crucial to understanding the trajectory of post-TRIPS’ events and processes in the twenty-first century. Also, understanding the nature of TRIPS-plus commitments will bring to the fore the implications of regional and bilateral agreements on access to health care services in SSA. TRIPS-plus refers to obligations in agreements and instruments that impose more stringent IP protections and

rights beyond those required by the *TRIPS Agreements*.<sup>197</sup> Such high standards may relate to the scope, term and subject matter of patent protection. TRIPS-plus may also involve using bilateral trade agreements to compel less developed countries to implement and enforce TRIPS before the end of its specified transition period.<sup>198</sup> In addition, TRIPS-plus may involve the use of a bilateral ‘bargain’ to procure compliance with the obligations of other multilateral IP-related treaties.<sup>199</sup>

As earlier indicated, since 1997, multilateral standards for protecting pharmaceuticals have come under severe scrutiny from governmental organizations and NGOs. Starting from the late-twentieth-century economic dispute between the South African and the US governments to the Doha Round of trade negotiations to the present, less developed countries have achieved some political victories in international patent law making activities. First, countries secured the adoption of the Doha Declaration to address public health problems in poor countries. The Doha Round attempts to remedy TRIPS imbalances, make future negotiations and obligations more equitable, and to enhance TRIPS flexibilities.<sup>200</sup> Second, the WTO General Council reached the ‘August 30’ Decision to allow LDCs with insufficient manufacturing capacities to import cheaper generic medicines from other countries. These mitigation measures have culminated in the amendment of the *TRIPS Agreement* (i.e., Article 31*bis* which enters into force when two-thirds of WTO members ratify the amendment) to facilitate the export and import of generics.

Despite the above rectification measures, the *TRIPS Agreement* does not set maximum standards of patent protection. The Agreement contemplates that WTO member-countries

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<sup>197</sup> Pedro Paranagua, “Strategies to Implement WIPO’s Development Agenda: A Brazilian Perspective and Beyond” in Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization’s Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009) 140 at 142.

<sup>198</sup> Helfer, “Regime Shifting”, *supra* note 82 at 4.

<sup>199</sup> Helfer, “Regime Shifting”, *ibid* at 4.

<sup>200</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 153.

may adopt higher standards of IP protection by setting only minimum standards.<sup>201</sup> This leeway for states to adopt higher standards of IP has emboldened the West to push for TRIPS-plus obligations in bilateral and regional agreements with countries in SSA. Recently, this TRIPS-plus paradigm has also gained momentum in light of persistent disagreements between developed and less developed countries at the multilateral level. Proponents of trade/IP bilateralism urge the view that increased IP standards in bilateral agreements would further economic growth and development.<sup>202</sup>

On the one hand, there is growing discontent among southern countries over the impact of the globalized patent norms and TRIPS-plus commitments, among others, in light of the escalating HIV/AIDS, malaria, and TB epidemics in poor regions. Limitations of the globalized patent framework are viewed as severe restraints on access to essential medicines and cheaper generics.<sup>203</sup> As a result, walk-outs, delays and threat of collapse have characterized multilateral trade negotiations from Seattle to Cancun to Hong Kong. These growing discontents and agitations by less developed countries have contributed to derail the completion of the Doha Round of trade negotiations.

On the other hand, the West led by the US and the EU felt frustrated by these demands of the South and vowed to pursue freer trade liberalization agendas via bilateral and regional agreements. In the words of Robert Zoellick, the US will separate the “can-do” countries from the “won’t-do” countries and “will move towards free trade with can-do countries.”<sup>204</sup> Subsequent to Zoellick’s declaration, the US and other western states have “initiated a divide-and-conquer strategy that seeks to reward countries that are willing to

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<sup>201</sup> Laurence R Helfer, “Regime Shifting in the International Intellectual Property System” (2009) 7 Perspectives on Politics 39 at 43 [Helfer, “Regime Shifting in International IPS”].

<sup>202</sup> See the Preambles to the US FTAs with developing countries at: <<http://www.ustr.gov/trade-agreements/free-trade-agreements>>; Richard D Smith et al, “Trade, TRIPS, and Pharmaceuticals” (2009) 373 *Lancet* 684 at 688.

<sup>203</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 223.

<sup>204</sup> Robert B Zoellick, “America Will Not Wait for the Won’t-Do Countries” *Financial Times* (22 September 2003) at 23.

work with the United States while undermining efforts by Brazil, India and other G20 members to establish a united negotiating front for less developed countries.”<sup>205</sup> Zoellick’s successor further underscored that she would pursue an “ambitious agenda for bilateral and regional agreements that will broaden and deepen trade relations with key, like-minded countries.”<sup>206</sup>

Accordingly, the US and the EU have ignored perceived obstinate states in the multilateral arena to pursue their desire for stronger IP protection via bilateral and regional agreements. This push for increased IP protection in bilateral agreements is based on the idea that if IP is good, then more IP is better. Illustrative of this trend is the US-Southern African Customs Union (SACU) Free Trade Agreement, and the EU-African, Caribbean and Pacific (ACP) Economic Partnership Agreements (EPAs).<sup>207</sup> The objectives of these bilateral and regional agreements is to “establish commitments for...countries to strengthen significantly their domestic enforcement procedures, such as by ensuring that government agencies may initiate criminal proceedings on their own initiative and seize suspected pirated and counterfeit goods, equipment used to make or transmit these good, and documentary evidence.”<sup>208</sup> Although negotiations relating to the EU-ACP EPAs are ongoing, similar negotiations between the US and SACU have been

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<sup>205</sup> Peter K Yu “Building Intellectual Property Coalitions for Development” in Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization’s Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009) 79 at 83.

<sup>206</sup> Susan C Schwab, US Trade Representative-Designate, Opening Statement to the US Senate Committee on Finance 11 (May 16, 2006).

<sup>207</sup> The US-SACU FTA is not yet concluded. For the EU-ACP EPAs, see the Revised Cotonou Agreement [http://eCeuropAeu/development/icenter/repository/second\\_revision\\_cotonou\\_agreement\\_20100311.pdf](http://eCeuropAeu/development/icenter/repository/second_revision_cotonou_agreement_20100311.pdf)

<sup>208</sup> USTR, *Senate Letter: USTR Notifies Congress Administration Intends to Initiate Free Trade Negotiations with Sub-Saharan Nations* (2002) <[http://www.ustr.gov/Document\\_Library/Letters\\_to\\_Congress/2002/USTR\\_Notifies\\_Congress\\_Administration\\_Intends\\_to\\_Initiate\\_Free\\_Trade\\_Negotiations\\_with\\_Sub-Saharan\\_Nations.html](http://www.ustr.gov/Document_Library/Letters_to_Congress/2002/USTR_Notifies_Congress_Administration_Intends_to_Initiate_Free_Trade_Negotiations_with_Sub-Saharan_Nations.html)>

hampered by the latter's insistence that issues of concern to the US, such as IP rights, should be negotiated and adopted in a follow-up agreement.<sup>209</sup>

Thus, a common feature of these bilateral and regional trade agreements is that they limit potential exclusions from patentability, require the grant of patents for 'new uses' of known compounds, require patent extensions under certain conditions, limit parallel imports and the grounds under which compulsory licensing may be granted, and protect data needed for making generic medicines.<sup>210</sup> These pro-industry conditions are prevalent in existing US FTAs with countries such as Morocco, Bahrain, El Salvador, Jordan, and Peru, among others.<sup>211</sup> In consequence, bilateral and regional trade agreements ultimately support increased IP protection that states did not previously agree to at the multilateral level.<sup>212</sup> Indeed, a number of studies have shown that such relatively high IP standards limit the fragile flexibilities under TRIPS and Doha. For Drahos, TRIPS-plus standards limit the terms of trade of SSA countries as primary consumers of pharmaceutical products and processes.<sup>213</sup> For example, desperately poor countries such as Guinea, Guinea Bissau and the Gambia protect pharmaceutical patents even though they are not required to grant such protection under international law. More worrisome, such countries spend their scarce resources creating TRIPS-complaint and TRIPS-plus laws at the expense of health, among others priorities.<sup>214</sup>

According to Abbott, we live in a time in which tremendous pressure is exerted at the bilateral and regional level for new and more restrictive rules that eliminate socio-

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<sup>209</sup> See "SACU Stills Wants FTA with US that Delays Talks on Investment, IPR", *Inside US Trade*, 24 February 2006.

<sup>210</sup> Abbott, "Toward a New Era of Objective Assessment", *supra* note 128 at 89-90.

<sup>211</sup> These Free Trade Agreements (FTAs) are available online at: <<http://www.ustr.gov/trade-agreements/free-trade-agreements>>.

<sup>212</sup> Jean-Frederic Morin, "Multilateralizing TRIPS-Plus Agreements: Is the US Strategy a Failure" (2009) 12 *Journal of World Intellectual Property* 175 at 176.

<sup>213</sup> See e.g. Peter Drahos, "BITs and BIPs: Bilateralism in Intellectual Property" (2001) 4 *Journal of World Intellectual Property* 791.

<sup>214</sup> Mgebeji, "TRIPS and TRIPS-Plus in Africa", *supra* note 43 at 280.

economic policy space for national governments.<sup>215</sup> Accordingly, developed countries such as “the United States uses its economic clout to compel weaker developing countries to adopt rules that better protect the rights of IP holders, and thus make it less likely that developing countries will invoke the exceptions allowed in parallel multilateral agreements.”<sup>216</sup> Amani argues that TRIPS-plus will inhibit countries from taking advantage of the flexibilities inherent in TRIPS; it will also limit countries’ ability to invoke TRIPS provisions as defences at the WTO.<sup>217</sup> Bilateral agreements, which impede efforts to invoke the flexibilities under TRIPS, in turn, exacerbate access to medicines challenges in SSA. That way, the human rights and human development needs of the citizens of poor countries will be at the mercy of big pharma.

On their part, Bhagwati & Panagariya urge the view that bilateralism undermines multilateral efforts negotiated through the WTO and thus establishes “a ‘spaghetti bowl’ of rules, arbitrary definitions of which products come from where, and a multiplicity of tariffs depending on source.”<sup>218</sup> Bilateral rules set new IP standards (generally TRIPS-plus in nature) that may translate into new multilateral standards in the future. Scholars agree that similar bilateral agreements negotiated in the nineteenth century acted as models in concluding the provisions of the *Paris Convention*.<sup>219</sup> In addition, others lament that the provisions in bilateral and regional trade agreements could be invoked to interpret multilateral trade agreements.<sup>220</sup> Employing TRIPS-plus commitments in bilateral agreements as interpretative tools within the WTO system does not augur well for the supposed regulatory consistency and certainty that was promised under the multilateral trading system.

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<sup>215</sup> Abbott, “Toward a New Era of Objective Assessment”, *supra* note 128 at 100.

<sup>216</sup> Helfer, “Regime Shifting in International IPS”, *supra* note 201 at 43.

<sup>217</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 174-175

<sup>218</sup> Jagdish Bhagwati & Arvind Panagariya, “Bilateral Trade Treaties Are a Sham”, *Financial Times* (14 July 2003).

<sup>219</sup> See e.g. Daniel J Gervais, “The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New” (2002) 12 *Fordham IP Media and Ent LJ* 929.

<sup>220</sup> See Morin, “Multilateralizing TRIPS-Plus Agreements”, *supra* note 212 at 186-187.

Furthermore, the implication of bilateral treaties on access to medicines in poor countries is not lost on a number of intergovernmental organizations. In 2005, UNCTAD published a report on TRIPS flexibilities that supported the claim that TRIPS-plus in bilateral agreements violate the *TRIPS Agreement*. As UNCTAD put it,

An important interpretative question is whether a member that demands the adoption of TRIPS-plus standards in the bilateral or regional context might be failing to perform its TRIPS Agreement obligations in good faith. The argument on behalf of a Member's being subjected to such demands would be that it accepted its TRIPS obligations as part of a set of reciprocally negotiated commitments that represent a balance of rights and obligations on which that Member is entitled to rely. Bilateral pressure to exceed the agreed upon commitments is contrary to the object and purpose of the WTO Agreement and TRIPS Agreement to provide a secure framework for the conduct of international trade relations.<sup>221</sup>

In the alternative, the UNDP advocates the adoption of a "TRIPS-minus model that significantly reduces the length of protection and the scope of coverage and increases national decision-making authority on standards and coverage of protection while maintaining a minimalist agenda at the international level."<sup>222</sup> This suggestion will significantly affect the direction of patent and development discourse in the years to come. It will assist less developed countries to negotiate for recognition of the differences in their levels of development in order to optimize strategies that can promote access to life-saving medicines.

## **VI. Domestic Implementation of TRIPS Obligations in SSA**

The story of the evolution of the concept of patent law implicates the influence of western hegemony and their industries in global trade relations; it also confirms the lack of meaningful participation by countries in SSA in international patent law making. In

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<sup>221</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005) at 24-25.

<sup>222</sup> UNDP, *Making Global Trade Work for People* (New York: Earthscan, 2003) at 221.

addition, the globalized patent regime has not adequately taken into consideration the needs of the citizens of SSA in combating epidemics. Rather, the system follows a ‘trickle down’ approach by instructing national governments in SSA to comply with international patent obligations without sufficient consideration of social realities. Such unilateral ‘commands’ have come to be fulfilled by expressly enacting legislation to give effect to international obligations or whole heartedly accepting the international agreement as a part of national laws.

This ‘top-down’ approach to globalization has created a different kind of exclusion for SSA countries and their citizens. This second-tier of marginalization stems from the approach to technical assistance offered by developed countries and intergovernmental institutions such as WIPO to SSA countries. On the one hand, technical assistance activities offered by developed countries have mainly resulted in establishing and administering offices related to IP, creating awareness about IP law among the citizens of SSA, and pursuing anti-piracy activities. These pro-IP protection efforts do not highlight access to medicine issues in SSA. On the other hand, much of the technical assistance from WIPO has steered SSA countries to adopt TRIPS-plus approaches to patent protection. WIPO has socialized patent administrators and institutions in SSA to protect and enforce IP rights with minimal concern for the public interest dimension of IP law. As May aptly outlines, “capacity building programmes socialize policy makers, practitioners and others into a specific way of dealing with, and regulating, IPRs. It encourages the development of a TRIPS-mind-set.”<sup>223</sup>

Article 67 of the *TRIPS Agreement* provides the juridical basis for providing technical assistance to achieve compliance with the standard of international patent law. It provides that:

In order to facilitate the implementation of this Agreement, developed country Members *shall* provide, on request and on mutually agreed terms

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<sup>223</sup> May, “Capacity Building”, *supra* note 172 at 822.

and conditions, technical and financial cooperation in favour of developing and least-developing country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

Furthermore, the WTO TRIPS Council identifies the following four constitutive elements of the concept of technical assistance.<sup>224</sup> They include:

- (1) General assistance in the development of human resources;
- (2) Assisting in the preparation of laws and regulations on the protection and enforcement of IP rights as well as on the prevention of their abuse;
- (3) Support regarding the establishment or reinforcement of the relevant domestic offices and agencies;
- (4) Other types of assistance, specifically the promotion of public awareness of IP and the exploitation of IP rights.

These four components of technical assistance, identified by the TRIPS Council, are not significantly different from the provisions of Article 67. In substance, the above four guidelines provide indications of the technical assistance initiatives that have been undertaken by developed countries and WIPO in SSA. Most often, western technical assistance initiatives are skewed in favour of preparing laws and regulations on the ‘protection and enforcement of intellectual property rights.’ Accordingly, the impact of the TRIPS’ Article 67 provision on preventing abuse of patent rights is undercut by the fact that the said prevention is envisaged after such protective laws and regulations are already entrenched. Also, there is a deafening silence on technical assistance in promoting TRIPS flexibilities. As Matthews & Munoz-Tellez note, “article 67 fails to place an obligation on developed nations to assist developing countries in utilizing TRIPS flexibilities such as those in relation to compulsory licensing that could help ensure

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<sup>224</sup> See *Summary of the Information on Technical Cooperation Activities: Secretariat of the WTO TRIPS Council* (IP/C/W/22, 26 April, 1996).

access to medicines.”<sup>225</sup> In effect, technical support initiatives by the West and WIPO do not enhance the public interest aspects of the objectives (Article 7) and principles (Article 8) of the *TRIPS Agreement*.

#### **A. Technical Assistance by Developed Countries**

Research confirms that the technical assistance initiatives provided by the US, EU, and Japan in domesticating TRIPS obligations share the common objective of seeking strong protection and enforcement of IP rights in less developed countries.<sup>226</sup> Empirical studies confirm that the patent offices of the US, EC, and Japan have institutional mechanisms in place to promote global governance on patents, that serves the interests of multinational companies.<sup>227</sup> For instance, between 1996 and 2005, the US technical assistance initiatives included,

preparation of laws and regulations on IP protection and enforcement in accordance with TRIPS and other bilateral and international agreements; assistance in the establishment, modernization and administration of domestic offices related to IP, such as patent offices; and activities to promote awareness in the private sector and general public in developing countries about the positive relationship between IP and economic growth, and against piracy and counterfeiting.<sup>228</sup>

These patent-friendly initiatives were undertaken via seminars, workshops and study visits for staff of domestic IP offices, legislators and government officials, students, as well as specialized training for judges, prosecutors, customs and other officials involved in IP enforcement.<sup>229</sup>

Specifically to SSA, two examples of the US technical assistance initiatives illustrate the above point: the US Department of State organized ‘IP Right Crime Law Enforcement

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<sup>225</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *supra* note 123 at 632.

<sup>226</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *ibid* at 634.

<sup>227</sup> On this point see Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (New York: Cambridge University Press, 2010).

<sup>228</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *supra* note 123 at 635.

<sup>229</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *ibid*.

Training’ for prosecutors and law enforcement officials in South Africa in the month of December, 2004. In addition, a workshop on ‘Counterfeit Medicines in Sub-Saharan Africa’ was organized by the US Patent and Trade Mark Office in Johannesburg for judges, prosecutors, police, custom officials, Health Ministries, and other government officials in SSA to explore the problems of counterfeiting in the region.<sup>230</sup>

Japan’s technical assistance activities also focus on ensuring adequate protection of IP in order to promote foreign direct investment and technology transfer to less developed countries. As a result, prosecutors, custom officials, police and administrative officials in Namibia, South Africa and Kenya received training in 2005 on how to conduct anti-piracy and -counterfeiting operations.<sup>231</sup> It is therefore not fortuitous that Kenya’s *Anti-Counterfeit Act* of 2008 places excessive restrictions on the country’s ability to import generic medicines. The Kenyan Act has been criticized for failing to draw a clear distinction between generic medicines and counterfeit drugs, thereby giving the customs officials unbridled powers to seize imported generics from abroad. Recently, three people living with HIV launched a court application against the law on grounds that it conflates counterfeit and generic medicines which will deny them the right to affordable and life-saving generic antiretrovirals. In upholding this contention, via the grant of an interim order, the Constitutional Court suspended Article 2 of the Act which interfered with the importation and distribution of generic medicines in Kenya.<sup>232</sup>

The EU, on its part, provides technical assistance to less developed countries in order to strengthen and enforce IP protection.<sup>233</sup> In SSA, EU-sponsored technical assistance

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<sup>230</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *ibid* at 636.

<sup>231</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *ibid* at 639. Admittedly the bulk of Japan’s anti-piracy seminars have focused on copyright law.

<sup>232</sup> See *Patricia Asero Achieng & 2 Others vs The Attorney General* MISC409/09; Suleiman Mbatiah, “Court Victory against ‘Anti-Counterfeit’ Agenda”, online <<http://ipsnews.net/news.asp?idnews=51168>>; Suleiman Mbatiah, “Agency Unaware of Anti-Counterfeit Law Suspension”, online <<http://ipsnews.net/news.asp?idnews=52015>>.

<sup>233</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *supra* note 123 at 637.

activities also receive articulation in economic partnership agreements such as EU-ACP EPAs. Individual EU member-states have also provided technical assistance training via their national patent offices to SSA countries. For example, France provided technical assistance support to OAPI in 2004 and 2005. In that same period, Sweden and the UK also provided capacity building training for policy-makers in Malawi, Kenya, Tanzania, and Uganda.<sup>234</sup> There is also a Swiss-Ghana IP (SGIP) project to provide assistance to Ghana in modernizing the administration of IP rights in order to encourage innovation, provide the transfer of technology, and facilitate industrial competitiveness. One of the key activities under the SGIP project is the training of judges in Ghana on the enforcement and resolution of disputes in IP related cases.<sup>235</sup> This training is expected take place under the auspices of the Ghana Judiciary Training Institute.

It cannot be gainsaid that developed countries, through their technical assistance initiatives, target key domestic policy-makers in driving home their one-sided patent-friendly agenda. A common thread that runs through western-sponsored technical assistance activities is that they lack important components on the use of TRIPS flexibilities in SSA.<sup>236</sup> In all of those technical assistance activities, the influence of big pharma and its associations such as Pharmaceutical Research and Manufacturers of America (PhRMA), the International Anti-Counterfeiting Coalition (IACC), among others, ensures high standards of IP protection and enforcement.<sup>237</sup>

On the flip side, conspicuously absent from most of these policy deliberations are the public interest civil society organizations and the affected communities in SSA. As Matthews & Munoz-Tellez observe, public interest NGOs and academics with the

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<sup>234</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *ibid* at 646-647.

<sup>235</sup> See <https://www.ip4allch/en/legal-info/international-cooperation/country-specific-projects/ghanAhtml>.

<sup>236</sup> One important caveat is that in July 2004, the UK-sponsored capacity building seminar in Kenya and Malawi also focused on the use of TRIPS flexibilities to promote access to medicines.

<sup>237</sup> Matthews & Munoz-Tellez, “Bilateral Technical Assistance and TRIPS”, *supra* note 123 at 637.

knowledge and expertise to draw attention to TRIPS flexibilities do not participate in such technical assistance programs in SSA.<sup>238</sup> The point is that, listening to opposite views will allow policy-makers in SSA to learn about the lives of the masses different from themselves.<sup>239</sup> Also, the participation of civil society and communities affected by IP systems will prevent proponents of strong patent rules from always having their way and eventually supply the missing dots on utilizing TRIPS flexibilities.

## **B. Technical Assistance by WIPO**

WIPO is the primary intergovernmental organization that has provided technical assistance to SSA countries in the design of IP laws and policies. WIPO's technical assistance activities have become the primary means through which international patent standards find their way into domestic laws in SSA. WIPO undertakes these technical assistance activities through its International Bureau. Between 1996 and 2000, the International Bureau drafted 214 IP laws and also commented on or drafted 235 legislative amendments for less developed countries.<sup>240</sup> Presently, WIPO has several ongoing projects, *inter alia*, on innovation and technology transfer for national institutions, and to strengthening capacity to manage creative industries in SSA countries.<sup>241</sup>

The legal basis of WIPO's technical support mandate is its 1967 founding Convention, which mandates the organization "to promote the protection of intellectual property throughout the world."<sup>242</sup> This mandate is solidified by the WIPO-WTO Cooperation

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<sup>238</sup> Matthews & Munoz-Tellez, "Bilateral Technical Assistance and TRIPS", *ibid* at 638.

<sup>239</sup> Karen Syma Czapanskiy & Rashida Manjoo, "The Right of Public Participation in the Law-Making Process and the Role of Legislature in the Promotion of this Right" (2008) 19 Duke J Comp & Int'l L 1 at 19 [Czapanskiy & Manjoo, "The Right of Public Participation in Law-Making"].

<sup>240</sup> See *WIPO's Legal and Technical Assistance to Developing Countries for the Implementation of the TRIPS Agreement from 1 January 1996 to 31 December 2000* (Geneva: WIPO, 2001).

<sup>241</sup> A study of the impacts of the WIPO projects on SSA is ongoing under the Open AIR Project, which is being funded by IDRC Canada and Germany's BMZ.

<sup>242</sup> See Article 3, *Convention Establishing the World Intellectual Property Organization*, 1967, 848 UNTS 3.

Agreement to oversee technical assistance programs for less developed countries in order to facilitate compliance with TRIPS obligations.<sup>243</sup> In pursuit of this objective, WIPO has adopted a maximalist approach to IP protection by socializing states to implement international treaty obligations. As May aptly notes:

[WIPO] has deployed significant resources to attempt to socialize policy makers, legislators, negotiators and enforcement personnel in the ‘world of intellectual property.’ The WIPO encourages them to accept the stories deployed to justify the use of IPRs where the evidence that intellectual property directly promotes innovation and economic development is often absent.<sup>244</sup>

WIPO’s patent-friendly approach in domesticating international IP standards appears to contradict its UN mandate to take “a more appropriate action in accordance with its basic instrument, treaties and agreements administered by it, *inter alia*, for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development.”<sup>245</sup> It is this latter mandate that has re-vitalized WIPO to adopt a Development Agenda as part of its norm setting-activities.

Yet, WIPO’s traditional approach to technical assistance is markedly different from the tenor of its UN mandate. For example, the experience with the drafting of Ghana’s IP legislation, like most IP legislation in SSA, shows that WIPO liaises with the Justice Ministry or the drafting authority on how to comply with TRIPS obligations. WIPO then sends its personnel from Geneva, armed with standardized laws which are produced far away in the corridors of the UN. Once in ‘town’, efforts are made to domesticate this WIPO-engineered legislation with assistance from the local ‘experts’ (who are often

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<sup>243</sup> See Joint WTO-WIPO Press Release, 21 July 1998, Press/108, online: <[www.wto.org/english/news\\_e/pres98\\_e/pr108\\_e.htm](http://www.wto.org/english/news_e/pres98_e/pr108_e.htm)>.

<sup>244</sup> Christopher May, “The World Intellectual Property Organization and the Development Agenda” (paper presented at the Center for the Study of Regulated Industries Conference (8 September 2006, Bath, UK) at 104, online: <[http://www.bath.ac.uk/csi/pdf/ecpr\\_pdf/1\\_May.pdf](http://www.bath.ac.uk/csi/pdf/ecpr_pdf/1_May.pdf)>.

<sup>245</sup> Article 1, *Agreement between the UN and the WIPO*, 1974, available at <<http://www.wipo.int/treaties/en/agreement/index.html>>.

closely allied with the political elite). The practice is that the re-design, if not a mere affirmation, of the WIPO-supplied precedent takes place in the national capitals, thereby neglecting inputs from local communities and public interest civil society groups. This ‘domesticated’ version is then passed by the Legislature, if any, with minimal modifications by lawmakers (who may not have significant knowledge on IP law) before it becomes law.<sup>246</sup>

May offers a slightly different account (though largely complementary to the above narrative) of how WIPO provides technical assistance to countries in drafting TRIPS-compliant legislation.<sup>247</sup> He notes that the proposed draft law is circulated between a government legislative team and WIPO for comments before a final draft is settled on. This, he urges, may involve visits by WIPO officials or invitations to key legislators and/or civil servants to Geneva for consultation. Thereafter, the ‘agreed’ bill is passed into law. It suffices to indicate that the expertise of those ‘key legislators and/or civil servants’ who are selected for such consultations in IP law making is suspect. Indeed, in many African countries, the selection is based on a person’s political association, rather than competence.

Significantly, WIPO’s technical assistance activities in SSA do not end at the level of formal lawmaking. Once the law comes into force, WIPO liaises with key policy makers to ‘educate’ them on the scope and mechanisms for enforcing the law. As May aptly captures it “once the law has been enacted, WIPO offers national workshops, judicial symposia and training for enforcement officers.”<sup>248</sup> For example, WIPO in conjunction with the Ghana Judiciary Training Institute organized training programs for judges in May 2007. Similar trainings have also been conducted in other SSA countries for patent administrators. WIPO also works with ARIPO to train patent attorneys on how to draft

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<sup>246</sup> This conclusion was reached based on the author’s experience from working in Ghana and interactions with IP policy-makers and practitioners in Kenya and Uganda.

<sup>247</sup> See May, “Capacity Building”, *supra* note 172 at 825.

<sup>248</sup> May, “Capacity Building”, *ibid.*

patent claims and prosecute patent applications in SSA. These training initiatives are intended to ‘educate’ the judges, prosecutors, and administrators about the scope of obligations under international and national laws, and also broaden their knowledge on how to enforce these obligations. The scope, frequency or contents of WIPO’s technical assistance initiatives depend on the availability of financial as well as human resources.

Traditionally, WIPO’s technical assistance activities have endorsed industry rhetoric for strict protection and enforcement of high patent standards. In this regard, SSA states do not get the opportunity to adopt TRIPS-compliant laws that also promote “statutory exclusions and available defences, and issue interpretative patent practice guidelines through national patent offices as a way of establishing more stringent application of the patentability requirements.”<sup>249</sup> The issue here is not that the provision of technical assistance to poor countries is a bad idea. The point is that one-sided technical assistance activities undermine efforts to achieve the social benefit goals of patent law in promoting technology transfer such as access to medicines.

The good news is that, with the adoption of the WIPO Development Agenda, member-states have assumed more active roles in determining the scope and frequency of technical support initiatives. Today, WIPO’s technical support initiatives are subjected to rigorous debate and scrutiny by the Committee on Development and Intellectual Property (CDIP), which committee is dominated by less developed countries. WIPO member states also deliberate over issues of budgetary allocations in a more democratic fashion. There are also transparent mechanisms for assessing whether any WIPO-supported technical assistance initiatives are beneficial to the societies involved. On that score, there is a database that has tracked and monitored such technical support programs since

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<sup>249</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 6-7.

2007.<sup>250</sup> Such monitoring mechanisms within the WIPO set-up were hitherto either weak or non-existent, however.

WIPO cannot take all the blame for its traditionally one-sided technical support activities. In some instances, countries themselves seek stringent and TRIPS-plus patent standards so as to comply with their bilateral agreements with the West that require such standards.<sup>251</sup> Also, Amani has reasoned that positivist readings of international obligations by the courts, administrative patent offices, law and policy makers, and trade technocrats in countries tend to eviscerate their understanding of international patent standards.<sup>252</sup> Worse still, misapprehension relating to the dictates of the *TRIPS Agreement* has plunged many states in SSA into a domestic regulatory quandary: patent rights are easy to obtain and enforce at the expense of the public right to access medicine. As I elaborate in chapter 5, there are insufficient institutional checks and balances in SSA to ensure that pharmaceutical patent grants meet domestic regulatory standards on patentability.

In addition, citizens directly affected by patent systems and public interest groups do not get the opportunity to participate in WIPO's technical support programs. This exclusion disables persons, especially those affected by diseases, from influencing patent and access to medicine policies. One may argue that their representatives take part on their behalf. Such an argument is still unconvincing in situations where patent laws are generated from elsewhere and imposed by a few elites on the masses without taking into account the domestic social costs. The argument also fails to account for the need to involve citizens in crucial national decision-making processes in-between elections, if

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<sup>250</sup> WIPO, "Technical Assistance Database" online at: <<http://www.wipo.int/tad/en/>>. For instance, WIPO member states have recently approved a project to build a common digital platform which will help streamline the identification of protected musical works across eleven West African countries, including Benin, Burkina Faso, Côte d'Ivoire, Gambia, Ghana, Guinea, Mali, Niger, Nigeria, Senegal and Togo.

<sup>251</sup> See e.g. Drahos, "DC and International IP Standard-Setting", *supra* note 142 at 777.

<sup>252</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 13 at 7.

any. According to Czapanskiy & Manjoo, democratic law-making process requires active, animated citizens, who engage with each other to identify and understand their political interests, to discover their social values and to decide public issues through debate.<sup>253</sup> More importantly, designing patent legislation to regulate access to medicine issues is so fundamental that the citizens who are directly affected by epidemics deserve to have their views heard. Involving the public will help enrich the perspectives of policy-makers in SSA in implementing international patent obligations.

Needless to say, the inability of the citizens of SSA countries to participate in the design of patent legislation and policies undermines the legitimacy of the outcomes. To be legitimate, one would expect real participation by the people in the enactment of such laws and policies that affect access to medicines. According to Fuentes, democracy entails “the idea that all citizens have a right to participate in the decision-making processes that lead to the adoption of policies that are applicable in their societies.”<sup>254</sup> If this requirement of the citizen’s right to participate is too onerous, at least the participation of public interest civil society and their communities in the design of such crucial domestic laws is essential. Anything less in enacting patent laws may raise questions about the legitimacy of the juridical outcomes for regulating pharmaceuticals in SSA. Admittedly, this proposal for increased participation in domestic patent law making cannot flourish in SSA countries with autocratic regimes. Also although the absence of public participation in law making may be a general problem in SSA, this study limits the arguments herein to patents and access to medicine issues.

In this light, the jurisprudence of the South African Constitutional Court in the enactment of health-related statutes provides interesting lessons. Recently, the South African Constitutional Court had the opportunity to determine whether elected leaders in a democratic state have an obligation to involve citizens in the law making process. In the

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<sup>253</sup> Czapanskiy & Manjoo, “The Right of Public Participation in Law-Making”, *supra* note 239 at 15.

<sup>254</sup> Ximena Fuentes, “International Law-Making”, *supra* note 179 at 13.

*Doctors for Life International v The Speaker of the National Assembly & Others*,<sup>255</sup> the applicant's contention was that the refusal of the South African Legislature to facilitate the participation of citizens in the enactment of the 'health statutes'<sup>256</sup> infringed the right to participate in the law making process, thereby undermining human rights values. In upholding this contention, the Court held that the failure of the South African Parliament to involve the citizens before passing two crucial pieces of legislation (i.e., the *Choice on Termination of Pregnancy Amendment Act* and the *Traditional Health Practitioners Act*) violated the constitutional duty to facilitate public participation in the law making process. Consequently, the Court declared both statutes null and void on grounds that they were enacted in violation of the requirements of the South African Constitution.<sup>257</sup>

The Court further noted that given the crucial nature of a piece of legislation, it may not be sufficient to meet the requirement of 'public participation' in the legislative process if Parliament merely provides an opportunity to make either written or oral submission at some point in the legislative process. Thus, in enacting crucial and controversial pieces of legislation, public hearing may be needed to address public outcry and concerns. In some instances, the Legislature must facilitate public input into legislation. In addition, patent legislative reforms in SSA must be based on the country's economic and social circumstances, including the prevalent levels of epidemic in that country.

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<sup>255</sup> 2006 (12) BCLR 1399 (CC) (SA).

<sup>256</sup> The health statutes include: *Traditional Health Practitioners Act* 35 of 2004 (recognizing and regulating traditional health healers); *Choice on Termination of Pregnancy Amendment Act* 38 of 2004 (making provision for registered nurses, other than midwives, to perform termination of pregnancies at certain public and private facilities); *Dental Technicians Amendment Act* 24 of 2004 (providing for persons who have been employed as dental laboratory assistants for a period of not less than five years under the supervision of a dentist or dental technician, and who have been trained by these professionals, to perform the work of a dental technician); and the *Sterilisation Amendment Act* 3 of 2005 (providing for additional information to be considered when contemplating sterilization and others).

<sup>257</sup> Since the statutes were, at the time of judgment, in force, the Court's decision was suspended for 18 months to enable Parliament to re-enact those legislation taking into account the requirements of the Constitution. The remaining two pieces of legislation were held to be duly enacted.

This decision, though limited to South Africa, supports a case for the citizens of SSA to be more actively involved in passing patent legislation, which eventually implicates access to life-saving medicines. The reasoning of this decision also offers a model for courts in other SSA countries to scrutinize patent legislative processes and see to it that they meet the requirement of public participation guaranteed in most national constitutions. This can only occur if civil society organizations take the fight to the courts and competition tribunals. Civil society groups play a key role in raising public awareness of the implications of the current patent system and the *TRIPS Agreement* for access to medicine issues.<sup>258</sup> In SSA, there is documented evidence of such activism by civil society groups to enhance access to essential medicines as well as lower prices of medicines.<sup>259</sup> As I explain further in chapter 5, the views of citizens and public interest-oriented institutions should thus be considered in enacting/revising patent rules in order to make pharmaceutical patent-grants relevant in SSA countries. Admittedly, the participation of citizens and public interest organizations may not guarantee instant economic justice, but it may open the door for individuals to make the connections with other like-minded groups that are necessary to achieve the social benefit goals of patent law.<sup>260</sup> Perhaps, this will in turn eradicate a number of misapprehensions that militate against the public interest in ensuring access to medicines at affordable prices in SSA.

## VII. Conclusion

This chapter offers an analytical description of the historical context of the political economy of the globalized patent system. It articulates the key developments and

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<sup>258</sup> UNAIDS, “Using TRIPS Flexibilities to Improve Access to HIV Treatment” in *AIDS at 30: Nations at the Crossroads* (2011) at 5, online <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

<sup>259</sup> See Fact sheet on settlement agreements. Cape Town, Treatment Action Campaign, (2003) <[http://www.taCorg.za/newsletter/2003/ns10\\_12\\_2003.htm](http://www.taCorg.za/newsletter/2003/ns10_12_2003.htm)>; Tenu Avafia et al, *The Ability of Select sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* (ICTSD, UNCTAD and tralac, 2006), online: <<http://apps.who.int/medicinedocs/documents/s18249en/s18249en.pdf>>.

<sup>260</sup> Czapanskiy & Manjoo, “The Right of Public Participation in Law-Making”, *supra* note 239 at 23.

negotiations in the evolution of the concept of patent law from the early days to the present. The rules of the game reflect the ideological biases and vested financial interests of western pharmaceutical companies and institutional cohorts. The power to make pharmaceutical patent rules among others lies with the North. The drafting history of TRIPS confirms this point. Also, decisions bordering on pharmaceutical patent protection and regulation are made not to solve human problems but to satisfy the vested interest and beliefs of those who matter.<sup>261</sup> The place of SSA countries in global trade governance is at the periphery of international patent law making. Therefore, the claim that WTO members have the decision-making power in international economic law making is not wholly accurate.<sup>262</sup>

Further, the implementation of international patent standards in SSA countries is not free from the influence of western hegemons and their industries. For the most part, legislative drafting assistance programs involve picking western-model laws off the shelf and imposing them on SSA countries irrespective of their appropriateness for the affected communities.<sup>263</sup> Domestic patent law making activities do not reflect human needs and socio-economic realities in SSA. Recognizing this reality provides an important context for comprehending the sources and substance of the patent regulatory and institutional standards in SSA. In domesticating international obligations, policy-makers in SSA must involve the inputs of the citizens and public interest organizations. That way, SSA countries can challenge some of the tired assumptions that have been employed by proponents to direct and sustain the trajectory of the international patent system and its resultant TRIPS-plus commitments. Chapter 4, therefore, examines some of the

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<sup>261</sup> See Stiglitz, *Globalization and Its Discontents*, *supra* note 70 at x.

<sup>262</sup> See “Statement to the media by Pascal Lamy upon taking office on 1 September 2005”, online: <[http://www.wto.org/english/news\\_e/news05\\_e/dg\\_lamy\\_1sept05\\_e.htm](http://www.wto.org/english/news_e/news05_e/dg_lamy_1sept05_e.htm)>.

<sup>263</sup> See Michael Blakeney, “A Critical Analysis of the TRIPS Agreement” in Meir Perez Pugatch, ed, *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (MA: Edward Elgar, 2006) 17 at 24.

justifications/assumptions employed to justify the grant of patent protection, which also apply to pharmaceuticals, and to assess how they fit within the context of SSA.

## Chapter 4

### The 'Myth' of Patent Justifications: Triumph and Failure Dichotomy in the North and South

#### I. Introduction

The preceding chapter 3 has revealed that the arguments to protect and enforce pharmaceutical patent rights are anchored on both classical and neoclassical theories for securing private proprietary interests over knowledge-based products and processes. Theories proffered in defence of the patent system include natural rights theory, reward theory, contract/disclosure of secret theory, incentive theory, prospect theory, race-to-invent theory, and the rent-dissipation theory.<sup>1</sup> These theoretical assumptions have been used by scholars to justify the prevailing international patent regime and its reflections in the domestic laws of both developed and less developed countries alike. Particularly, the natural rights theory in tandem with the incentive theory played a crucial rhetorical role in the strategy of industry groups to convince governments in developed countries to demand strong patent systems across the globe.<sup>2</sup> The *TRIPS Agreement* and its underlying theories have thus effectively secured standards of patents similar to those adopted in industrialized countries. The consequence is that the justifications for patents contribute to perpetuating the notion of the applicability of a one-size-fits-all pharmaceutical patent protection regime across countries/regions.

Despite the variety of theories advanced to rationalize the ideology of the patent system, the growing liberalization of IP- and trade-related issues has propelled the economic rationale to the forefront of global economic relations. This dominant economic rationale assumes that the grant of patent protection leads to technology transfer and knowledge

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<sup>1</sup> Although I discuss all of these theoretical justifications for patents, the bulk of the analysis in this chapter will focus on the dominant economic/property-right-inspired justifications, which have influenced the globalized patent system and its reflections in SSA.

<sup>2</sup> See e.g. A Samuel Oddi, "TRIPS – Natural Rights and a 'Polite Form of Economic Imperialism'" (1996) 29 Vand J Transnat'l L 415 at 432 [Oddi, "TRIPS – Natural Rights"].

dissemination;<sup>3</sup> that it serves as an incentive for further research and development (R&D);<sup>4</sup> that it leads to increased foreign direct investment;<sup>5</sup> that it provides incentives for the advancement of indigenous knowledge and innovation;<sup>6</sup> and, that it also creates wealth.<sup>7</sup> In accord with the lofty ideals of contemporary capitalism, proponents of these assumptions have asserted that tightened patent protection spurs economic growth and development.<sup>8</sup> Put simply, in the absence of patent exclusivity, the competitive market would not allow the inventor to make profits that could induce the optimal amount of innovation.<sup>9</sup>

The purpose of this chapter is to examine the foundations of the theories/assumptions proffered by scholars to justify the grant of patent protection and to assess how they fit within the context of SSA. I interrogate the claim by neoliberal scholars that the

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<sup>3</sup> For a discussion of some of these assumptions, see generally: G Tumwine-Mukubwa, "Patents and Technology Transfer to Underdeveloped Countries" (1975-1977) 7-9 *Zambia Law Journal* 1; E Richard Gold et al, "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" (2004) 18:4 *Public Affairs Quarterly* 299.

<sup>4</sup> See Joseph E Stiglitz, "Economic Foundations of Intellectual Property Rights" (2008) 57 *Duke LJ* 1693 at 1695; see also *Diamond v Chakrabarty*, 447 US 303 (1980) at 304.

<sup>5</sup> See Rajnish Kumar Rai, "Effects of the TRIPS-Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry" (2009) 11 *Journal of World Intellectual Property* 404.

<sup>6</sup> See Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002) at 2.

<sup>7</sup> Paul Martin, then Canada's Finance Minister, in his Budget Speech on 28 February 2000, said: "Today, the strength of a nation is measured not by the weapons it wields, but by the *patents* it produces; not by the territory it controls, but by the ideas it advances; not only by the wealth of its resources, but by the 'resourcefulness of its people. In such a world, successful nations will only be those that foster a culture of innovation. They will be those that create new knowledge and bring the product of that knowledge quickly to market. Our goal as a nation must be to lead the way.", online: <<http://www.fin.gc.ca/budget00/speech/speech1e.htm#New>> (emphasis added).

<sup>8</sup> For a detailed discussion of the alleged nexus between patents protection and industrial growth and development, see Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005); for a discussion on the need for stronger protection of IP, see the following: Richard Rapp & Richard P Rozek, "Benefits and Costs of Intellectual Property Protection in Developing Countries" (1990) 75/77 *J World Trade* 75; Alan S Gutterman, "The North-South Debate Regarding the Protection of Intellectual Property Rights" (1993) 28 *Wake Forest L Rev* 89; David M Gould & William C Gruben, "The Role of Intellectual Property Rights in Economic Growth" (1996) 48 *J Dev Econ* 323.

<sup>9</sup> Irina Haracoglou, *Competition Law and Patents: A Follow-on Innovation Perspective in the Biopharmaceutical Industry* (Mass.: Edward Elgar, 2008) at 21.

globalized patent system will work in the less developed world.<sup>10</sup> In so doing, I contend that the apparent belief that the grant of pharmaceutical patents has worked in the developed world and for that matter a similar approach will work elsewhere is a 'myth': a dysfunction that can create and sustain economic dependency of SSA countries. Indeed, extending the patent regulatory standards of developed countries to less developed countries in SSA, which are worst affected by epidemics, and thus in dire need of life-saving medicines, could be deceptive. This defect in the globalized patent framework is synonymous with the promise of Enlightenment thinking that human reason was the primary source and legitimacy for authority.<sup>11</sup> As it turned out, Enlightenment thinking perpetuated a discourse, which through colonialism, imposed the political ideals and institutions of powerful states on less powerful countries.<sup>12</sup>

Likewise, these theoretical and enlightenment assumptions embedded in neoliberal discourse have been instrumental in persuading policy- and law-makers in SSA to adopt patents and institutional regulatory frameworks that privilege protectionism over diffusion, against their own best interests. In many cases, particularly in relation to the adoption of strong patent regimes, one could even say they were deceived.<sup>13</sup> This 'myth' regarding patents is borne out by the fact that: first, the justifications for patents (as discussed in greater depth below) are premised on erroneous assumptions about IP and over-generalized notions about western concepts of property. Second, the promises made to less developed countries to sign TRIPS in return for technology transfer and export

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<sup>10</sup> See Edmund W Kitch, "The Patent Policy of Developing Countries" (1994) 13 UCLA Pac Basin LJ 166 at 171 [the incentive to invent, commercialize and market technologies that meet the needs of less developed countries will only exist if there are patents to protect innovation]. See also, Alan O Sykes, "TRIPS, Pharmaceuticals, Developing Countries and the Doha 'Solution'" (2002) 3 Chicago J Int'l L 47 [introducing high levels of patent protection in less developed countries induces firms to invent products such as anti-malaria medicines and to engage in technology transfer].

<sup>11</sup> For a detailed discussion of the failure of the Enlightenment thinking which took humanity down the barbaric path of Nazism, see Max Horkheimer & Theodor W Adorno, *Dialectic of Enlightenment*, John Cumming, ed (New York: Continuum, 1995).

<sup>12</sup> Joseph E Stiglitz, *Globalization and Its Discontents* (New York: W.W. Norton & Co., 2002) at 282.

<sup>13</sup> See e.g. Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003).

subsidies have not been met. For Kennedy, the *TRIPS Agreement* dangles the carrot of technology transfer to induce less developed countries to embrace the concept of single undertaking, and thus cede their sovereignty in matters of domestic IP law and policy to the WTO.<sup>14</sup> Third, assurances that developed countries would refrain from resorting to unilateral and bilateral pressures against less developed countries if the latter signed up to TRIPS have become illusory.<sup>15</sup> A recent increase in bilateral trade and investment agreements which impose TRIPS-plus obligations on countries in Africa shows the troubling dimensions of the West's broken promises.<sup>16</sup>

Ordinarily, the much trumpeted theoretical justifications fail to glitter when tested against the prevailing circumstances in SSA. The fact that diseases such as HIV/AIDS, malaria, and TB have become endemic in SSA, among other factors, necessitates a rethink of the theoretical justifications which perpetuate the one-size-fits-all mantra of pharmaceutical patent protection across countries and regions. Also, the fact that the theoretical justifications fail to differentiate between essential life-saving medicines and non-essential commodities contributes to creating regulatory dysfunctions which impede access to medicines for the masses in poor countries. The traditional worldview of patent protection that development will be furthered by recognizing and enforcing IP rights irrespective of the disparate needs and levels of development among states is unsustainable.<sup>17</sup>

Presently, the needs of SSA countries are acutely basic: medicines are needed to combat epidemics such as HIV/AIDS, malaria, and TB. On the other hand, developed countries have a relatively high standard of living for their people and their goal is to sustain their

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<sup>14</sup> Kevin Kennedy, "The 2005 TRIPS Extension for the Least-Developed Countries: A Failure of the Single Undertaking Approach" (2006) 40 Int'l Law 683.

<sup>15</sup> Mohammed El-Said, "The Road from TRIPS-Minus, to TRIPS, to TRIPS-Plus: Implications of IPRS for the Arab World" (2005) 8 Journal of World Intellectual Property 53 at 55.

<sup>16</sup> See El-Said, "From TRIPS-Minus, to TRIPS, to TRIPS-Plus", *ibid* at 59-61.

<sup>17</sup> Christopher May, *The World Intellectual Property Organisation and the Development Agenda* (2006) at 11, online: <[http://www.bath.ac.uk/cri/pdf/ecpr\\_pdf/1\\_May.pdf](http://www.bath.ac.uk/cri/pdf/ecpr_pdf/1_May.pdf)>.

dominant economic power.<sup>18</sup> The story of this contrast between developed and less developed countries is eloquently articulated elsewhere that “in an environment of remarkable opulence and ‘ingenuity’ in the developed world as against one of extreme deprivation, disease and scarcity in the developing world, it is unworkable to adopt a western-archetype patent system across the board.”<sup>19</sup> Therefore, testing the theories/assumptions on which the globalized patent system is premised will encourage and promote a nuanced understanding of the functioning and efficiency of the patent systems in SSA to promote social benefits. It is a starting point in making a case for recalibrating the globalized patent system to be cognizant of the human development needs and interests of the people in SSA.

Following this introduction, part II offers a brief overview of the theories of patent protection that have been advanced by legal and non-legal scholars in the literature. It discusses theories such as the natural rights theory of patents, reward theory, contract/disclosure of secret theory, incentive theory, prospect theory, race-to-invent theory, and the rent-dissipation theory of patents. This discussion points out the problems associated with the theoretical justifications that have been used to ground contemporary patent systems including those in SSA.

Part III highlights the dysfunctions (including granting too many patents and patents that are overly broad) associated with the globalized patent regulatory system. This discussion of the dysfunctions or inequities associated with the globalized patent system is based within the framework of the international patent system under TRIPS. A major caveat, however, is that although the dysfunctions that will be discussed in part III reflect a general defect in the globalized patent system, the principles underlying the discussion apply equally to pharmaceuticals.

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<sup>18</sup> See Robert L Ostergard, *The Development Dilemma: The Political Economy of Intellectual Property Rights in the International System*, Eric Rice ed (New York: LFB Scholarly, 2003) at 3.

<sup>19</sup> Poku Adusei, “Regulatory Diversity as Key to the ‘Myth’ of Drug Patenting in Sub-Saharan Africa” (2010) 54 J Afr L 26 at 30-31.

Putting theory into context, part IV urges a move beyond the veil of theoretical assumptions and thus advocates a need to re-conceptualize the justifications for patents to take account of what Abbott calls 'the impact-in-fact'<sup>20</sup> of patent rules on societies in SSA. Patent law should serve the social benefit goal of promoting access to life-saving medicines for the citizens of SSA countries. In consequence, I suggest the adoption of diverse regulatory strategies to overcome access-to-medicine barriers in SSA. The final part V concludes this chapter based on the foregoing discussion.

## II. Theoretical Justifications

As I elaborate below, patent-friendly theories such as the natural rights theory and the incentive theory have cumulatively influenced the trajectory of the globalized patent system as epitomized by TRIPS. In the same vein, the patent systems in SSA support the grant of strong pharmaceutical patent rights over public access issues. The explanations for this development are not far-fetched: first, the laws of countries in SSA have been 'modernized and revised'<sup>21</sup> to bring them into compliance with TRIPS.

Second, there are instances in SSA whereby domestic patent laws are made subservient to international patent law (i.e., TRIPS) such that in the event of any conflict the latter prevails. One such example will be adequate for now. Section 38 of Ghana's *Patents Act*, 2003 (Act 657) provides that "the provisions of any international treaties in respect of industrial property to which the country is a party shall apply to matters dealt with by this Act and, in case of a conflict with this Act, the international treaty shall prevail over the Act."<sup>22</sup> Similar provisions in regard to the implementation of international patent standards cannot be found in the patent legislation of developed countries, however. The point is that giving primacy to international patent law over domestic patent laws in parts

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<sup>20</sup> Frederick M Abbott, "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" (2005) 8 J Int'l Econ L 77 at 78.

<sup>21</sup> This phrase or its *ejusdem generis* finds articulation in the Memoranda to the patent laws of countries in SSA: see e.g. Ghana's *Patents Bill*, 2003 (now *Patents Act*, 2003 – Act 657).

<sup>22</sup> See section 38 of Ghana's *Patents Act*, 2003 (Act 657).

of Africa poses a significant challenge to the exercise of domestic discretion in matters of IP law and policy. It could also promote the dictates of the natural law and economic-friendly justifications for strong patent protection often championed by the TRIPS-based patent framework and spearheaded by the developed world. The next task, therefore, is to describe and critique the justifications for patents and their attendant underlying hypotheses.

### A. Natural Rights Theory

Proponents of the natural rights theory argue that an inventor has an inherent right in the fruits of his/her intellect which include patents. Their belief is that “patents are the heart and core of property rights, and once they are destroyed, the destruction of all other property rights will follow automatically...”<sup>23</sup> As Locke expresses it, “every man has a property in his own person. The labour of his body, and the work of his hands, we may say are properly his.”<sup>24</sup> Likewise, Smith posits that “the labours of the mind and productions of the brain are as justly entitled to the benefit and emoluments that may arise from them, as the labours of the body are.”<sup>25</sup> For proponents of this theory, the grant of patent monopoly serves as a precondition for a liberal economic order.<sup>26</sup> And, the society, represented by the state, has an obligation to recognize, protect, and enforce the

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<sup>23</sup> Ayn Rand, *Capitalism: The Unknown Ideal* (New York: New American Library, 1966) at 128.

<sup>24</sup> John Locke, *Second Treatise of Government*, CB Macpherson ed (1980) paragraph 27. The full text of Locke’s famous paragraph 27 of the *Second Treatise* reads: “Though the earth, and all inferior creatures, be common to all men, yet every man has a *property* in his own *person*: this nobody has a right to but himself. The *labour* of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes then he takes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*. It being by him removed from the common state nature hath placed it in, it hath by this *labour* something annexed to it, that excludes the common right of other men: for this *labour* being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good, left in common for others.”

<sup>25</sup> Adam Smith, *The Wealth of Nations*, Alan B Krueger, ed (New York: Bantam, 2003) at 103 [1776].

<sup>26</sup> Jean-Frederic Morin, “The Strategic Use of Ethical Arguments in International Patent Lawmaking” in E Richard Gold & Bartha Maria Knoppers, eds, *Biotechnology IP & Ethics* (Markham, ON: LexisNexis, 2009) 69 at 80.

property rights that accrue from an invention.<sup>27</sup> In essence, the natural rights theory of patents serves the economic interests of private right holders, by supporting the grant of strong patents for inventions.

More fundamentally, the natural rights theory played a crucial rhetorical role in the strategy of industry groups to convince governments in developed countries to demand an 'effective' and 'adequate' protection for patents across countries.<sup>28</sup> As Oddi observes, during the Uruguay Round, the argument, based on a natural rights premise, was that 'counterfeiting', 'theft', 'pirating', and 'infringement' occur any time a patented invention is copied.<sup>29</sup> Accordingly, Article 27 of TRIPS – on patentable subject matter – implements natural rights theory, by providing that all inventions, including certain categories of inventions that have been traditionally excluded from protection by many countries, are now of such importance to international trade that they must be protected universally.<sup>30</sup> In addition, efforts by less developed countries to limit patent rights on grounds of public health and interest are made subject to the condition that such measures must not restrain trade and must be consistent with TRIPS.<sup>31</sup>

Thus, as argued in chapter 3, industry groups succeeded in obliging countries to recognize this variant form of patents-as-natural-entitlement claim for 20 years under their domestic positive laws irrespective of the perceived value of the invention to a particular country and the welfare cost. The natural rights theory was thus employed to entrench the economic interests of pharmaceutical right holders. The downside is that relying on the natural rights theory to characterize the privilege conferred by the patent system as a claimed property right (as manifested in TRIPS) could imperil public health

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<sup>27</sup> On this point see Ikechi Mgbefo, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006) at 19.

<sup>28</sup> Oddi, "TRIPS – Natural Rights", *supra* note 2 at 432.

<sup>29</sup> Oddi, "TRIPS – Natural Rights", *ibid* at 432.

<sup>30</sup> Oddi, "TRIPS – Natural Rights", *ibid* at 436.

<sup>31</sup> See Article 8 of the *TRIPS Agreement*.

in poor countries. This potential threat to public health and access to medicine issues is especially pronounced in SSA, where the level of local inventiveness is low. The fact that the overwhelming majority of pharmaceutical patents granted by SSA countries are to foreigners speaks loudest.<sup>32</sup>

Nonetheless, there are limitations inherent in the natural rights theory of property as espoused by scholars. For example, Locke admits that to appropriate from the public domain, “enough and as good [must be] left in common for others.”<sup>33</sup> In addition, the appropriation should not cause any ‘waste.’ Today, patents as the primary juridical mechanism for controlling inventions run afoul of this proviso by giving the inventor the exclusive right to make, use, sell and/or import the invention (subject to a time limit and the other exceptions that limit patents).<sup>34</sup> The limitations in the natural rights theory should thus be employed to moderate the far reaching claims of patents-as-natural-rights in academic and policy discourse. That way, the public would not be made worse-off by the appropriation from the public domain of intangible resources.

Related to the above is the criticism that the natural rights theory fails to acknowledge the cumulative nature of the inventive process. Inventors rely on and build upon an existing stock of knowledge and inventions that may be in the public domain. As Mgbeoji aptly opines, “the reality is that inventions and innovations do not spring *ex nihilo*. Inventors, artists and creative people draw from the stock of pre-existing human knowledge and cultures.”<sup>35</sup> This lack of truly independent inventions makes it imperative to acknowledge the interests of the ‘other’ contributors to innovation in matters of pricing and distributing pharmaceuticals in the market place. On her part, Piper observes that the failure to

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<sup>32</sup> See Mgbeoji, “TRIPS and TRIPS-Plus Impacts in Africa” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 259 at 292-293.

<sup>33</sup> Locke, *Second Treatise of Government*, *supra* note 24 at para 27.

<sup>34</sup> Edwin C Hettinger, “Justifying Intellectual Property” (1989) 18 *Philosophy & Public Affairs* 31 at 44.

<sup>35</sup> Mgbeoji, *Global Biopiracy*, *supra* note 27 at 18.

conceive of innovation and the social good as being cumulative has impoverished patent theory and practice.<sup>36</sup>

The natural rights theory also focuses on the individual inventor and thus fails to provide an explanation for granting pharmaceutical patents to companies. The natural rights theory does not explain the phenomenon in which an employer holds the right in the 'inventive genius' of the employee.<sup>37</sup> It also does not acknowledge the existence of interests in collectively-engineered inventions within indigenous communities. Critics also point out that the patents-as-natural-rights hypothesis does not fully explain the positive character of patent law. As Penrose notes, the patent system is a social institution established for a social purpose.<sup>38</sup> Patent law is not derived from any notion of reason, upon which the concept of natural right is justified; patent rights are a creature of statute. Indeed, 'natural' phenomena are excluded from patentability. The fact that inventors have to go through administrative processes to obtain patent rights undercuts any notions of patents-as-natural-rights. Notwithstanding these criticisms levelled at the natural rights theory, this theory played a crucial role in justifying the design of the globalized patent system as epitomized by TRIPS. This natural rights entitlement approach was adopted because it represented the position of more powerful nations.<sup>39</sup>

## **B. Reward Theory**

Like the natural rights theory, the essence of the reward theory is that an inventor deserves reward for introducing new solutions to human problems. It posits that an inventor has a right to receive rewards for the useful services, via inventions, rendered to

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<sup>36</sup> Stamatia Tina Piper, "The Emergence of a Medical Exception from Patentability in the 20<sup>th</sup> Century" (DPhil Thesis, University of Oxford, 2008) at 65.

<sup>37</sup> Mgbeoji, *Global Biopiracy*, *supra* note 27 at 17.

<sup>38</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Westport, Connecticut: Greenwood Press, 1973) at 22.

<sup>39</sup> Wesley A Cann, "On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism" (2004) 25 U Pa J Int'l Econ L 755 at 784.

society, and, that society has a moral obligation to protect this exclusive reward.<sup>40</sup> This theory also argues that the reward offered to inventors serves as a morale booster for inventors to apply their inventive genius. It follows that without the 'prize' under the patent system inventions would not be made. This argument is, however, nuanced by studies, which indicate that the "current patent law discouraged drug companies from developing new drugs by allowing them to make excessive profits through minor changes to existing pharmaceuticals."<sup>41</sup> In addition, the patent system administered today is unable to ensure, in many instances, that the reward goes where it is most deserved.<sup>42</sup>

There are also several inventions that were made without taking into consideration the reward rationale for the grant of patents to inventions. The aphorism that 'necessity is the mother of invention' reflects the reality that a number of significant inventions would be made irrespective of the availability of patent reward.<sup>43</sup> In most instances, the reward comes into the fray after the invention has hit the market-place. There are also instances whereby the inventor never enjoys this supposed reward or recognition in his/her lifetime. For example, Rosalind Franklin's contributions to the discovery of the structure of the DNA were acknowledged only after the Nobel Prize was awarded to Francis Crick, James Watson, and Maurice Wilkins in 1962. In addition, a number of ground-breaking inventions exist by means that can be attributed to accidental discoveries.

Yet, another flaw in the reward theory is that it confuses inventiveness with the commercialization of inventions. Perhaps, a more accurate argument is that patents serve as a useful incentive for commercializing an invention, by offering profits to those

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<sup>40</sup> Penrose, *Economics of the International Patent System*, *supra* note 38 at 6.

<sup>41</sup> See The US Government Accountability Office, "New Drug Development, Science, Business, Regulatory, and Intellectual Property Issues cited as Hampering Drug Development Efforts" in a *Report of the United States Government Accountability Office* (November 2006), online: <<http://oversight.house.gov/Documents/20061219094529-73424.pdf>>.

<sup>42</sup> Penrose, *Economics of the International Patent System*, *supra* note 38 at 27.

<sup>43</sup> See A Samuel Oddi, "The International Patent System and Third World Development: Reality or Myth?" (1987) 63 Duke LJ 831 at 838.

desirous of such commercial enterprises.<sup>44</sup> In essence, the argument of the reward theory becomes relevant after the invention has been undertaken. Again, most of the criticisms that have been levelled at the natural rights theory also apply to the reward theory, and, therefore, need not be rehashed here. Suffice it to say that the reward rationale for patents is not attuned to the communal character of ownership in traditional knowledge/resources in SSA.

### C. Contract / Disclosure Theory

The idea of this theory is that a patent constitutes a bargain between the inventor and the public, in which the patentee obtains exclusive protection for a set-period of time in exchange for giving the public information about the invention.<sup>45</sup> This disclosure is expected to take place in a form of publication of the invention and the details of how it works in the course of the patent application process. This contract theory also assumes that the information disclosed in return for the grant of an exclusive patent right is enough for the public to work the invention. As Amani explains, “the disclosure essentially functions as a ‘how-to’ guide providing information so that others are able to make and use the invention.”<sup>46</sup>

The disclosure theory is not free from criticism, however. It is axiomatic that inventors have made it a practice to disclose as little as they can in order to stifle competition. As Vaver perspicaciously puts it,

The game for patentees, especially in highly competitive industries, is to reveal as little and to claim as much as possible. The less disclosed, the

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<sup>44</sup> Mgbeoji, *Global Biopiracy*, *supra* note 27 at 20.

<sup>45</sup> Christopher A Cotropia & Mark M Lemley, “Copying in Patent Law” (2009) 87 NCL Rev 1421 at 1431.

<sup>46</sup> Bitu Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (England: Ashgate, 2009) at 46.

more that can be retained as competitive edge. The wider one claims, the tougher it is for imitators.<sup>47</sup>

The art of drafting patents in an arcane manner in order to disclose as little information as possible has rendered this disclosure rationale meaningless.<sup>48</sup> It may be said that this practice of disclosing little information during the patent application process undermines the *TRIPS Agreement*. Specifically, Article 29.1 mandates applicants to describe the invention in enough detail that a person skilled in the art may carry out the invention from the information disclosed. This goal of patent law as a *quid pro quo* did not gain significant influence in the design of the patent rules under TRIPS as compared to the copyright rules. Patent law focuses mainly on the pecuniary benefits for inventors to the disadvantage of the public interest. In consequence, the alleged contract between an inventor and society is out of balance, because patent law has become a primary tool for securing private market share.<sup>49</sup> The implication is that the grant of exclusive pharmaceutical patent rights generates short term benefits for the right holder but in the long term the welfare cost is detrimental to human development in poor countries.

Moreover, even if the alleged disclosure is sufficient to work the invention, most countries in SSA lack the capability to assimilate even the state-of-the-art into their technological base.<sup>50</sup> In SSA, the capacity of most countries (save South Africa) to manufacture medicines remains largely utopian. Also SSA countries generally lack the technological competence to collate and make accessible to local researchers and innovators, the technical and scientific information contained in pharmaceutical patent applications. Accordingly, the disclosure of technical biotech information during the application process may not be sufficient to work the invention in such countries. Such

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<sup>47</sup> David Vaver, *Intellectual Property Law Copyright, Patents, Trademarks* (Concord, ON: Irwin Law, 1997) at 139.

<sup>48</sup> *Brenner v Mason*, 383 US 519 (1966) at 533.

<sup>49</sup> Ostergard, *The Development Dilemma*, *supra* note 18 at 18.

<sup>50</sup> Oddi, "The International Patent System", *supra* note 43 at 843.

technical information could be of great value to countries in SSA if they invest in the viable scientific and technological infrastructure needed to work the invention.

In addition, the IP systems in SSA countries still have in place juridical mechanisms for protecting trade secrets in accordance with TRIPS. Therefore, if inventors believed that the use of trade secret laws or confidential information systems would better serve their interests, the patent system would be of minimal use to them. Again, the disclosure theory confuses the commercialization of inventions with the encouragement of inventiveness through the grant of patents.<sup>51</sup> It is speculative in most instances to estimate the economic value of an invention prior to its commercialization, and, therefore, this social contract theory cannot reasonably explain why inventions occur. Thus, the social contract argument comes into play after the invention has been made and at a time when the inventor seeks to exploit the economic reward. Also, the fact that inventions are called forth by the needs of society renders the rationale of the disclosure theory questionable.<sup>52</sup>

#### **D. Incentive theory**

The incentive theory is arguably the most popular in contemporary patent discourse. The reason is that the economic rationale of the incentive theory resonates with the ideology of capitalism and free market economics spearheaded by the US. For example, the US Constitution explicitly grants Congress the power “*to promote the progress of Science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.*”<sup>53</sup> The US Supreme Court has also affirmed that patent protection is based on the idea of economic incentives.<sup>54</sup> This economic worldview of patents has shaped the trajectory of the globalized patent system, by giving

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<sup>51</sup> Mgebeji, *Global Biopiracy*, *supra* note 27 at 20.

<sup>52</sup> See e.g. Penrose, *Economics of the International Patent System*, *supra* note 38 at 33.

<sup>53</sup> US Constitution, Article 1 s 8 cl 8.

<sup>54</sup> See *Graham v John Deere Co*, 383 US 1 (1966).

primacy to the rights of pharmaceutical holders over the public interest to have access to medicines.

The hypothesis of the incentive rationale is that patent-incentives are needed to encourage technology transfer, R&D, and economic growth. The assumption, according to Penrose, is that it is desirable to encourage invention for its own sake and that a patent monopoly is the best mode of executing it.<sup>55</sup> Put differently, proponents of this theory argue that the patent system creates incentives that are needed to induce people to produce particular objects beneficial to society.<sup>56</sup> For his part, Merges notes that the patent system's key economic goal is to reward "the achievement of a significant technical advance and thereby to spur innovative technological development."<sup>57</sup> Thus, without the grant of patent-incentives potential inventors would be unwilling to put their industry to work.

As shown in chapter 3, during the Uruguay Round, industry groups argued that globalizing US/western IP standards would fuel creativity and innovation, generate higher rents, attract foreign investment, and encourage a more rapid transfer of technology. This incentives argument by industry was embraced by developed nations seeking to protect their economic interests and it consequently gained a cogent articulation in the *TRIPS Agreement*. For example, the main objectives of the *TRIPS Agreement* stipulate that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology...."<sup>58</sup> This goal is further strengthened in Article 66.2, which provides that incentives must be provided to enterprises to encourage technology transfer

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<sup>55</sup> Penrose, *Economics of the International Patent System*, *supra* note 38 at 17.

<sup>56</sup> See Robert L Ostergard, "Economic Growth and Intellectual Property Rights Protection: A Reassessment of the Conventional Wisdom" in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 115 at 129.

<sup>57</sup> Robert P Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation" (1988) 76 Cal L Rev 803 at 805.

<sup>58</sup> Article 7 of the *TRIPS Agreement*.

to LDCs. Thus far, TRIPS consolidates the expression of protectionism as a necessary condition to promote innovation and to stimulate technology and capital flows to less developed countries.<sup>59</sup> The downside is that the use of patents as the primary juridical mechanism for providing incentives can serve as a drawback in the pursuit of alternative mechanisms to encourage innovation.

Furthermore, the incentive theory attempts to establish a causal relationship between patent incentives, inventiveness and economic progress. In so doing, it posits that adopting a strong IP protection system will ensure that a country's resources are allocated to their most valuable uses and thus promote economic growth and development.<sup>60</sup> However, both scholarly and economic studies of the international patent system conclude that the 'relationship' between strong patents and technology transfer is either weak or non-existent.<sup>61</sup> As Mgbeoji argues, the evidence presented in defence of the alleged connection between strong patents, foreign direct investment and economic growth is anecdotal; in other instances the outcomes of such studies are based on debatable assumptions.<sup>62</sup> Indeed, China's explosive economic growth and technological advancement does not support revisionist's attempts to correlate strong patent protection

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<sup>59</sup> BK Keayla, *TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All* (New Delhi: CSGTSD, 1998) at 259.

<sup>60</sup> See Glynn S Lunney, "Patents and Growth: Empirical Evidence from the States" (2009) 87 NCL Rev 1467 at 1470; Carsten Fink & Carlos A Primo Braga, "How Stronger Protection of Intellectual Property Rights Affects International Trade Flows" in Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005) 19 at 34 [to date there has been no cogent empirical evidence to establish a nexus between high patent standards and economic development].

<sup>61</sup> See generally Keith E Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer" in Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005) 41; Penrose, *Economics of the International Patent System*, *supra* note 38; Fritz Machlup, *An Economic Review of the Patent System* (1958, Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, United States Senate, 85<sup>th</sup> Congress, 2<sup>nd</sup> Session. Study No. 15).

<sup>62</sup> On this point see Mgbeoji, *Global Biopiracy*, *supra* note 27 at 21, citing Robert Sherwood, *Intellectual Property and Economic Development* (Boulder, CO: Westview Press, 1990).

to economic development.<sup>63</sup> The point here is that enhanced patent protection does not necessarily stimulate innovation and technological advancement.<sup>64</sup>

Moreover, there is little question that many inventions are created as a result of competitive market pressures.<sup>65</sup> As Chandra rightly notes, “the patent system stimulates innovation only where industry sees the opportunity for increasing sales and market shares.”<sup>66</sup> It is also difficult to deny that patents-as-incentive theory is more suited to developed countries than less developed countries in SSA. This is because patents do not incentivize the creation of drugs to treat diseases prevalent in poor countries.<sup>67</sup> The incentive argument for pharmaceutical patents in SSA is also not credible because “patent-driven research is primarily supported by profits derived from the lucrative western markets and not by any anticipated profits in impoverished nations.”<sup>68</sup> Further, the grant of patents does not offer any incentive for inventiveness when a country lacks infrastructure necessary to create patent-induced innovation.<sup>69</sup> In support of this conclusion is Oddi’s observation that the ratio of patent-induced inventions to total inventions in less developed countries is minimal.<sup>70</sup> For his part, Sachs points to a global chasm in innovation and technological advance, indicating that there is “a 96-fold higher ratio of patents per capita in the top ten countries than in the rest of the world.”<sup>71</sup> There is limited correlation between the number of registered patents and innovation. For this

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<sup>63</sup> Abbott, “Toward a New Era of Objective Assessment”, *supra* note 20 at 81.

<sup>64</sup> Keith E Maskus, *Reforming US Patent Policy: Getting the Incentives Right* (CSR No. 19, November 2006) at 15.

<sup>65</sup> Oddi, “TRIPS – Natural Rights”, *supra* note 2 at 441.

<sup>66</sup> Rajshree Chandra, *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Rights* (New Delhi: Oxford University Press, 2010) at 193.

<sup>67</sup> Anupam Chander & Madhavi Sunder, “Is Nozick Kicking Rawls’ Ass? Intellectual Property and Social Justice” (2007) 40 UC Davis L Rev 563 at 566.

<sup>68</sup> Cann, “IP Rights and Less Developed Countries”, *supra* note 39 at 796.

<sup>69</sup> Chander & Sunder, “Is Nozick Kicking Rawls’ Ass?”, *supra* note 67. See also Gutterman, “The North-South Debate”, *supra* note 8 at 122.

<sup>70</sup> Oddi, “The International Patent System”, *supra* note 43 at 844.

<sup>71</sup> Jeffrey Sachs, “The Global Innovation Divide” (2003) 3 Innovation Policy & the Economy 131 at 132.

reason, strong patent regimes should not be promoted as the means to secure direct investment in pharmaceuticals to less developed countries.<sup>72</sup>

Also, the patents-as-stimulant for inventiveness argument does not take account of several other factors within the environment in which the inventive activities occur. Factors that contribute to technological innovation include the desire for academic honour, promotion, respect among peers, job security, the presence of biological resources in the global south, and the contribution of the labour force.<sup>73</sup> Without doubt, the providers of the social environment conducive to inventiveness contribute towards innovation.<sup>74</sup> As such, “the recognition that innovation is a social, collaborative phenomenon changes the way that policy-makers, researchers, industry and technology consumers ought to view and appreciate IP: as something to be shared and built upon rather than as something to accumulate for its own sake.”<sup>75</sup>

Again, the presence of a number of serendipitous, but significant, inventions assails the incentive-inducement argument of the patent system. Historical evidence suggests that there was no dearth of inventions before the concept of patent law was introduced in Europe. As shown in chapter 3, Brunelleschi invented his sea-craft before the patent system was first introduced in Florence Italy. Also, the patent system was introduced when Venice was already at the height of its development.<sup>76</sup> Indeed, the delayed adoption of a patent system allowed most developed countries to develop technological bases in

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<sup>72</sup> Abbott, “Toward a New Era of Objective Assessment”, *supra* note 20 at 83.

<sup>73</sup> Mgbefi, *Global Biopiracy*, *supra* note 27 at 21.

<sup>74</sup> Mgbefi, *Global Biopiracy*, *ibid* at 25.

<sup>75</sup> Richard Gold et al, “Toward a New Era of Intellectual Property: From Confrontation to Negotiation” (2008) *A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property*, at 15, online: [http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf).

<sup>76</sup> Ulf Anderfelt, *International Patent Legislation and Developing Countries* (The Hague: Martinus Nijhoff, 1971) at 6.

order to propel industrial advancement. As Hestermeyer presciently notes, “Switzerland and the Netherlands both industrialized without a patent system.”<sup>77</sup>

Another view is that patent rights do not generally vest in the natural person who is supposed to be incentivized. The fact that 90 per cent of all patents are granted to employers, renders the argument of the incentive theory tantamount to “saying that you can spur the donkey on by offering a carrot to its rider.”<sup>78</sup> Mgbeoji notes that recognizing an employer’s property in the invention of the employee contradicts the original purpose of the patent system, which was to provide incentives to individual inventors for their ‘inventive genius.’<sup>79</sup> Also, the patents-propel-inventiveness hypothesis conflates the distinction between inventiveness and commercialization, by virtue of the fact that employers, rather than individual inventors, who are supposed to be motivated, are the primary owners of patent rights.

However, the above criticisms do not suggest that the incentive theory may not serve any useful purpose in encouraging some kinds of inventions. These patent-induced inventions are generally classified as ‘revolutionary inventions.’<sup>80</sup> Today, revolutionary inventions are rare. The bulk of inventions constitute improvements on existing technology. It thus follows that inventive activities (the bulk of which are non-revolutionary) are less dependent on the patent system.<sup>81</sup> A more tenable argument is that the patent system is a useful mechanism to guarantee the investment of risk capital needed to commercialize an invention.<sup>82</sup> This patents-propel-commercialization argument is quite different from

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<sup>77</sup> Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 27.

<sup>78</sup> Bhupinder Chimni, “Hard Patent Regime Completely Unjustifiable” in Subrata Chowdhry et al, eds, *The Right to Development in International Law* (Dordrecht: Martinus Nijhoff, 1992) 315 at 317.

<sup>79</sup> Mgbeoji, *Global Biopiracy*, *supra* note 27 at 24.

<sup>80</sup> Revolutionary inventions are those inventions that produce revolutionary changes in consumption or production. They require considerable developmental investment, and have a significant risk of failure. Today, such inventions are rare, however: Oddi, “TRIPS – Natural Rights”, *supra* note 2 at 442.

<sup>81</sup> Oddi, “TRIPS – Natural Rights”, *ibid* at 443.

<sup>82</sup> Mgbeoji, *Global Biopiracy*, *supra* note 27 at 26.

saying that the patent system is a *sine qua non* (i.e., essential condition) for inventiveness in the scientific world. That notwithstanding, during the Uruguay Round, industry groups and the developed world emphasized the need for increased private wealth as a precondition for IP/trade liberalization. This trend of granting strong patents to pharmaceuticals, based on an economic incentives premise, has also been followed in SSA countries.

### **E. Prospect / Improvement theory**

The prospect theory provides that the patent system and the exclusive rights it entails present an opportunity to develop a known technology in order to increase output from existing technological resources.<sup>83</sup> It posits that patent law assists and prompts other inventors to generate improved versions of the already-patented technology.<sup>84</sup> The prospect theory rejects the traditional view that patent protection should be limited to what has already been invented. Instead, it proposes that patent monopoly should extend to future inventions, which include technologies needed to commercialize the original invention.<sup>85</sup> As Cotropia & Lemley explain, “patent law facilitates the creation of improvements by both communicating the existence and technical details of the base technology and then providing patent protection for any patentable improvements that are developed.”<sup>86</sup>

This theory also argues that *broad* patents should be granted *early* in order to encourage an initial inventor to invest in development without fear that another inventor will steal the work. The prospect rationale supports the need to provide the inventor with the necessary legal security for the work. It also supports the view that the grant of patent

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<sup>83</sup> Edmund W Kitch, “The Nature and Function of the Patent System” (1977) 20 JL & Econ 265 [in propounding the prospect theory, Kitch compares the patent to the mineral claim system of the public lands of the west].

<sup>84</sup> Cotropia & Lemley, “Copying in Patent Law”, *supra* note 45 at 1432.

<sup>85</sup> See Roger L Beck, “The Prospect Theory of the Patent System and Unproductive Competition” (1983) 5 Research in Law and Economics 193 at 194 [Beck, “The Prospect Theory”].

<sup>86</sup> Cotropia & Lemley, “Copying in Patent Law”, *supra* note 45 at 1433.

monopoly in future inventions would limit unproductive competition for the economic rent from future inventions. Like the disclosure theory, the prospect theory assumes that the public can learn about the base technology from either the patent itself or its commercial embodiment. This assumption arises because of the belief that the technical information is publicly available and readily accessible for further R&D.

Inherent in the underlying ethos of the prospect theory are several flaws, however. First, in order to sustain this prospect theory, resources must be allocated and managed in an efficient manner<sup>87</sup> However, in practice, a perfect allocation of intangible property just does not happen, as the property itself is imperfect and inexhaustible. For Gold, the boundaries around knowledge assets are inherently fuzzy, because there is no objective method to identify the edges of knowledge assets.<sup>88</sup> Second, the prospect theory treats property rights in patents as if they are tangible property rights. It is, however, axiomatic that tangible and intangible property rights are not the same. Whereas the consumption of tangible property is rivalrous, the consumption of intangible property is non-rivalrous.

Third, and again, what is disclosed in the patent claim is generally not enough to work the patent. Empirical studies confirm that the disclosure function of the patent system is not working.<sup>89</sup> Even if the disclosure function of the patent system works well, most SSA countries lack the capability to assimilate the state-of-the-art-technology into their industrial base. This lack of adequate scientific infrastructure in SSA makes it difficult to implement the intricacies of the base technology, especially in the field of biotechnology. Thus, a state's level of proficiency in technology is crucial to attaining the goals of this prospect justification for patents.

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<sup>87</sup> Kitch, "The Nature and Function of the Patent System", *supra* note 83 at 266.

<sup>88</sup> E Richard Gold, "Commentary: Mending the Gap – Intellectual Property, Competition Law, and Compulsory Licensing" in Marcel Boyer et al, eds, *Competition Policy and Intellectual Property* (Toronto: Irwin Law, 2009) 396 at 396-397.

<sup>89</sup> Cotropia & Lemley, "Copying in Patent Law", *supra* note 45 at 1465.

Fourth, proponents of the prospect theory fail to appreciate the fact that patent law limits independent invention that may trespass into an existing 'fence' of protection. Patent law, unlike copyright law, does not permit the independent creation of a work similar to an existing work. The requirement of 'anticipation by prior art' ensures that the patent system limits the creation of subsequent similar inventions. Adding insult to injury, contemporary patent systems, at least in the developed world where the bulk of original innovations take place, grant protection to clinical test data spanning between 5 years and 11 years, thereby creating an additional form of monopoly for data needed to obtain marketing approval for generic medicines.<sup>90</sup> In consequence, protecting clinical test data could affect the possibility of making follow-up pharmaceutical inventions and thus renders the ideals of the prospect theory questionable in many SSA settings. Finally, the rationale of the prospect theory in protecting future inventions does not reflect the reality of the regime of patents in SSA and beyond; patent rights are granted to protect actual inventions *prior* to applying for the patent.<sup>91</sup>

#### **F. Race-to-invent theory**

This theory posits that creating inventions at a faster rate benefits society.<sup>92</sup> Accordingly, it argues that society would benefit from granting patents at a faster rate, but with a relatively narrow scope, in order to encourage innovation.<sup>93</sup> In the opinion of Merges & Nelson, since a broad scope of patents increases the likelihood of infringement, patents should be granted with limited scope in order to enable patent offices and the courts to

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<sup>90</sup> US *Drug Price Competition and Patent Term Restoration Act* of 1984, Pub L No. 98-417, 98 Stat. 1585 [granting protection to marketing exclusivity for 5 years extends from the approval of the original drug to the approval of a generic version based on bioequivalence]; Canada Food and Drug Regulations (as amended) 2006 [granting clinical test data protection for 8 years. However, the generic companies are able to submit application for approval drug using such data after 6 years of protection]; Directive 2004/27/EC [granting protection to clinical data exclusivity for 11 years].

<sup>91</sup> Beck, "The Prospect Theory", *supra* note 85 at 195.

<sup>92</sup> Robert Merges & Richard Nelson, "On the Complex Economics of Patent Scope" (1990) 90 Columbia L Rev 839 at 878.

<sup>93</sup> See Mgbеoji, *Global Biopiracy*, *supra* note 27 at 26-27.

exercise discretion in determining questions of patentability and infringement.<sup>94</sup> They argue that limiting the scope of patent protection would place inventors of significant improvements in a strong bargaining position *vis-a-vis* inventors of basic inventions.<sup>95</sup>

In advancing the race-to-invent theory, Merges & Nelson criticize the prospect theory on the grounds that technological developments have regressed in industries where broad patents are granted.<sup>96</sup> They conclude that granting a relatively narrow scope of patent protection would facilitate a race-to-improve upon patented inventions to the end of increasing productivity.<sup>97</sup>

The race-to-invent theory might have been a more explanatory theory in the pre-TRIPS era when states had relative regulatory freedom over matters of domestic patent law. For now, this theory has theoretical importance only. It does not reflect the reality of the globalized patent system. Presently, patent rules have been harmonized across jurisdictions via TRIPS. Also, developed countries are pushing less developed counterparts to assume enhanced obligations, which limit domestic regulatory discretion over pharmaceuticals. In consequence, the limitations imposed by the globalized patent regime call the practical relevance of the race-to-invent theory into question.

Furthermore, the race-to-invent theory does not respond to criticisms that it over-relies on the first-to-file rule of the patent system, which rule is followed in the patent legislation of countries in SSA. The ARIPO instrument also employs the first-to-file rule in granting regional patents in SSA. The downside is that the race-to-invent theory creates incentives for aggressive patenting, by allowing improvidently granted patents to survive in the

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<sup>94</sup> Merges & Nelson, "On the Complex Economics of Patent Scope", *supra* note 92 at 877.

<sup>95</sup> Merges & Nelson, "On the Complex Economics of Patent Scope", *ibid* at 876.

<sup>96</sup> Merges & Nelson, "On the Complex Economics of Patent Scope", *ibid* at 877, 884-908 (analyzing electrical and chemical industries, among others).

<sup>97</sup> Merges & Nelson, "On the Complex Economics of Patent Scope", *ibid* at 876.

market place.<sup>98</sup> Further, the race-to-invent theory may turn into a race-to-file system, by creating patent thickets to ward off genuine inventions. That way, inventors would not consider the negative effect of patents on other competitors and the public.<sup>99</sup>

Critics also suggest that the incentives that the race-to-invent theory is supposed to provide could be achieved through market-induced incentives, such as lead time, and market recognition in racing inventions to the market-place.<sup>100</sup> Again, lacking the base technology and proficient scientific infrastructure would not permit countries in SSA to chalk up any success in the heated-race to invent.

### **G. Rent-dissipation theory**

Proponents of this theory assert that the patent system should aim at minimizing rent dissipation at stages of conception and innovation.<sup>101</sup> As Grady & Alexander put it, “patents prevent rewards from being dissipated by competing imitations, thus preserving the incentive to innovate.”<sup>102</sup> The basis of this hypothesis is that the incentives provided by the patent system may be channeled into redundant investments that would not benefit society. Further, Grady & Alexander posit that, under the rent dissipation theory, natural phenomena are unpatentable – not because they are comparatively worthless – but because a subsequent race among improvers is unlikely.<sup>103</sup> It is significant to note that proponents of this theory identify three potential sources of rent dissipation under the

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<sup>98</sup> Jay P Kesan & Andres A Gallo, “The Political Economy of the Patent System” (2009) NCL Rev 1341 at 1345.

<sup>99</sup> Haracoglou, *Competition Law and Patents*, *supra* note 9 at 111.

<sup>100</sup> A Samuel Oddi, “Un-Unified Economic Theories of Patents – The Not-Quite-Holy Grail” (1996) 71 Notre Dame L Rev 267 at 283 [Oddi, “Un-Unified Economic Theories of Patents”].

<sup>101</sup> See Oddi, “Un-Unified Economic Theories of Patents”, *ibid* at 284.

<sup>102</sup> Mark F Grady & Jay I Alexander, “Patent Law and Rent Dissipation” (1992) 78(1) Va L Rev 305 at 306.

<sup>103</sup> Grady & Alexander, “Patent Law and Rent Dissipation”, *ibid* at 309.

patent system.<sup>104</sup> First, the patent system allows one competitor to take the prize in its entirety upon winning the race to invent. A patent system based on a winner-takes-all structure leaves other potential inventors and competitors with no prize. Second, the quest to build on pioneer inventions may divert attention from basic research and generate unnecessary competition among potential inventors. Thus, competitors may over-invest in improving pioneer inventions. Third, the patent system may encourage excessive investment in protecting inventions via secrecy. Accordingly, in order to avoid this possible rent dissipation, the innovator should receive a 'patent monopoly' for the difference between what society is willing to pay for the invention and the development costs.

The flaws in the rent dissipation theory have also not been lost on commentators. According to Oddi, applying the rent dissipation theory would serve as a disincentive to invest in basic or pioneer research.<sup>105</sup> He also notes that the rent dissipation theory is difficult to apply to actual patent cases. In addition, it is difficult to determine when an invention constitutes an important improvement on existing technology and when it does not.<sup>106</sup> The rent dissipation theory also assumes that the primary purpose of the patent system is to seek rent. I think that the rent dissipation theory is more of a critique of the economic-related theories discussed earlier, rather than being a justification for patents.

In short, none of the theories discussed so far offers a credible justification for patents in SSA.<sup>107</sup> Yet, the natural rights theory in tandem with the incentive theory played a significant role in the development of the globalized patent rules on pharmaceuticals. Both theories are deeply rooted in the western tradition that emphasizes private property

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<sup>104</sup> For a synthesis of the three sources of rent dissipation under the patent system see Oddi, "Un-Unified Economic Theories of Patents" *supra* note 100 at 284; Grady & Alexander, "Patent Law and Rent Dissipation", *ibid* at 308-309.

<sup>105</sup> Oddi, "Un-Unified Economic Theories of Patents", *ibid* at 285.

<sup>106</sup> Oddi, "Un-Unified Economic Theories of Patents", *ibid*.

<sup>107</sup> See Mgbeoji, *Global Biopiracy*, *supra* note 27 at 27.

and its importance to western economic development. The theories do not adequately consider the values, ideologies, and economics of marginalized states in the design of patent regulatory and institutional frameworks in SSA. Yet, as shown in chapter 5, the natural rights theory and the incentive theory are followed in SSA countries, at least through the implementation of TRIPS. Generally, Rawls on his part advocates a public justification that can be accepted even by those who disagree, because it proceeds from shared concepts and norms.<sup>108</sup> The justifications for patents as presently understood fail to measure up to this Rawlsian benchmark of a public justification.

More importantly, the existence of disparities in the technological and scientific capacities of developed and less developed countries affects the ability of the latter economies to experience the supposed benefits of the globalized patent system.<sup>109</sup> Rather, the beneficiaries of the economic-inspired theories that have influenced the globalized patent system are the multilateral corporations in developed countries that create inventions and are heavily engaged in international trade.<sup>110</sup> Oddi surmises that the pharmaceutical and agricultural chemical industries are the chief beneficiaries of globalized patent norms under TRIPS.<sup>111</sup> By implication, developed countries benefit from the globalized patent regime by virtue of the 'trickle down' effect from patent owning enterprises having primary industrial bases within such countries.<sup>112</sup>

The reverse is, however, the case in SSA: countries fare poorly if these western-engineered theories and assumptions are employed to justify the adoption of strong patent systems. The low levels of inventiveness in SSA countries mean that the justifications for patents and their underlying assumptions do not benefit these countries. Also, the

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<sup>108</sup> See John Rawls, *A Theory of Justice*, revised ed (Cambridge, Mass.: Harvard University Press, 1999) at 508.

<sup>109</sup> Olufunmilayo B Arewa, "TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Frameworks" (2006) 10 Marq Intell Prop L Rev 155 at 167-168.

<sup>110</sup> Oddi, "TRIPS – Natural Rights", *supra* note 2 at 455.

<sup>111</sup> Oddi, "TRIPS – Natural Rights", *ibid*.

<sup>112</sup> Oddi, "TRIPS – Natural Rights", *ibid* at 457.

theoretical justifications do not adequately take into consideration the shared values in promoting access to medicines in poor countries. The lack of robust public interest-oriented justifications has thus positioned SSA countries at the receiving end of dysfunctional<sup>113</sup> patent regulatory and institutional frameworks that impede access to medicines to treat epidemics. The next task, then, is to provide a synthesis of the failures or inadequacies in the functioning of the justifications proffered in defence of the globalized patent system. As earlier mentioned, this discussion of the inadequacies inherent in the globalized patent regime applies equally to pharmaceutical patent regulation.

### III. Patent Regulatory Dysfunctions

Without discounting the influence of other factors such as bad governance, corruption, economic mismanagement, poverty, and conflicts,<sup>114</sup> the theories employed to ground the globalized patent regime have contributed to the dysfunctions associated with the prevailing international patent system. The system is dysfunctional because: it fails to take cognizance of the differences in individual states' (in)capacities; it establishes a monopoly that allows the West to reap the bulk of the benefits while people suffer in the south; it is based on an economic ideology of self-interest that obliterates human values and the practices of indigenous communities;<sup>115</sup> it fails to acknowledge the communal nature of ownership interests in resources in less developed countries; and, it also fails to differentiate between essential life-saving medicines and non-essential commodities. The fact that the globalized patent system creates dysfunctions in less developed countries is further illustrated in the discussion below.

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<sup>113</sup> Others call it "social disorganization" or "social dysfunction" in reference to the failures or inadequacies in the functioning of a given social system. See Melissa Smith & Philip Smith, "The Problem of Drug Prohibition for Drug Users: A Mertonian Analysis of Everyday Experience" (2005) *Electronic Journal of Sociology* 1.

<sup>114</sup> For a description of some of the ills of the African continent, see George BN Ayittey, *Africa in Chaos* (New York: St Martin's Press, 1998).

<sup>115</sup> See James Boyd White, "Economics and Law: Two Cultures in Tension" (1986) 54 *Tenn L Rev* 162.

**A. Non Recognition of States' (in)capacities**

The globalized pharmaceutical patent regime fails to recognize that there is a wide chasm between developed and less developed countries in terms of HIV/AIDS, malaria, and TB infection rate and the accessibility/availability of medicines. Similarly, it fails to take cognizance of the differences in states' capacities as well as incapacities when it comes to available knowledge and innovativeness. The varying levels of development among states are due to the differences in goals, values, cultures, histories, political climate, economic and technological capacities of states.<sup>116</sup> Under the WTO system, countries are classified into three broad economic groups: least developed countries, developing countries, and developed countries. Although, WTO law does not define 'developing countries', Article XVIII:1 of the GATT defines such countries as having economies with low standards of living and are in early stages of development. Naturally, LDCs (most of which are in SSA) are in a deeper hole in terms of their citizens' standards of living and their limited capacities to commercialize innovation. Therefore, if a patent system, which is based on developed countries' IP standards is implemented across the board it will hinder economically poor countries in SSA from benefiting.

Other explanations for this dysfunction are not far-fetched: developed and less developed countries have different goals. For his part, Ostergard articulated the differences in the goals of developed and less developed countries as:

Developed countries have attained a level of economic and political development that provides a high standard of living for their people. Their goal, at minimum, is to maintain that level of development. Developing countries have not attained the same level of economic or political development. Their goals reflect the desire to improve the standard of living for their people.”<sup>117</sup>

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<sup>116</sup> Donald P Harris, “Carrying a Joke Too Far: TRIPS and Treaties of Adhesion” (2006) 27 U Pa J Int'l Econ L 681 at 724.

<sup>117</sup> Ostergard, *The Development Dilemma*, *supra* note 18 at 3.

Most countries in SSA fall within the category of least developed states. Also, the HIV/AIDS, malaria, and TB infection rate in this region is much higher than that of the developed world. While some countries in SSA have an HIV/AIDS prevalence rate of about 30 per cent, others in the developed world have a low rate of about 0.1 per cent.<sup>118</sup> Indeed, it is estimated that over 68 million people will die from HIV/AIDS-related causes in the most affected nations by 2020.<sup>119</sup> Therefore, pharmaceutical regulatory policies that are good for the developed world could be the reverse (and most often are) in countries that are hardest hit by the HIV/AIDS, malaria, and TB epidemics.

In the context of the international patent system, the *TRIPS Agreement* obliges WTO members to grant patent rights without discrimination as to place of invention, the field of technology and whether the products are imported or locally produced.<sup>120</sup> It also treats WTO member states as complete equals before the Dispute Settlement Body. Accordingly, SSA countries and those in the developed world compete on the same normative terms and condition within the WTO system. Additionally, both the Most Favoured Nation (MFN) and the national treatment principles insist that WTO members comply with the minimum standards under TRIPS regardless of their level of development.<sup>121</sup> In consequence, the notion of the applicability of a 'one-size-fits-all' patent protection regime across countries/regions calls the practical relevance of the formal suspension of TRIPS' implementation for least developed countries into question. As Yu surmises, "had the level of intellectual property protection been adjusted to reflect the countries' needs, interests, and conditions, those transitional provisions in the TRIPS Agreement might not have been needed."<sup>122</sup> Worse still, technical assistance initiatives

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<sup>118</sup> UNAIDS, *Report on the Global Aids Epidemic* (2008), online: [http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008\\_Global\\_report.asp](http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp).

<sup>119</sup> Cann, "IP Rights and Less Developed Countries", *supra* note 39 at 757.

<sup>120</sup> See Article 27.1 of the *TRIPS Agreement*.

<sup>121</sup> See Articles 3 & 4 of TRIPS.

<sup>122</sup> Peter Yu, "Four Common Misconceptions about Copyright Piracy" (2003) 26 Loy Los Angeles Int'l & Comp L Rev 127 at 135.

have steered many LDCs in SSA to adopt international patent standards in utter disregard of the moratorium under the WTO system.

In addition, the theoretical justifications for patents, such as the natural rights theory and the incentive theory that support increasing patent standards to the disadvantage of the public right to health care are unsustainable in SSA. As primary consumers of technology, granting strong patents could pose obstacles to the realization of the right of access to medicines for the masses in SSA. Consequently, forcing less developed countries to adopt western-style patent protection of medicines, which in turn inhibits access, is unjust and deserves a rethink.

## **B. Pharmaceutical Patent Monopoly**

A patent was originally a grant of privilege.<sup>123</sup> The protection it provided therefore signified societal sacrifices in offering legal protection to an otherwise unprotected private property right. But now, due to the influence of natural law rhetoric, patent protection is considered by proponents as a claimed-right.<sup>124</sup> In treating pharmaceutical patent protection as a claimed-right, the globalized regulatory framework has created a monopoly in the hands of a few persons.<sup>125</sup> By monopoly, I mean a situation in which there is only one or limited supplier(s) of a good that is lacking close substitutes.<sup>126</sup> It also involves allowing the producer to choose either to produce at a larger quantity in order to

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<sup>123</sup> See generally: Penrose, *Economics of the International Patent System*, *supra* note 38 at 2, 12; Peter Drahos, "Death of Patent System – Introduction" in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 1; Susan Sell & C May, "Moments in Law: Contestation and Settlement in the History of Intellectual Property" (2001) 8 *Review of International Political Economy* 467; Sell, *Private Power, Public Law*, *supra* note 13 at 5.

<sup>124</sup> For a discussion of terminologies such as "right", "duty", "privilege", and "power" see Arthur L Corbin, "Legal Analysis and Terminology" in Ray D Henson, ed, *Landmarks of Law* (Boston: Beacon Press, 1960) 196; see also Wesley Newcomb Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, David Campbell & Philip Thomas, eds, (Aldershot, England: Ashgate, 2001).

<sup>125</sup> Stiglitz, "Economic Foundations of IPRs", *supra* note 4 at 1700.

<sup>126</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 77 at 143.

sell at a lower price or to produce a smaller quantity to be sold at a higher price.<sup>127</sup> This point is echoed by Prindle who remarked that “patents are the best and most effective means of controlling competition. They occasionally give absolute command of the market, enabling their owner to name the price without regard to cost of production.”<sup>128</sup>

Heller for his part argues that patents contribute to the reduction in the capacity of the pharmaceutical industry to generate new products.<sup>129</sup> In support of this assertion is a 2006 Report by the US Government Accountability Office which has concluded that the “current patent law discouraged drug companies from developing new drugs by allowing them to make excessive profits through minor changes to existing pharmaceuticals.”<sup>130</sup> Temin has also remarked that the pharmaceutical companies spend huge costs on excessive advertisement to sustain a form of price-fixing cartel and monopolize the market, rather than focusing on real research to produce new medicines.<sup>131</sup> For instance, AstraZeneca is said to have spent a half billion dollars to advertise Nexium alone.<sup>132</sup> In addition, pharmaceutical companies spend millions of dollars on legal fees and other lobbying activities to ward off generic manufacturers and other potential infringers.<sup>133</sup>

A divergent viewpoint presented by Kitch is that the incentive to invent and market technologies will only exist if there are strong patents available to protect innovators in those markets.<sup>134</sup> Therefore, it is in the interest of the less developed world to adopt

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<sup>127</sup> Hestermeyer, *Human Rights and the WTO*, *ibid* at 143.

<sup>128</sup> Edwin J Prindle quoted in David F Noble, *America by Design: Science, Technology, and the Rise of Corporate Capitalism* (New York: Knopf, 1977) at 89.

<sup>129</sup> Michael Heller, *The Gridlock Economy: How too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* (New York: Basic Books, 2008) at 59 [Heller, *The Gridlock Economy*].

<sup>130</sup> US, “New Drug Development, Science, Business, Regulatory, and Intellectual Property Issues cited as Hampering Drug Development Efforts”, *Report of the United States Government Accountability Office*, 2006.

<sup>131</sup> Peter Temin, “Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry” (1979) 10 *Bell J Econ* 429 at 440 [Temin, “Technology, Regulation”].

<sup>132</sup> Marcia Angell, *The Truth About the Drug Companies: How they Deceive us and What to do About it* (New York: Random House, 2004) 78 [Angell, *The Truth about the Drug Companies*].

<sup>133</sup> Heller, *The Gridlock Economy*, *supra* note 129 at 51.

<sup>134</sup> Kitch, “The Patent Policy of Developing Countries”, *supra* note 10 at 171.

strong patent systems to attract foreign technology and consequently develop local capacities. Even if we concede that strong patents protect innovators, both historical and contemporary evidence suggest that strong patent laws are not important instruments in developing indigenous manufacturing capacity in the less developed world, however. It bears emphasizing that countries, such as Switzerland and the Netherlands developed their industrial capacities without recourse to a strong patent system. Indeed, American inventors imported British technology freely between 1790 and 1836 because the former then had a lax patent system. In this regard, the US Congress admits that “when the United States was a relatively young and developing country it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development.”<sup>135</sup> India is another remarkable example of how the absence of a strong patent regime could enable a country to develop a vibrant generic pharmaceutical sector.<sup>136</sup> The point here is that patent exclusivity may slow innovation and create monopoly.

As to why patents slow innovation and create monopoly, Stiglitz explains that,

Knowledge is the most important input into the production of knowledge. Intellectual property restricts this input; indeed, it works by limiting access to knowledge. One way of thinking about this is in terms of any standard production process. If you increase the price of an input, it reduces the supply of the output. In this case, the input is knowledge; patents increase the price of this input, which in turn reduces the output.<sup>137</sup>

This monopoly can be extended by the accumulation of many different patents in the hands of one patentee and by restrictive licensing mechanisms.<sup>138</sup> The patent system is said to threaten a tragedy of the anti-commons.<sup>139</sup>

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<sup>135</sup> US Congress, Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronics and Information* (1987) at 230.

<sup>136</sup> Kevin Outterson, “Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets” (2005) 5 *Yale J Health Pol’y L & Ethics* 193 at 246 [Outterson, “Pharmaceutical Arbitrage”].

<sup>137</sup> Stiglitz, “Economic Foundations of IPRs”, *supra* note 4 at 1710.

<sup>138</sup> Penrose, *Economics of the International Patent System*, *supra* note 38 at 103.

The effect of monopoly is that it stifles innovation and creates rent-seeking behaviour. It “gives all the rewards to a lucky and often-undeserving person who manages, in one way or other, to get the patent and grab the monopoly power.”<sup>140</sup> In fact, pharmaceutical patent monopoly leads to high prices of medicines on the market.<sup>141</sup> This fact is confirmed by the WHO-Health Action International survey which has predicted that essential medicines will be very expensive and not universally available due to the prevailing patent regime.<sup>142</sup> Patent monopoly also impedes access to the ‘necessaries of life’, including medicines without which the citizens of SSA cannot reasonably exist and be productive.<sup>143</sup> Monopolists in the pharmaceutical industry have increased their profits by discouraging innovation by generic rivals and raising the latter’s costs.

The irony is that most SSA countries do not have antitrust (anti-monopoly) legislation to check pharmaceutical patent abuses. For instance, efforts to pass comprehensive competition legislation in Ghana have been strongly resisted by industry groups and lobbyists such as Unilever. Alternatively, a number of SSA countries with anti-trust legislation may face enforcement obstacles. In Kenya and South Africa, for instance, recorded attempts to foster such competition by allowing third parties to produce generic

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<sup>139</sup> Heller, *The Gridlock Economy*, *supra* note 129 at 1-22; Amani, *State Agency and the Patenting of Life*, *supra* note 46 at 59.

<sup>140</sup> Michele Boldrin & David Levine, *Against Intellectual Monopoly* (NY: Cambridge University Press, 2008) at 208.

<sup>141</sup> See: Heller, *The Gridlock Economy*, *supra* note 129; Ostergard, *The Development Dilemma*, *supra* note 18; Sell, *Private Power, Public Law*, *supra* note 13; Boldrin & Levine, *Against Intellectual Monopoly*, *ibid* at 69.

<sup>142</sup> See ZUD Babar et al, “Evaluating Drug Prices, Availability Affordability and Price Components: Implications for Access to Drugs in Malaysia” (2007) 4 PLoS Med 82.

<sup>143</sup> See *Chapple v Cooper* (1844) 13 M & W 252. At p.258, and as far back as 1844, Alderson B provided a traditional test for determining what should qualify as ‘necessaries’ thus: “[t]hings necessary are those things without which an individual cannot reasonably exist. In the first place, food, raiment, lodging and the like. About these there is no doubt....But in all these cases, it must be out that the class itself is one in which the things furnished are essential to the existence and reasonable advantage and comfort....Thus, articles of mere luxury are always excluded, though luxurious articles of utility are in some cases allowed.” See also *Nash v Inman* (1908) 2 KB 1.

versions of patented medicines were pre-empted by ways of voluntary settlements.<sup>144</sup> In another reported case, the South African Competition Tribunal's refusal to sanction a merger between two health care groups in the 'capitated managed care' market was overturned on appeal by the Competition Appeal Court. The Tribunal had reasoned that "the general state of healthcare provisioning in South Africa, the policy objectives of the South African Government in the realm of healthcare provision, the mechanisms whereby government intends achieving those objectives, and the place and role of the private sector" worked against the merger.<sup>145</sup> However, on 31 January 2006, the Competition Appeal Court overturned the ruling of the Competition Tribunal and approved the merger unconditionally.<sup>146</sup> It noted that the Tribunal misdirected itself by adopting a 'cautious and circumspect approach' to the merger and over-relying on public interest considerations before reaching its decision. Further, it noted that the proposed merger would allow other competitors with sound financial and administrative networks to compete. The power politics employed by the pharmaceutical industry pose a significant challenge to the enforcement of competition laws, if any, by institutions in SSA countries. The point is that a lack of a pro-competitive patent environment allows what Drahos & Braithwaite refer to as 'biogopolies'<sup>147</sup> or what Temin calls 'oligopoly' – a price fixing cartel.<sup>148</sup>

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<sup>144</sup> For the Kenyan story see Tenu Avafia et al, "The Ability to Utilize TRIPS Flexibilities in sub-Saharan African Countries" in Ricardo Melendez-Ortiz & Pedro Roffe, eds, *Intellectual Property and Sustainable Development: Development Agendas in a Changing World* (Cheltenham, UK: Edward Elgar, 2009) 175 at 182. For the South African story, see Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) at 52-54.

<sup>145</sup> *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd* (Competition Tribunal, case no: 11/LM/Mar05, 13 October 2005).

<sup>146</sup> *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd v The Competition Commission*, 55/CAC/Sep05. Available at: <<http://www.comptribco.za/assets/Uploads/Case-Documents/Medicross%2055CACSep05.pdf>>.

<sup>147</sup> Drahos & Braithwaite, *Information Feudalism*, *supra* note 2 at c 10 ['Biogopolies' – monopoly that arises from stringent intellectual property protection of biotechnological processes and products].

<sup>148</sup> Temin, "Technology, Regulation", *supra* note 131 at 440.

The aggregation of pharmaceutical patents into a cartel becomes a great enemy to good management.<sup>149</sup> It works to the advantage of a few but not to the general good of society. It causes the markets to be under-stocked and regulated at a level that keeps the prices of medicines very high.<sup>150</sup> This affects the efficiency and innovativeness of the economy in less developed countries.<sup>151</sup> It also lessens consumer choice because of the high costs of brand name medicines. Regulating pharmaceutical markets from the unilateral angle of producers without corresponding consideration for the interests of consumers creates distortions.<sup>152</sup> A monopoly thus makes the public worse-off and creates a false incentive for a few.<sup>153</sup> The converse is that the public would be better-off without monopoly and the patent industry would grow by leaps and bounds. In bestowing a patent monopoly, SSA countries should ensure that they get their money's worth through other regulatory trade-offs, such as the use and enforcement of competition legislation.<sup>154</sup>

### C. Biopiracy

Generally, it is estimated that over 70 per cent of the world's biological resources are located in local and indigenous communities.<sup>155</sup> As knowledge or ideas (including traditional medicine practices) held and used by people who identify themselves as indigenous, traditional knowledge (TK) differs from formal knowledge in the ways it is acquired, stored and transmitted.<sup>156</sup> However, indigenous ideas are not patentable because it is considered that "the public interest is best served if *abstract* ideas circulate freely".<sup>157</sup>

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<sup>149</sup> See Smith, *The Wealth of Nations*, *supra* note 25 at 202-203.

<sup>150</sup> Smith, *The Wealth of Nations*, *ibid* at 87.

<sup>151</sup> Stiglitz, "Economic Foundations of IPRs", *supra* note 4 at 1699.

<sup>152</sup> Smith, *The Wealth of Nations*, *supra* note 25 at 839.

<sup>153</sup> See J Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (Cambridge, MA: Harvard University Press, 1996) at 179.

<sup>154</sup> See Heller, *The Gridlock Economy*, *supra* note 129 at 75.

<sup>155</sup> Chidi Oguamanam, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (Toronto: University of Toronto Press, 2006) at 23.

<sup>156</sup> Paul F Kihwelo, "Indigenous Knowledge: What is it? How and why do we protect it?" (2005) 8 *Journal of World Intellectual Property* 345 at 346 [Kihwelo, "Indigenous Knowledge"].

<sup>157</sup> HC Havighurst "The right to compensation for an idea" in RD Henson, ed, *Landmarks of Law* (Boston: Beacon Press, 1960) 399 at 402 (emphasis added).

It is, however, important to observe that ideas in communities in Africa go beyond abstract ideas. They consist of rich, traditional knowledge, lived and practiced by indigenous communities. They develop as the collective property of society, and are passed on to generations by word of mouth or through community practices. In essence, the individualist conception of patents is not suited to the communal character of indigenous resources.

This difficulty that patent legislation has in adequately addressing issues bordering on traditional knowledge has created what has been described as a “crisis of legitimacy in the intellectual property system.”<sup>158</sup> This crisis affects communities in SSA, as they are rich in indigenous ideas and traditional knowledge. An instance of this crisis in SSA has happened with respect to the hoodia cactus plant known to the Kung Bushmen of South Africa as cure for obesity.<sup>159</sup> The hoodia cactus plant has been patented by a British pharmaceutical firm (i.e., Phytopharm), and this company has, in turn, licensed its patent to Pfizer at the expense of the indigenous people.<sup>160</sup> Again, patents have been granted to the neem tree oil in the US. In Europe, patent protection for the neem tree was granted to a US pharmaceutical corporation until India’s challenge before the European Court caused its reversal.<sup>161</sup> In most countries in Africa, as in India, the neem tree serves as communal medicine for treating various illnesses.

Pharmaceutical patent laws (including TRIPS) do not grant protection to traditional knowledge, because TK is not considered scientifically valid. As a tool of capitalism, the concept of patent law and its underlying justifications are viewed as unsuited for cultural knowledge, because it contradicts the historic status of traditional knowledge as a

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<sup>158</sup> Rosemary J Coombe, “The Recognition of Indigenous Peoples’ and Community Traditional Knowledge in International Law” (2001) 14 St Thomas L Rev 275 at 285.

<sup>159</sup> See Kihwelo, “Indigenous Knowledge”, *supra* note 156 at 347.

<sup>160</sup> See Kihwelo, “Indigenous Knowledge”, *ibid* at 348.

<sup>161</sup> See Stiglitz, “Economic Foundations of IPRs”, *supra* note 4 at 1716, citing Vandana Shiva & Ruth Brand, “The Fight Against Patents on the Neem Tree” in Ernst Ulrich von Weizsäcker et al, eds, *Limits to Privatization: How to Avoid too Much of a Good Thing* (London: Earthscan, 2005).

common heritage held in trust for the public good.<sup>162</sup> Traditional knowledge is considered *terra nullius* (i.e., land belonging to no one), because patent law is based on the western conception of ownership. Indeed, patents are designed to legitimize western biomedicine over traditional medicine and consequently overlook the socio-cultural character of science.<sup>163</sup> This lack of protection for indigenous knowledge in less developed countries provides avenues for industrialized nations to plunder native lore.<sup>164</sup> For Shiva, the failure of the western patent system to protect traditional knowledge promotes biopiracy.<sup>165</sup> Also western appropriation of traditional knowledge (biopiracy) results in the enclosure of the commons.<sup>166</sup> It further squelches domestic firms that have long provided services with those traditional resources.<sup>167</sup>

What is worse is that countries in the South have been coerced to grant protection to rights that are individualistic, contrary to the communal nature of traditional knowledge in those countries. Indeed, individualism is the mantra of neo-liberalization. It is in accord with this spirit that patent protection is granted to natural and artificial persons but not to communities. For Oguamanam, TRIPS' disregard for traditional knowledge leaves it open to unbridled appropriation,<sup>168</sup> and sidelines the traditional custodians of wild habitat.<sup>169</sup> In reality, modern inventors and researchers feed on the common resources of indigenous communities, but fail to acknowledge the traditional owners.

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<sup>162</sup> Stephen Brush & Doreen Stabinsky, *Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights* (Washington, DC: Island Press, 1996) at 3.

<sup>163</sup> Oguamanam, *International Law and Indigenous Knowledge*, *supra* note 155 at 145.

<sup>164</sup> Kihwelo, "Indigenous Knowledge", *supra* note 156 at 348.

<sup>165</sup> See Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (Boston MA: South End Press, 1997).

<sup>166</sup> Vandana Shiva, "TRIPS, Human Rights and the Public Domain" (2004) 7 *Journal of World Intellectual Property* 665 at 667.

<sup>167</sup> Stiglitz, *Globalization and Its Discontents*, *supra* note 12 at 246.

<sup>168</sup> Chidi Oguamanam, "Local Knowledge as Trapped Knowledge: Intellectual Property, Culture, Power and Politics" (2008) 11 *Journal of World Intellectual Property* 29 at 32.

<sup>169</sup> Oguamanam, *International Law and Indigenous Knowledge*, *supra* note 155 at 7.

The commonly trumpeted 'defence' is that traditional knowledge is unreliable because it has not been mentioned in previously published materials.<sup>170</sup> The response is that writing is not, and has never been, a *sine qua non* for measuring the utilitarian value of traditional knowledge. Consequently, the claim for reciprocal reward and acknowledgement by less developed countries (as owners of traditional knowledge) cannot be said to be unwarranted. In essence, (mis-)appropriating traditional knowledge and patenting it after scientific tinkering, without recognizing its true source and factoring in the interest of dispossessed communities is unethical, if not illegal. Further, exclusionary criteria, such as newness, novelty, non-obviousness, inventiveness and industrial applicability, which are used as *sine quibus non* for patent protection to deny any legal status to local knowledge, deserve rethinking.<sup>171</sup> The reason is that these exclusionary criteria are premised on erroneous assumptions about IP and over-generalized notions about local knowledge.<sup>172</sup>

#### **D. Insufficient Disclosure / Utility**

To receive patent protection, the inventor is obliged to disclose sufficient information during the patent application process. In line with this contract theory, the inventor is promised that, upon disclosure, the state will grant exclusive monopoly in the exploitation of the patented invention. This exploitation takes the form of the grant of an exclusive right to make, import, sell or use the patented invention. This exclusive monopoly is granted in the hope that the disclosure will aid future advancement of science and technology. Thus, monopolistic protection is granted so that the public can have access to the information for further R&D of other inventions. Unfortunately, inventors subvert this requirement by making insufficient disclosure. As shown earlier, the disclosure function of the patent system is subverted by the arcane language in which

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<sup>170</sup> Such a 'defence' was raised when India successfully challenged the grant of patent in the US to the turmeric — US Patent No. 5,401,504 (Filed December 28, 1993).

<sup>171</sup> See Oguamanam, *International Law and Indigenous Knowledge*, *supra* note 155 at 41.

<sup>172</sup> Oguamanam, *International Law and Indigenous Knowledge*, *ibid.*

patent claims are couched. In the pharmaceutical industry, the *practice* is to reveal as little and to claim as much protection as possible in order to ward off generic manufacturers and other potential infringers. Worse still, inventors are also granted patent protection for a patentable product which is otherwise not fully developed. And there is evidence of this trend in the global pharmaceutical patent order.<sup>173</sup> Scholars also agree that pharmaceutical patent claims are interpreted to favour pharmaceutical companies.<sup>174</sup>

To sum up, the foregoing discussion shows that the assumptions upon which the globalized patent system is based are not sustainable in both pharmaceutical producing and consuming nations. Countries in SSA as ardent consumers of pharmaceutical products and processes with no corresponding inventive and manufacturing capacities are ill-prepared to swallow the justifications for patents, which are predicated upon western epistemology and knowledge values. Further, scholars predict that there would be very significant outflow of patent rents from South to North based on the globalized patent system under TRIPS.<sup>175</sup> This stands against the backdrop of the fact that there are only 83 scientists and engineers per 1 million people in SSA as compared to China, which has 454 researchers per million people.<sup>176</sup> Worse still, most SSA countries lack mechanisms to collate scientific technical data contained in patent applications (even if such data is disclosed) in order to make it accessible to local researchers. Like the 'myth' in

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<sup>173</sup> See for e.g., *Apotex Inc v Wellcome Foundation*, [2002] 4 SCR 153, 2002 SCC 77.

<sup>174</sup> See Daniel J O'Connor & Tamsen Valoir, "The Supreme Court Tilts toward Drug Developers: Drug Discovery after *Merck v Integra*" (2006) 5 Chicago-Kent J Intell Prop 124.

<sup>175</sup> J Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round*, Study for the Asian Development Bank 2002, at 13–19, 25. Finger notes that for six countries (United States, Germany, Japan, France, United Kingdom and Switzerland) the net increase in patent rents from TRIPS implementation is estimated by the World Bank at \$40 billion per year. Total net payment outflows (including other forms of IP) based on full implementation are estimated at \$60 billion per year, quoted in Abbott, "Toward a New Era of Objective Assessment", *supra* note 20 at 80-81].

<sup>176</sup> See UNCTAD, *Foreign Direct Investment and the Challenge of Development*, in World Investment Report (1999). Others indicate that there are 113 researchers per million populations in SSA: Karen L Durrell & Louise Bernier, "Are Gene Patents Really a Threat?: Vulnerable Populations and Access to Genetics" in E Richard Gold & Bartha Maria Knoppers, eds, *Biotechnology IP & Ethics* (Markham, ON: LexisNexis, 2009) 203 at 230-231.

Enlightenment thinking, the upsurge in patent standards, framed as a viable means for technology transfer, can create and sustain the economic dependency of SSA countries.

Nonetheless, countries in SSA have relied on the mythic justifications, which establish 'assumptions-fit-all' regulatory mechanisms, to ground their patent systems. The assumptions have been repeated over and over again to the extent that they seem to have attained a semblance of credibility, because of the faith that policy-makers (who also live under the 'myth') vest in it.<sup>177</sup> This false sense of optimism among policy makers in SSA is part of the neoliberal ideology of deception that has entrenched itself for years. Indeed, by embracing the promises of economic rhetoric, countries in SSA have reversed, or have been forced to reverse, the pursuit of human needs as the ultimate source of rights.<sup>178</sup> This outcome has led to a "corresponding neglect of the social dimensions of human personhood."<sup>179</sup> Indeed, the 'myth' in the globalized patent system has produced a truncated human reality: millions of persons die from diseases in SSA due to the high cost of medicines engineered by western patents. A more nuanced approach is to move beyond questionable assumptions, by making the globalized patent system sensitive to the social conditions in SSA countries.

#### IV. Overcoming Patent Regulatory Dysfunctions in SSA

Having recounted the dysfunctions associated with the globalized patent system, this part advocates a need to re-conceptualize the justifications for patents to reflect the impact-in-fact of patent rules on societies in SSA. This re-conceptualization requires countries to adopt diverse regulatory strategies to keep their laws attuned to human development in SSA. That way, SSA countries can make medicines available and/or accessible to the

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<sup>177</sup> Desmond Manderson, "As if": The Court of Shakespeare and the Relationships of Law and Literature" (2008) 4 Law, Culture and the Humanities 3 [arguing that it is faith that makes people believe in the law].

<sup>178</sup> On the issue of human need as the ultimate source of rights, see Jeanne M Woods, "Justiciable Social Rights as a Critique of the Liberal Paradigm" (2003) 38 Tex Int'l LJ 763 at 764.

<sup>179</sup> Mary Ann Glendon, *Rights Talk: The Impoverishment of Political Discourse* (New York: Free Press, 1991) at 109, cited in Woods, "Justiciable Social Rights", *ibid*

masses worst affected by HIV/AIDS, malaria, and TB epidemics. Thus, taking account of the impact-in-fact of patent rules on the access to medicine needs of the citizens of SSA countries would address some of the inadequacies or dysfunctions inherent in the globalized patent system and its institutional frameworks.

Therefore, the following sections outline a number of regulatory strategies that can assist SSA countries design patent rules that are tailored to local needs, interests, and goals. In so doing, I rely upon academic commentaries and draw from experiences in countries such as Canada, India, South Africa, and the US to inform the discussion. One important caveat is that such regulatory strategies must be pursued against the backdrop of the minimum standards required by TRIPS. I will detail these minimum standards in chapter 5 of this study. Thus, rather than leave this discussion hanging with a critique of the globalized patent regime, the sections that follow propose the use of diverse mechanisms to scale up access to medicines in SSA. This discussion will serve as a prelude to the more extensive recommendations made in chapters 6, 7 and 8 of this study.

#### **A. Use of Product Differentiation Mechanisms and More**

One strategy to cope with regulatory dysfunctions is that in implementing international patent standards espoused by TRIPS, SSA countries must distinguish/differentiate between patent rights in medicines (i.e., essential goods) and patent rights in non-life-saving technology such as software (i.e., non-essential goods). This is because the relevance of inventions differs among societies depending on their use and socio-economic context. As one commentator notes, when the product is a compact disc, perhaps countries in SSA can bear with the deprivation. But, when the product is a life-saving medicine, dead-weight losses quickly translate into dead patients.<sup>180</sup> More concretely, medicines should not be considered as being like other merchandise,

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<sup>180</sup> See Kevin Outterson, "Pharmaceutical Innovation: Law and the Public's Health" (2009) 37 J L Med & Ethics 173.

otherwise health will always be subject to the market, with remedies and treatments available only to those with enough purchasing power.<sup>181</sup> Indeed, the importance of patent rights in medicines to countries endemic for HIV/AIDS, malaria, and TB far outweighs patent rights even in defence-related products and processes.

Consequently, a distinction between essential life-saving medicines and non-essential commodities is crucial to making the theoretical justifications useful in the context of SSA. In South Africa, for instance, section 1 of the Competition Act 89 of 1998 defines *essential facility* as an “infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide *goods or services* to their customers.” Such facilities are considered as necessities of life. In Ghana, necessities are statutorily defined as “goods suitable to the condition in life of the person to whom they are delivered and to his actual requirements at the time of the delivery.”<sup>182</sup> Similar definitions in regard to commercial transactions are found in the commercial statutes of many SSA countries and should thus inform domestic patent law making that affects access to medicine issues. Another guide is the WHO definition of essential medicines, as including drugs that satisfy the priority health care needs of the majority of the population.<sup>183</sup> Presently, antiretroviral and anti-malaria medicines are sorely needed for human survival in SSA. The HIV/AIDS pandemic has reached such proportions in SSA that, without access to antiretroviral medicines, it is impossible to ensure any meaningful human survival. Also affordable medicines are needed to treat malaria and TB-related cases that are rampant in SSA. It is therefore essential that life-saving medicines for treating HIV/AIDS, malaria, and TB epidemics are included as part of the necessities of life. Such a move would also force drugs manufacturers to reduce prices for fear of compulsory licensing by governments in SSA

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<sup>181</sup> Germán Velásquez, “Trade Agreements, Intellectual Property and Access to Medicines: An Introduction” in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 1 at 4, online: <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)>.

<sup>182</sup> Section 2(3) of Ghana’s *Sale of Goods Act*, 1962 (Act 137).

<sup>183</sup> See WHO, *The World Medicines Situation* (Geneva: WHO, 2004).

Indeed, the consensus among scholars is that the use of product differentiation to preserve public health is permitted under Article 27.1 of the *TRIPS Agreement*.<sup>184</sup> According to Hestermeyer, (permissible) differential treatment in the field of pharmaceuticals, as against (impermissible) discrimination, provides more latitude when legislating to preserve public health than in other fields.<sup>185</sup> The WTO Appellate Body has also made it clear that “the pejorative concept of ‘discrimination’ must be distinguished from differentiation for legitimate reasons.”<sup>186</sup> For her part, Amani argues that domestic regulatory diversity should be encouraged so long as the “policies or practices do not violate the national treatment principle and are not forms of disguised or unjustifiable discrimination offensive to trade.”<sup>187</sup>

However, in promoting such regulatory diversity, countries must set objective standards guided by factors including: first, the prevalent rate of the epidemic; second, control of essential medicines/facilities by a monopolist; third, the public’s inability to have access to life-saving medicines; fourth, the non-discriminatory nature of the policy; fifth, the inability to produce generics, in which case compulsory licensing and parallel imports (under the doctrine of international exhaustion) become handy.<sup>188</sup> By taking account of these factors in the design of patents and access to medicine policies, countries can channel their resources into promoting the core values of access and use and thus promote public health. This prescription is also necessary to prevent the abuse of pharmaceutical patent rights and to promote the public interest rationale of TRIPS.<sup>189</sup>

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<sup>184</sup> Graeme B Dinwoodie & Rochelle C Dreyfuss, “Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement” (2007) 13 Mich Telecomm Tech L Rev 445.

<sup>185</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 77 at 60.

<sup>186</sup> Abbott, “Toward a New Era of Objective Assessment”, *supra* note 20 at 85, citing *Canada – Patent Protection of pharmaceutical Products* WT/DS114/R (17 March 2000).

<sup>187</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 46 at 262.

<sup>188</sup> See generally Christopher M Seelen, “The Essential Facilities Doctrine: What Does it Mean to be Essential?” (1997) 80 Marq L Rev 1117.

<sup>189</sup> See Article 8 of the *TRIPS Agreement*.

Additionally, the use of 'special and differential treatment' to promote access to medicines for all, especially in less developed countries, is an integral part of the goals of the WTO system.<sup>190</sup> For the same reasons, serious consideration should be given to suggestions to adopt differential pricing mechanisms to promote access to life-saving medicines in poor countries. According to Boldrin & Levine, the use of effective price discrimination would enable the large pharmaceutical companies to charge a low price to Africans without lowering the price they charge rich westerners.<sup>191</sup> This would require putting safeguards in place to avoid re-exportation of such medicines into places where they are not intended for consumption. Indeed, the use of such branding safeguards is supported by the WTO General Council's 'August 30' Decision to promote access to generic medicines in less developed countries.

Furthermore, countries should explore alternative affordability-enhancing mechanisms including the setting up of an effective prize-system, research guaranteed fund, insurance schemes, and the use of public-private financing mechanisms to de-link R&D costs from drug-pricing.<sup>192</sup> The success of such initiatives would, however, depend on the establishment of an institutional framework that can foster private/public collaboration. Additionally, in support of this proposal are calls for countries to adopt comprehensive health insurance schemes, and to increase the budget allocations to health care beyond the reported \$8 per person per annum in countries such as Ghana, Nigeria and Tanzania.<sup>193</sup> This, it is argued, can promote a burden-benefit sharing approach to patent regulation of medicines, rather than over-reliance on a patent regime that is based on a winner-takes-all

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<sup>190</sup> See Para 44 of the WTO Ministerial Declaration; Article 66 of the TRIPS Agreement on transitional period for LDCs. Patent obligations on pharmaceutical products have been extended to 2016 by the TRIPS General Council.

<sup>191</sup> Boldrin & Levine, *Against Intellectual Monopoly*, *supra* note 140 at 70.

<sup>192</sup> See Stiglitz, "Economic Foundations of IPRs", *supra* note 4 at 1720-1723.

<sup>193</sup> Cann, "IP Rights and Less Developed Countries", *supra* note 39 at 803. Indeed, the average annual per capita health expenditure in SSA is \$6 as compared to over \$2000 in OECD countries: see Chidi Oguamanam, "Patents and Pharmaceutical R&D: Consolidating Private–Public Partnership Approach to Global Public Health Crises" (2010) 13 *Journal of World Intellectual Property* 556 at 561, citing 2008 OECD report.

reward structure.<sup>194</sup> This prescription can address the present situation in which many pharmaceuticals are priced and sold beyond the means of the people in SSA.

## **B. Compulsory Licenses for Domestic Production**

The grant of compulsory licenses for purposes of local production of medicines is another proven mechanism to contain the high cost of medicines. Such a license is compulsory because it is forced upon the patent right holder. It involves licensing the use of a patented invention to a third party or a government agency without the consent of the patent holder by paying adequate compensation to the owner.<sup>195</sup> As Gold & Lam put it, the use of such non-commercial license on grounds of public health may offer countries a “mechanism to proactively address the impact of patent rights on their health care systems.”<sup>196</sup> The use of compulsory licenses is permitted under the WTO system. Specifically, paragraph 5 of the Doha Declaration emboldens domestic governments to determine the grounds upon which such licenses are granted to tackle health related emergencies. States are also not required to consult patent right holders before issuing compulsory licenses to address public health concerns.<sup>197</sup> This waiver of prior consultation is aimed at avoiding inordinate delays in the issuance of compulsory licenses in cases of national emergency.

Indeed, research has shown that sovereign threats of compulsory licensing have proven efficient in forcing pharmaceutical companies to reduce prices. As Outtersson points out, “Brazil’s threat to issue a compulsory license, coupled with its non-recognition of pharmaceutical patents prior to the adoption of TRIPS, permitted the distribution of free ARVs within Brazil.”<sup>198</sup> The US also resorted to the threat of compulsory licensing to

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<sup>194</sup> Stiglitz, “Economic Foundations of IPRs”, *supra* note 4 at 1720-.

<sup>195</sup> See Article 31 of the *TRIPS Agreement*.

<sup>196</sup> E Richard Gold & Danial K Lam, “Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing” (2003) 6 *Journal of World Intellectual Property* 5 at 30.

<sup>197</sup> See Article 31(b) of the *TRIPS Agreement*.

<sup>198</sup> Outtersson, “Pharmaceutical Arbitrage”, *supra* note 136 at 225.

scale up access to ciprofloxacin during the 2001 anthrax scare. In addition, Kenya's decision to allow Cosmos Pharmaceuticals to manufacture generic drugs for the East African market forced GlaxoSmithKline to reduce its prices for AZT, 3TC and combivar.<sup>199</sup>

As a price leveraging instrument, countries in SSA must create national frameworks to facilitate the use of compulsory licensing for the manufacture of antiretroviral medicines.<sup>200</sup> This may require changes in domestic patent regulatory frameworks which restrict the possibility of granting sub-licenses to third parties. For instance, between 1969 and 1992, Canada issued 613 compulsory licenses as part of its measures to reduce the cost of medicines.<sup>201</sup> Through this, price competition for medicines was promoted; it also helped to develop the capacity of the local generic pharmaceutical industry.<sup>202</sup>

A contrary viewpoint presented by one commentator associated with the pharmaceutical industry is that compulsory licensing by countries such as Zimbabwe, Mozambique and Zambia proved counter-productive; rather compulsory licensing "seriously damage[s] the relationships between governments and producers of innovative drugs necessary to address public health needs"<sup>203</sup> This claim by Noehrenberg is however not supported by evidence in parts of SSA. The lapses in the use of compulsory licenses in Zimbabwe, Mozambique and Zambia were due to their lack of production capacities. Indeed, the oft-cited South African experience under the *Medicines and Related Substances Control (Amendment) Act*, 1997 disproves this industry rhetoric; the reason for the success story in South Africa was because it has such manufacturing capacity. Outside the use of

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<sup>199</sup> See Avafia et al, "The Ability to Utilize TRIPS Flexibilities", *supra* note 144 175 at 182.

<sup>200</sup> See WHO, "Public Health, Innovation and Intellectual Property Rights" *Report of the Commission on Intellectual Property Rights, Innovation and Health of the World Health Organization* (2006) at 139.

<sup>201</sup> See Hoen, *The Global Politics*, *supra* note 144 at ix.

<sup>202</sup> Hoen, *The Global Politics*, *ibid* at 41.

<sup>203</sup> Eric Noehrenberg, "The Realities of TRIPS, Patents and Access to Medicines in Developing Countries" in Meir Perez Pugatch, ed, *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (MA: Edward Elgar, 2006) 170 at 182. It bears noting that Noehrenberg is a Director at the International Federation of Pharmaceutical Manufacturers & Associations.

compulsory licenses for domestic production, countries that lack the capacity to manufacture generic medicines should explore the option of parallel importation of generics as a means for sourcing lower-priced medicines from abroad.

### C. Parallel Imports

Parallel importation by countries which do not have domestic capacity to manufacture essential medicines is another mechanism available for sourcing lower-priced medicines from abroad. Parallel imports involve cross-border trade in patented products without the permission of the patent holder. It allows countries that do not have the manufacturing capacity to purchase medicines from other countries after comparing prices in different markets.<sup>204</sup> This power of governments to import relatively cheaper medicines from other markets tends to force domestic distributors to reduce prices of medicines and also increase competition.<sup>205</sup>

In the lexicon of IP law, this approach of importing lower-priced medicines from abroad falls under the doctrine of exhaustion.<sup>206</sup> This doctrine provides that the first sale of a patented drug exhausts the public law rights of the patent holder for that item.<sup>207</sup> This exhaustion rule can operate at the domestic level or at the international level. By international exhaustion, the first global sale is considered to exhaust the owner's right to control the said product because the right holder is presumed to have received an adequate reward from that first sale.<sup>208</sup> Worth emphasizing is that international exhaustion provides more latitude for the resale of patented drugs without the permission of the right holder. As Outtersson opines, a liberal approach to international exhaustion

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<sup>204</sup> Richard D Smith et al, "Trade, TRIPS, and Pharmaceuticals" (2009) 373 *Lancet* 684 at 686.

<sup>205</sup> J Kuanpoth, "Patents and Access to Antiretroviral Medicines in Vietnam after the World Trade Accession" (2007) 10 *Journal of World Intellectual Property* 201 at 204.

<sup>206</sup> See Article 6 of the *TRIPS Agreement*.

<sup>207</sup> See Outtersson, "Pharmaceutical Arbitrage", *supra* note 136 at 209.

<sup>208</sup> Cynthia M Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (New York: Oxford University Press, 2011) at 40.

would remove patent law barriers to cross-border trade in patented and generic medicines.<sup>209</sup>

In addition, Correa identifies two other grounds upon which generic medicines manufactured and sold elsewhere can be imported into a country. These include: (1) import of generic medicines in situations where there is no existing patents, and (2) parallel import of medicines put on the market with authorisation of the patent holder.<sup>210</sup> Also, with the WTO Council's 'August 30' Decision, exploring the possibilities of parallel imports of generic medicines has become a truly viable alternative for states to consider. This can be done without any challenge by pharmaceutical patent holders.<sup>211</sup>

Indeed, countries in SSA have a lesson to learn from India. India for instance has embodied the 'August 30' Decision in its legislative framework as follows:

Compulsory licensing shall be available for manufacture of and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licensing has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.<sup>212</sup>

This provision opens the door for countries in SSA to work together with India to procure medicines at affordable cost. All that is required of countries in SSA is that they should have 'by notification or otherwise [have been] allowed importation of patented pharmaceutical products from India.' The onus therefore rests on countries in SSA to take steps to notify the TRIPS Council of their intention to make use of the 'August 30' Decision.

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<sup>209</sup> Outtersson, "Pharmaceutical Arbitrage", *supra* note 136 at 209-210.

<sup>210</sup> Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva: South Centre, 2000) at 100-102.

<sup>211</sup> See paragraph 5(d) of the Doha Declaration.

<sup>212</sup> Section 92(A) of the Indian *Patent (Amendment) Act*, 2005.

Others also suggest that since TRIPS is silent on price control mechanisms, states can use legitimate tax measures against pharmaceutical patent holders in order to take account of the needs of the public.<sup>213</sup> In addition, suggestions have been made to implement blanket royalty schemes, as used in copyright, to promote access to essential life-saving medicines in domestic jurisdictions.<sup>214</sup> This can be done through governmental negotiations with private right holders to scale up access to essential medicines, against the payment of royalties to right holders. In this case, the approaches being adopted in copyright administration could be a guide.<sup>215</sup>

#### **D. Use of Ordre Public & Other Exceptions**

The moral utility requirement in patent legislation provides a promising avenue to exclude inventions that are “injurious to the wellbeing, good policy, or good morals of society.”<sup>216</sup> Equally, public health emergency defences permit pharmaceutical patent rules to be relaxed in order to scale up access to medicines to treat widespread epidemics in parts of Africa.<sup>217</sup> History tells us that the use of such necessity-based approaches to restricting patent grants was employed by the developed world to improve their technological capacity and achieve economic development. The oft-cited instance of the use of public health emergencies defence involved the 2001 anthrax scare in the US. Here the only antibiotic (i.e., Bayer’s ciprofloxacin) approved for treating possible anthrax outbreak was in short supply. This artificial shortage, coupled with the high price charged by the patent holder Bayer, prompted the Canadian and the US governments to license

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<sup>213</sup> Cann, “IP Rights and Less Developed Countries”, *supra* note 39 at 833.

<sup>214</sup> Heller, *The Gridlock Economy*, *supra* note 129 at 72.

<sup>215</sup> This suggestion to introduce approaches in copyright administration into patents administration would require a legal framework in place to support it.

<sup>216</sup> See *Tol-O-Matic, Inc v Proma Produkt-Und Marketing GmbH* 945 f. 2d 1546, at 1552-3 (Fed Cir, 1991).

<sup>217</sup> See Michael A Carrier, “Cabining Intellectual Property through a Property Paradigm” (2004) 54 Duke LJ 1 at 123 [Carrier, “Cabining IP through a Property Paradigm”].

generic manufacturers to produce the drugs.<sup>218</sup> This initiative caused Bayer to agree to concessions in pricing its *Cipro* medication, and the US still maintained an option to purchase more from generic companies abroad.

As far back as 2001, African heads of state proclaimed that the HIV/AIDS pandemic has become a state of emergency in the whole continent. Indeed, given the scale of the HIV/AIDS pandemic (i.e., nearing 30 per cent and more) in places such as Swaziland, Botswana, Zimbabwe, and South Africa, there is no doubt that the disease has reached a critical threshold. The point is that when the vitality of a state is threatened by epidemics, general international law supports non-adherence to strict pharmaceutical patent rules. Further, Article 27.2 of TRIPS allows WTO Member states to bar the exploitation of an invention which offends the notion of *ordre public* or morality. It must be borne in mind that the WTO panel and the Appellate Body would be unlikely to challenge a member's determination of its public interest or a sector of vital public importance.<sup>219</sup> In this light, epidemics such as HIV/AIDS, malaria, and TB should be invoked as *ordre public* justifications to regulate pharmaceutical patent rules that restrict access to life-saving medicines in SSA. This limitation must, however, be invoked to scale up access to medicines on a non-profit and on a non-commercial basis.

On top of that, patent examiners should be trained to interpret patentability requirements strictly before granting pharmaceutical patents.<sup>220</sup> India for instance has raised the criteria for patentability so as to prevent 'evergreen patents' from being registered.<sup>221</sup> In the Indian situation, applicants are made to establish to a high degree of certainty that the medicine for which application for patent has been made is *more effective than* what is

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<sup>218</sup> For the various accounts of the anthrax story see: Hestermeyer, *Human Rights and the WTO*, *supra* note 77 at 15-17; Carrier, "Cabining IP through a Property Paradigm", *ibid* at 124-125.

<sup>219</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3<sup>rd</sup> ed (London: Sweet & Maxwell, 2008) at 210 [Gervais, *The TRIPS Agreement*].

<sup>220</sup> Heller, *The Gridlock Economy*, *supra* note 129 at 76.

<sup>221</sup> See section 3(d) of the Indian *Patent (Amendment) Act*, 2005.

already being used for the same condition.<sup>222</sup> This will make it harder for inventors to receive pharmaceutical patents for 'me-too' medicines — drugs which extend patent duration without significant improvement in efficacy.<sup>223</sup>

This approach of recognizing the impact-in-fact of patent rules also entails limiting the scope of protectable subject matter under patent systems in countries in SSA. This restriction must take cognizance of the socio-cultural needs of countries in SSA. As Chon writes, a functioning IP system must be culturally and contextually-sensitive as well as subject-matter-sensitive.<sup>224</sup> For instance, if Canada upholds patent protection for the genes and the modified cells that make up canola seeds (as it did in the case of *Monsanto Canada Inc. v Schmeiser*<sup>225</sup>) countries in Africa, the vast number of whose people are subsistence farmers, need not chart that course. Also, if the US grants patent protection to basmati rice (as it has done),<sup>226</sup> patenting plant varieties should be resisted by less developed countries whose populations are largely subsistence rice farmers. Additionally, patent protection should not be granted to medicines whose utility has not been established beyond doubt at the time of the application, contrary to the reasoning of the Supreme Court of Canada that such protection should be granted "even before their utility has been fully verified by tests."<sup>227</sup>

### **E. Avoiding TRIPS-plus Demands**

This section urges the point that adopting TRIPS-plus obligations in the protection of pharmaceutical products and processes could impede access to medicines in SSA,

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<sup>222</sup> See Angell, *The Truth about the Drug Companies*, *supra* note 132 at 75.

<sup>223</sup> Angell, *The Truth about the Drug Companies*, *ibid.*

<sup>224</sup> Margaret Chon, "Intellectual Property and the Development Divide" (2006) 27 *Cardozo L Rev* 2821 at 2910.

<sup>225</sup> 2004 SCC 34; [2004] 1 SCR 902.

<sup>226</sup> Stiglitz, "Economic Foundations of IPRs", *supra* note 4 at 1704. For a detailed exposition on the patenting of basmati rice, see: Harsh V Chandola, "Basmati Rice: Geographical Indication or Mis-Indication" (2006) 9 *Journal of World Intellectual Property* 166.

<sup>227</sup> See *Apotex Inc v Wellcome Foundation Ltd*, [2002] 4 SCR 153, 2002 SCC 77.

especially in LDCs. Although LDCs are not obliged to grant or enforce pharmaceutical patents until 2016, the trend is that they go to extra lengths to assume stricter obligations than the minimum standards required by TRIPS, a phenomenon commonly known as TRIPS-plus. These countries are sometimes deceived into accepting that higher protection will better serve their interests in receiving increased investments and other support from developed countries.<sup>228</sup> But as they stand, TRIPS-plus standards have largely failed to fulfil technology transfer promises. Also, such high levels of protection for pharmaceutical patents in particular prevent access to essential medicines in LDCs.<sup>229</sup>

Recent trends from the US and the EU provide disturbing signals; trade agreements being negotiated with countries of the Southern African Customs Union (SACU) show a push for TRIPS-plus conditions.<sup>230</sup> SACU's insistence that issues of concern to the US, such as IP rights, should be negotiated and adopted in a follow-up agreement has hampered the progress of negotiations as regards this regional agreement. Also, the European Partnership Agreements (EPAs) with African, Caribbean and Pacific (ACP) countries [the Cotonou Agreement] impose new TRIPS-plus obligations that could have negative effects on access to medicine issues.<sup>231</sup> The discussion in chapter 3 showed that these proposed agreements: limit the grounds and conditions for compulsory licences, provide

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<sup>228</sup> See Smith et al, "Trade, TRIPS, and Pharmaceuticals", *supra* note 204 at 688.

<sup>229</sup> See Hoen, *The Global Politics*, *supra* note 194 at xvii; Karin Timmermans, "Intertwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals" (2005) 8 *Journal of World Intellectual Property* 67 at 70; Smith et al, "Trade, TRIPS, and Pharmaceuticals", *ibid*.

<sup>230</sup> Hoen, *The Global Politics*, *supra* note 144 at 71.

<sup>231</sup> See for e.g. Article 46 of the *Revised Cotonou Agreement*, online: <[http://eCeuropAeu/development/icenter/repository/second\\_revision\\_cotonou\\_agreement\\_20100311.pdf](http://eCeuropAeu/development/icenter/repository/second_revision_cotonou_agreement_20100311.pdf)>; FM Abbott & JH Reichman, "Access to Essential Medicines: Lessons learned since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union" (2007) *Report to the Directorate-General/External Policies for the European Union*, cited in Hoen, *The Global Politics*, *ibid* at 75-76.

avenues for extending patent terms, delay marketing authorization for generics, and push for clinical test data protection.<sup>232</sup>

In particular, the EU TRIPS-plus demands include: (1) the acceptance of European IP treaties which will lead to more extensive protection of medicines in ACP countries, and (2) the implementation of EU IP Enforcement Directives, which permit seizure of medicines.<sup>233</sup> The rules effectively compel domestic regulatory institutions in SSA to act as 'patent police', so as to enforce frivolous patents.<sup>234</sup> They require national drug regulatory authorities, most of which have limited expertise in patents, to consider the patent status of medicines before granting market authorizations to generic manufacturers.<sup>235</sup> TRIPS-plus obligations in the EPAs thus sustain a dominant market position for pharmaceutical originator companies, and create substantial obstacles to the introduction of generic medicines.<sup>236</sup>

Furthermore, the US Free Trade Agreements (FTAs) with less developed countries have also produced similar affects. For example, empirical research into the impact of the 2001 Jordan-US FTA show that its TRIPS-plus rules impede the ability of the poor to have access to generic medicines.<sup>237</sup> Further, subsequent US FTAs with Morocco, Bahrain, Oman, Chile, and Singapore contain TRIPS-plus provisions that delay the introduction of generic medicines and increase the terms of patent protection in the latter countries.<sup>238</sup>

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<sup>232</sup> See UNAIDS, "Using TRIPS Flexibilities to Improve Access to HIV Treatment" in *AIDS at 30: Nations at the Crossroads* (2011) at 8 <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

<sup>233</sup> See the *Revised Cotonou Agreement*, *supra* note 231; Abbott & Reichman, "Access to Essential Medicines", *supra* note 231.

<sup>234</sup> Timmermans, "Intertwining Regimes", *supra* note 229 at 72.

<sup>235</sup> UNAIDS, "Using TRIPS Flexibilities to Improve Access to HIV Treatment" in *AIDS at 30: Nations at the Crossroads* (2011) at 8 <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

<sup>236</sup> See Abbott & Reichman, "Access to Essential Medicines", *supra* note 231.

<sup>237</sup> Hamed El-Said & Mohammed El-Said, "TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from the Jordan-United States Free Trade Agreement" (2007) 10 *Journal of World Intellectual Property* 438.

<sup>238</sup> El-Said & El-Said, "TRIPS-Plus Implications for Access to Medicines", *ibid* at 451.

The point here is that US FTAs with developing countries have pushed the frontiers of international patent law towards enhanced patent standards.

The stringent nature of TRIPS-plus obligations is not the only issue of concern; they also asphyxiate the existing fragile 'flexibilities' under TRIPS and the Doha Declaration.<sup>239</sup> For Morin, the imposition of TRIPS-plus obligations via bilateral free trade agreements represents the frontline of impeding access to affordable medicines in developing countries.<sup>240</sup> In the view of Waxman, a member of the US Congress, the imposition of TRIPS-plus obligations on developing countries via bilateral trade agreements is "irresponsible and even unethical."<sup>241</sup> Generally, countries enter into these TRIPS-plus bilateral arrangements with the aim of enhancing access to the markets of developed economies for their products. Also, countries sign on to such TRIPS-plus agreements as a result of economic pressure from developed countries.

Nonetheless, with the benefit of hindsight and experience from other FTAs, SSA countries should negotiate to exclude such TRIPS-plus obligations which tend to affect public health programs. Moreover, since the majority of countries in SSA are least developed, they should avoid rigid compliance with TRIPS, not to mention TRIPS-plus obligations. This could be done if domestic policy-makers in SSA understand their international patent obligations, an issue that could be addressed through capacity building initiatives. However, the success of such capacity building initiatives will depend on the participation of domestic civil society organizations and the affected communities in SSA. The participation of civil society and communities affected by IP systems, including public interest NGOs and academics with the knowledge and expertise

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<sup>239</sup> Gaëlle P Krikorian & Dorota M Szymkowiak, "Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine" (2007) 10 *Journal of World Intellectual Property* 388 at 395.

<sup>240</sup> See Jean-Frederic Morin, "Tripping up TRIPS Debates: IP and Health in Bilateral Agreements" (2006) 1 *International Journal of Intellectual Property Management* 37.

<sup>241</sup> See HA Waxman, *Statement for the Records*, US Congress, House Committee on Ways and Means, Washington D.C. (10 June 2003).

to draw attention to TRIPS flexibilities, will prevent proponents of strong patent rules from always having their way.<sup>242</sup>

#### **F. Disclosure of use of Bio-Resources / Regional Collaborations**

In dealing with biopiracy, SSA countries should adopt mechanisms to halt the appropriation, if not theft, of traditional medicines by giant corporations under the guise of invention. Boyle refers to the practice of privatizing something that was in the public domain as 'enclosing the commons'.<sup>243</sup> As earlier indicated, this enclosure happened with respect to the hoodia cactus plant known to the Kung Bushmen of South Africa as a cure for obesity.<sup>244</sup> It also happened to neem tree oil (*Azadirachta indica*) in the US. In most SSA countries, the neem tree serves as communal medicine for treating various illnesses. Granting patent protection to the neem tree so that, in subsequent years, people in the less developed world buy neem-medication from the developed world defies any sense of fairness.

It is for this reason that Oddi suggests that non-western countries should insist on complete disclosure of the source of the invention, especially those embodying bio-resources, in order to facilitate the manufacture and use of the invention in less developed countries.<sup>245</sup> Recently, ARIPO members have concluded a Protocol<sup>246</sup> to insist on complete disclosure of the source of the invention, especially those embodying bio-resources, in order to facilitate the manufacture and use of inventions in SSA. Similarly, South Africa's patent law insists that all patent applications should be accompanied by a

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<sup>242</sup> Duncan Matthews & Viviana Munoz-Tellez, "Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective" (2006) 9 *Journal of World Intellectual Property* 629 at 638.

<sup>243</sup> James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain" (2003) 66 *Law & Contemp Probs* 33 at 39.

<sup>244</sup> See Kihwelo, "Indigenous Knowledge", *supra* note 156 at 347.

<sup>245</sup> Oddi, "TRIPS – Natural Rights", *supra* note 2 at 463.

<sup>246</sup> See the *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore*, 2010.

statement disclosing whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.<sup>247</sup> Complying with the obligation to disclose the use of traditional knowledge should form the basis for states and communities to negotiate effective benefit sharing and use agreements, and to institute appropriate mechanisms for enforcement.<sup>248</sup> This requirement for complete disclosure should facilitate the working of the invention in order for SSA countries to benefit from the global trading system. This would, however, require SSA countries to harness economies of scale for purposes of building local innovative capacity, by working through regional groups such as the Economic Community of West African States (ECOWAS), Southern African Development Community (SADC), and the East African Community (EAC).

Already, such regional cooperation for drug-production facilities is gaining momentum in southern Africa with the conclusion of the SADC Pharmaceutical Business Plan. This Plan seeks to help member states explore the possibility of the joint procurement and production of essential medicines in the SADC region.<sup>249</sup> Plans are also far advanced to establish a regional Bioequivalence Centre for research, evaluation and administration of food and medicines in the EAC.<sup>250</sup> Without doubt, increased collaboration offers a promising avenue for maximizing TRIPS flexibilities in order to promote public health in SSA.<sup>251</sup> Aside from these initiatives, suggestions have been made for TRIPS to be reviewed to prohibit the granting of patents to inventions made with foreign genetic materials that are inconsistent with Article 15 of the *Convention on Biological Diversity*

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<sup>247</sup> See South Africa's *Patents Amendment Act No. 20* of 2005.

<sup>248</sup> See Jacques de Werra, "Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?" (2009) 42 *Vand J Transnat'l L* 143.

<sup>249</sup> See Brenda Pamela Mey, "Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: A Dead-End Journey for Patients? Kenya and India Case Studies" (2010) 13 *Journal of World Intellectual Property* 403 at 453 [Mey, "Unfettered Consumer Access to Affordable Therapies"].

<sup>250</sup> See Mey, "Unfettered Consumer Access to Affordable Therapies", *ibid* at 453.

<sup>251</sup> Mey, "Unfettered Consumer Access to Affordable Therapies", *ibid* at 454.

(CBD) relating to sovereignty and access to genetic resources.<sup>252</sup> Additionally, proposals have been made to the Council for TRIPS to establish a mandatory system for IP protection, with an ethical and economic focus, relating to traditional knowledge.<sup>253</sup> The point here is that efforts to address biopiracy in SSA should pay heed to some of the suggestions in this text.

### **G. Availability of Patent Opposition Proceedings**

This section takes up the suggestion that avenues should be provided for pre-grant opposition proceedings during patent application processes. The availability of pre-grant mechanisms ensures that, before the patent office completes its evaluation of the patent application, the public is informed about the pending patent application and be allowed to raise any objections as to the merits of the application. The use of a pre-grant policy option promotes compliance with statutory provisions on patentability. It also facilitates public participation in evaluating the strength/weaknesses of patent applications before the grant of patents. This will help pre-empt many post-patent-grant opposition processes in court since the court processes tend to be more expensive, and obtaining a decision may take years.<sup>254</sup> Gopakumar & Smith articulate these advantages more clearly: “Pre-grant opposition is usually cheaper, simpler and faster than opposing a patent after it has been granted, so it can be an effective means to help ensure that only high-quality patents are granted, for medicines that are really new, inventive and industrially applicable.”<sup>255</sup>

Elsewhere, the availability of pre-grant opposition mechanisms has helped to reduce the grant of patents to ‘me too’ drugs – medicines which extend patent duration without

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<sup>252</sup> See *Venezuela's 6 August 1999 Communication to the TRIPS Council*, WT/GC/W/282.

<sup>253</sup> See WT/GC/W/282.

<sup>254</sup> Carlos Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective* (Geneva, ICTSD, UNCTAD, WHO, UNDP, 2007) at 24, online: <[http://www.emro.who.int/emp/media/pdf/patentability\\_guidelines.pdf](http://www.emro.who.int/emp/media/pdf/patentability_guidelines.pdf)>.

<sup>255</sup> KM Gopakumar & Sanya R Smith, “IPR Provisions in FTAs: Implications for Access to Medicines” in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 141 at 144, online: <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)>.

significant improvement in its efficacy.<sup>256</sup> In India, section 3(d) of the *Patent (Amendment) Act, 2005* (IPA) allows the public to bring evidence of patent rejection to the attention of the patent controller. This remedial measure aided the Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People to successfully oppose GSK's patent application for zidovudine and lamivudine in 2006 on grounds that the patent claim in question was not for a new invention.<sup>257</sup> In a related case, Natco Pharmaceuticals, CIPLA, Alternative Law Forum and Lawyers Collective opposed the grant of patents to Novartis' Glivec cancer medication on grounds that the medicine in question was a modification of an already existing drug that did not improve its efficacy as required by section 3(d) of the IPA. This contention was upheld by the Controller of Patents and Designs on grounds that Glivec was only a new form of a known substance without having any significant improvement in efficacy.<sup>258</sup> Aggrieved by this decision, Novartis challenged section 3(d) of the IPA on grounds of, *inter alia*, lack of TRIPS compatibility and unconstitutionality. In upholding the validity and constitutionality of section 3(d), the Madras High Court noted that

India is a welfare country and its first obligation under the Constitution is to provide good health care to its citizens. When that is its priority commitment under the Constitution of India, the Union of India has every right to bring in any local law in discharging their obligations under "TRIPS" to suit to the needs and welfare of its citizens....In so doing, the Union of India would be right to take into account the various factual aspects prevailing in this big country and prevent evergreening by allowing generic medicine to be available in the market.<sup>259</sup>

Based on the above experiences, countries in SSA need pre-grant public health safeguards in their patent laws to protect the interests of their citizens. Countries should, therefore, develop and make available public-health sensitive patent examination

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<sup>256</sup> Angell, *The Truth about the Drug Companies*, *supra* note 132 at 75.

<sup>257</sup> See Hoen, *The Global Politics*, *supra* note 144 at 78.

<sup>258</sup> See Chennai Patent Office order in the application for patent no. 1602/MAS/98 (filed on 17 July 1998), online: <<http://www.gnaipr.com/Articles/Glivec%20Order.pdf>>.

<sup>259</sup> *Novartis AG & Another v Union of India & Others* (2007) 4 MLJ 1153, online: <[http://www.gnaipr.com/GNACaseLaws/Judgement\\_GliveCpdf](http://www.gnaipr.com/GNACaseLaws/Judgement_GliveCpdf)>.

guidelines that can help in pre-grant opposition procedures. A framework for designing such guidelines already exists at the international level.<sup>260</sup>

Moreover, if a country such as South Africa with the world's highest HIV infection rate lacks a requirement for pre-grant opposition proceedings, then its patent administration deserves a rethink. To buttress the use of pre-grant opposition proceedings, patent offices must insist on high standards of disclosure in order to deter the filing of bogus applications and thus promote the public spirit of the patent social contract.<sup>261</sup> This requires that patent offices in SSA are resourced to improve their internal procedures for checking patent quality.<sup>262</sup> Countries in SSA must also develop local expertise to evaluate and monitor patent applications in order to ensure that patent grants meet patentability needs. There must also be enhanced capacity of domestic pharmaceutical companies, ministries of health and civil society to deal with the intricacies of patent law.<sup>263</sup>

## H. Use of Competition Law

The use and enforcement of competition law in SSA can be another effective mechanism to check medicine pricing abuses on the markets. Competition law seeks to eliminate restrictions on competition which lead to higher prices and reduced output in the short run; it also removes restrictions which adversely affect innovation.<sup>264</sup> According to Gervais, the use of adequate competition law measures, as part of a well-functioning IP system, can promote the public interest goals of the *TRIPS Agreement*.<sup>265</sup> Pursuant to that, there are two ways by which competition law measures can be employed to check

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<sup>260</sup> See Correa, *Guidelines for the examination of pharmaceutical patents*, *supra* note 254.

<sup>261</sup> Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (New York: Cambridge University Press, 2010) at 37-38.

<sup>262</sup> Peter Drahos, *The Global Governance of Knowledge*, *ibid* at 295.

<sup>263</sup> See Correa, *Guidelines for the examination of pharmaceutical patents*, *supra* note 254.

<sup>264</sup> Jens Schovsbo, "Fire and Water Make Steam – Redefining the Role of Competition Law in TRIPS" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 308 at 309.

<sup>265</sup> Gervais, *The TRIPS Agreement*, *supra* note 219 at 211.

patent rights abuses. First, competition measures can be undertaken as an in-built mechanism within the IP administration; second and preferably, competition measures can be undertaken through specific legislation with distinct oversight mechanisms.

South Africa, for instance, follows the latter approach. Based on that, in 2002, *Treatment Action Campaign* launched a complaint against GlaxoSmithKline (GSK) and Boeringer Ingelheim (BI) at the South African Competition Bureau.<sup>266</sup> The complaint was that the companies engaged in excessive pricing of antiretroviral medicines. On October 16, 2003, the Competition Bureau found that the respondents had contravened the *Competition Act*, 1998 of South Africa by abusing their dominant positions. In particular the respondents were held to have hindered competitors from having equal access to the markets and engaged in excessive pricing and in an exclusionary act. In further reference to the Competition Tribunal, the Competition Bureau recommended: (1) the use of compulsory licenses to allow third parties to market generic versions of GSK's and BI's patented medicines, in return for the payment of a reasonable royalty, and (2) a 10 per cent penalty on GSK's and BI's annual turnovers in South Africa for each year that they are found to have violated the Act. These measures forced the two companies to the negotiating table. Eventually, the companies agreed to license four generic companies to produce, import, sell and distribute antiretroviral medicines to other countries in SSA.

The lesson from this South African experience is that anti-competitive practices or conditions adversely affect trade and dissemination of technology. In Europe, for instance, AstraZeneca was fined €60 million in 2005 for the abuse of the patent system and procedures for marketing pharmaceuticals to block or delay the entry of generic competitors and parallel traders to its ulcer drug – Losec.<sup>267</sup> Therefore, countries in SSA such as Ghana that do not have competition legislation and institutions to check anti-

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<sup>266</sup> For a detailed narrative of this complaint, see: Hoen, *The Global Politics*, *supra* note 144 at 52-54.

<sup>267</sup> See the European Commission Decision Case COMP/A37.507/F3 – AstraZeneca of 15 June 2005, OJ (2006) L 332/24.

competitive practices need such regulatory frameworks. Those that have competition legislation need to strengthen their enforcement mechanisms. The use of competition law in SSA should aim at providing adequate remedies in the form of statutory limitations or compulsory licences if: (a) the use of the patented product/process is indispensable for competition in the relevant market; or (b) the use of an IP right results in the abuse of a dominant position on the relevant market.<sup>268</sup> Also, NGOs need to play an important watchdog role of working with governments to tackle practices which stifle access to essential medicines. Such a move, as happened in South Africa, can force pharmaceutical companies to agree to voluntary settlements. In the South African situation, GSK and BI granted voluntary licenses to both private and public sector marketers in return for royalties below 5 per cent.

### **I. Lacuna in the Enforcement of Patent Rights**

It is not always the case that once a patent has been granted, the patentee will opt to enforce it. A case in point is the Myriad patents in Canada.<sup>269</sup> Although Myriad's genetic diagnostic testing is protected in Canada, the Utah-based patent holder has not yet enforced the patents against clinics that use the patented testing process. Presumably, the same situation will apply if countries with manufacturing capability in SSA target the production of generic life-saving medicines. The reason is that pharmaceutical companies are able to break-even by selling the brand name medicines in the industrialized markets. Also pharmaceutical companies have already recouped significant profits from the sale of first-line antiretroviral medicines and have now focused their energies on the more expensive anti-malarial and second-line antiretroviral regimen. As a consequence, pharmaceutical patent holders will be unwilling to litigate to stop the generic production

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<sup>268</sup> This suggestion is taken from: Schovsbo, "Fire and Water Make Steam", *supra* note 264 at 352.

<sup>269</sup> See ER Gold & J Carbone, "Myriad Genetics: In the Eye of the Policy Storm" *A Report from the International Expert Group on Biotechnology, Innovation & Intellectual Property*, online: The Innovation Partnership, [online <http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP\\_Myriad\\_Legal.pdf>](http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Legal.pdf).

of 'antiquated' malaria medicines and first-line antiretrovirals; rather, they will be willing to accept low royalty payments.

Also, enforcing patent rights via domestic judicial systems in many countries in SSA may not be lucrative. The fact that private patent holders lack legal standing before the WTO's Dispute Settlement Board will require aggrieved rights holders to proceed through a WTO member state. In most cases, those member-states will weigh the economic harm and its international reputation and opt not to take any action besides the usual rhetoric. Helfer succinctly explains this point thus:

Governments litigate only a subset of TRIPS disputes that rights holders bring to their attention. In some cases a state may decline to file a complaint because it fears a WTO countersuit. In others, it may refuse to do so because the probability of success is low or because victory will only marginally benefit domestic industries. In still others, geostrategic factors unrelated to trade or intellectual property may lead governments to refrain from litigating.<sup>270</sup>

This reality that supposed patent infringements are not always litigated gives room for states to target the production of essential medicines whose terms have almost expired. Indeed, taking steps to test the mettle of international law may not attract any sanction after all. Like 'a carcass that fears no knife',<sup>271</sup> countries in SSA should not fear the threats of legal suits in promoting the manufacture of generic medicines, subject of course to the payment of some form of royalty to the patent holder. Since SSA countries face significant health crises, a period of benign neglect in enforcing pharmaceutical patent rights might be appropriate.<sup>272</sup> Related to that, others suggest the use of 'standards estoppel', in which intentional non-assertion of a patent in the presence of its widespread

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<sup>270</sup> Laurence R Helfer, "The New Innovation Frontier? Intellectual Property and the European Court of Human Rights" (2008) 49 Harv Int'l LJ 1 at 44.

<sup>271</sup> This Ghanaian proverb is literally interpreted to mean: 'he who is down should fear no fall'. This point should, however, not be misinterpreted as advocating for a violation of international obligations.

<sup>272</sup> Abbott, "Toward a New Era of Objective Assessment", *supra* note 20 at 100.

violation should create immunity from patent infringement.<sup>273</sup> Although this proposal is not likely to receive support within the WTO dispute settlement system, it provides a useful pro-access mechanism for domestic judicial systems to explore.

In sum, the above proposals aim to encourage SSA to consider human development needs as central in drug patent regulation and relegate TRIPS autocracy to legal history. This approach has the benefit of reversing some of the dysfunctions associated with the globalized patent system. This will also go a long way to ameliorate crumbling health care systems and re-integrate countries in SSA meaningfully in international patent politics. The proposed regulatory strategies can be implemented through legislative and institutional reforms across countries in SSA. Implementation must also be embodied in a domestic policy guide on access to medicines. This guide must set out clear avenues to explore to promote access to medicines for impoverished populations. Suggestions on the contents of the proposed patent and access to medicine guides are advanced in the final chapter 8 of this study. Suffice it to say that since SSA countries have diverse needs, a state may need to invoke more than one strategy to overcome the barriers to access to medicine within its jurisdiction. The success of such regulatory changes will depend on practical governmental interventions, flexible patent administration and enforcement mechanisms, and the building of alliances through institutional frameworks in SSA to overcome access-barriers.

## **V. Conclusions**

This chapter has focused on the theoretical justifications that lie at the heart of the globalized patent system. It articulates the point that countries in SSA by virtue of their adherence to TRIPS follow the natural rights theory and the incentive theory of patents. The dominant justifications that have facilitated the legitimization and extension of

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<sup>273</sup> See Robert P Merges & Jeffrey M Kuhn, "An Estoppel Doctrine for Patented Standards" (2009) 97 Cal L Rev 1.

strong patent standards favour pre-existing entitlements and allocations, hence the developed world. The dominant property theories have worked to further and sustain the economic interests of pharmaceutical companies in the developed world. In contrast, the theories sit ill with the social realities in SSA countries. The reality of the pandemic situations in SSA coupled with access to medicines challenges makes the continued relevance and validity of these theoretical assumptions dubious.

As a consequence, suggestions have been made to re-calibrate the globalized patent system to be responsive to the needs and aspirations of the citizens of SSA. These suggestions involve addressing questions of pharmaceutical patent monopoly, biopiracy, and recognizing access to medicines needs of SSA countries. It also involves adopting regulatory strategies that: promote the use of compulsory licensing mechanisms, avoid TRIPS-plus obligations, limit the scope of pharmaceutical patents, and make use of competition legislation. It should, however, be mentioned that these regulatory strategies are not sufficient to overcome all the inflexibilities inherent in the globalized patent system. These regulatory strategies are meant to lay the ground work for the discussions in chapters 6, 7 and 8 of this study, which chapters make a case for reconstructing the globalized pharmaceutical patent framework to be sensitive to human rights/development needs and social justice concerns of the citizens of SSA. Meanwhile, chapter 5 that follows details the contents and the impacts of the prevailing international patent standards in SSA countries and suggests that the implementation of WTO patent rules must reflect social realities in SSA countries.

## Chapter 5

### Patent Regulatory and Institutional Mechanisms in Sub-Saharan Africa

#### I. Introduction

The preceding chapters have informed us about the historical processes (and its inherent inequities) that led to the prevailing international patent system. The historically rooted marginalization of SSA countries and their citizens in the adoption and implementation of TRIPS pose a significant challenge to the functioning of the globalized patent regime and its domestic variations in SSA. In addition, the dominant economic rationale undergirding the globalized patent system promotes a one-size-fits-all system, which is a poor fit for the social conditions in SSA, and eventually contributes to impoverishing countries in SSA. These conclusions have been arrived at both by critiquing developments that led to TRIPS and by examining the theoretical justifications for patents. Today, those same power politics and the messianic assumptions that have served the economic interests of big pharma continue to shape the international patent system and its reflections in SSA.

Building on the political processes and the theoretical assumptions detailed in the preceding chapters of this study, this chapter provides an analytical description of the patent regulatory and institutional frameworks in SSA countries and assesses the implications of these frameworks in Africa. This discussion seeks to achieve three objectives: first, to show that the concept of patent law has become part and parcel of the legal systems and institutional frameworks of SSA countries; second, to suggest patent regulatory and institutional changes that take into account the impact-in-fact of patent rules on societies in SSA; third, to provide a contextual background for understanding the discussions in the other chapters of this study. The discussion in this chapter will, however, be limited to the salient patent law provisions that affect public health and human development issues in SSA, with particular regard being paid to the patent

legislation of the four countries that are the primary focus of this study: Ghana, Uganda, Botswana, and South Africa. The South African patent regulatory and institutional framework will lead this comparative analysis as a case study.

Following this introduction, part II examines the sources of patent laws in domestic jurisdictions in SSA. It articulates the point that international IP instruments such as the *Paris Convention*,<sup>1</sup> the *Patent Cooperation Treaty* (PCT),<sup>2</sup> and the *TRIPS Agreement* have served as the sources of patent laws in SSA countries. These international instruments coupled with other African regional instruments have induced SSA countries to cede their autonomy in matters of domestic patent law and policy making to the World Trade Organization (WTO), the African Regional Intellectual Property Organization (ARIPO) and/or Organisation Africaine de la Propriété Intellectuelle (OAPI).

Part III then discusses the key international instrument (i.e., the *TRIPS Agreement*) that sets global minimum standards of protection for patents. It highlights some salient patent law provisions under TRIPS that affect public health and human development issues in SSA. Here, I also discuss post-TRIPS ‘humanitarian’ measures under the Doha Declaration and its subsequent WTO ‘August 30’ Decision. A major caveat, however, is that although the rules that will be discussed in this part reflect general norms on patents, the principles underlying the discussion apply equally to pharmaceuticals.

Part IV then undertakes a comparative analysis of some national patent law provisions and institutional mechanisms as they relate to access to medicine issues in SSA. This comparative analysis draws on the patent regulatory and institutional experiences of South Africa in making a case for pharmaceutical patent reforms across SSA. In so doing, it investigates whether pharmaceutical patent applications are evaluated by the national

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<sup>1</sup> *Paris Convention for the Protection of Industrial Property*, 1883, 21 UST 1538, 828 UNTS 305 (last revision: 14 July 1967).

<sup>2</sup> Concluded at Washington on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984, and on 3 October 2001.

patent offices to ensure compliance with the requirements of patentability under the patent laws of SSA countries. I conclude that SSA countries (save South Africa) lack the institutional capacity/competence to evaluate the merits of supposed pharmaceutical inventions as mandated by law. Instead, SSA countries accept the ‘examination-verdicts’ of foreign patent offices and/or institutions via the PCT/ARIPO/OAPI systems. Further, a number of statutory provisions in SSA countries impede efforts to invoke the flexibilities under the international patent system to supply medicines at affordable prices. I urge SSA countries to adopt evidenced-based approaches to implementing international patent norms in order to make patent rules relevant to their citizens. Part V concludes this chapter’s discussion.

## II. Sources of Patent Laws and their Effects in SSA

The juridical sources of patent laws in SSA do not differ from the traditional articulation of the sources of general international law.<sup>3</sup> Article 38 of the *Statute of the International Court of Justice* (ICJ Statute)<sup>4</sup> authoritatively provides the sources of general international law as:

- (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- (b) international custom, as evidence of a general practice accepted as law;
- (c) the general principles of law recognized by civilized nations;
- (d) judicial decisions and the teachings of the most highly qualified publicists of the various nations.

Despite controversies as to the extent of application of these primary and secondary sources of law, courts have accepted them as authoritative and apply these sources in resolving disputes.<sup>5</sup>

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<sup>3</sup> Ikechi Mgbefo, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006) at 45.

<sup>4</sup> 1976 YBUN 1052. This Statute was concluded in San Francisco on 26 June 1945, and entered into force on 24 October 1945.

<sup>5</sup> See Donald P Harris, “Carrying a Joke Too Far: TRIPS and Treaties of Adhesion” (2006) 27 U Pa J Int’l Econ L 681 at 694.

In regard to this study, the *TRIPS Agreement* serves as the key international instrument for the globalization of patent norms in both developed and developing countries alike. TRIPS has also become the main normative instrument in setting IP law and policy in SSA. TRIPS itself incorporates earlier pro-harmonization treaties such as the *Paris Convention*, which made the first international attempt at ‘harmonization’ of patent rules, among others. As discussed in chapter 3, the *Paris Convention* introduced the national treatment and right of priority rules to facilitate the cross-border patenting of inventions. Yet, ‘harmonization’ under the *Paris Convention* still permitted “the existence of asymmetries in the national systems of industrial property, particularly in the field of patents.”<sup>6</sup> Today, the existence of any regulatory diversity in the terms and scope of patents under the *Paris Convention* has abated with the coming into force of TRIPS.

The *TRIPS Agreement* operates alongside the PCT. The PCT has streamlined the administrative processes involved in filing a patent application in SSA countries. By the operations of the PCT, the cost of securing international protection for patents is lowered by allowing innovators to acquire patent protection in all PCT signatory-countries on the basis of a single application and examination.<sup>7</sup> Presently, more than 2 million patent applications have been filed under the PCT.

There are also other regional instruments reflecting the globalization of patent standards in Africa. These African regional instruments include the agreements for the creation of ARIPO<sup>8</sup> and OAPI.<sup>9</sup> The ARIPO and OAPI instruments are modelled along the same

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<sup>6</sup> See Nuno Pires de Carvalho, *The TRIPS Regime of Trademarks and Designs* (The Hague: Kluwer Law International, 2006) at 100.

<sup>7</sup> See Rochelle Dreyfuss et al, eds, *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford: Oxford University Press, 2004) at xi.

<sup>8</sup> This instrument was adopted on 9 December 1976, and amended by the Administrative Council of ARIPO on 10 December 1982, 12 December 1986 and 27 November 1996, and was further amended by the Council of Ministers on 13 August 2004. Presently, there are 18 ARIPO member states.

<sup>9</sup> OAPI was established in 1962 at Libreville. Presently, it has 16 member-states, which consist of Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo.

assumptions as the international patent regime; they are based on the presupposition that effective protection and administration of patents is what is needed for countries to attract technology transfer.<sup>10</sup> The two regional instruments vest the ARIPO and OAPI with powers to grant regional patents. Such regional patent grants are enforceable across all member states irrespective of any domestic regulatory and institutional lapses. Moreover, many SSA countries use the examination processes established by both ARIPO and OAPI in granting domestic patents.<sup>11</sup> Further, there is a system in place for domestic patent applicants to designate other ARIPO/OAPI contracting states as places where they want their inventions to be accorded automatic protection once the requirements of patentability are met.<sup>12</sup>

More fundamentally, ARIPO members have adopted an amendment to the Harare Protocol to facilitate the creation of a link between the ARIPO and the PCT.<sup>13</sup> This link allows for PCT applicants to designate any of the ARIPO member states in their patent applications. That way, the applicant would be deemed to have automatically designated all contracting states that are parties to the Harare Protocol and the PCT. Likewise, the ARIPO office would, as stipulated under the PCT, forthwith serve as a receiving office for all PCT contracting states.<sup>14</sup> Presently, it is possible for PCT applicants to designate for ARIPO patent applications in states such as Botswana, Ghana, Lesotho, Sierra Leone, Swaziland, Uganda, Zimbabwe, Malawi, and Sudan. According to Mgbeoji, this alliance

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<sup>10</sup> Edgar Tabaro, “Patent Law Reform in Uganda: Addressing Priorities and Strategies” (2009) 12 *Journal of World Intellectual Property* 571 at 579 [Tabaro, “Patent Law Reform in Uganda”].

<sup>11</sup> See the *Harare Protocol on Patents and Industrial Designs*, 1982. This Protocol amended the ARIPO instrument to accord the organization more powers.

<sup>12</sup> See Brenda Pamela Mey, “Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: A Dead-End Journey for Patients? Kenya and India Case Studies” (2010) 13 *Journal of World Intellectual Property* 403 at 408.

<sup>13</sup> This amendment by the Administrative Council of ARIPO took effect from 1 July 1994.

<sup>14</sup> See Mey, “Unfettered Consumer Access to Affordable Therapies”, *supra* note 12 at 408.

between the ARIPO and PCT systems amounts to an automatic extraterritorial application of patent law.<sup>15</sup>

In sum, patent laws and institutional frameworks have become established in SSA countries. This is backed by studies which confirm that over 90 per cent of the patent laws of SSA countries are TRIPS-compliant.<sup>16</sup> The linkage of IP rights issues to global trade governance has driven SSA to adopt an ‘effective’ and ‘adequate’ patent protection of pharmaceuticals in domestic jurisdictions. Economic globalization has thus induced SSA countries to cede their autonomy, and consequently embrace the dictates of the international patent regime as provided by TRIPS. This economic globalization became successful because developing countries were promised that they would receive agricultural and textile subsidies from the developed world. Another assurance was that developed countries would refrain from resorting to unilateral and bilateral pressures against developing countries if the latter signed up to TRIPS.<sup>17</sup> In essence, the absence of democratic bargaining in TRIPS negotiations has not discouraged policy makers from implementing TRIPS obligations in SSA countries.

However, as shown in chapter 3, the key proponents of TRIPS have failed to live up to their promises in various ways. A recent increase in bilateral trade and investment agreements which impose higher levels of IP protection (commonly known as TRIPS-plus obligations) shows the troubling dimensions of the west’s broken promises. The introduction of TRIPS-plus obligations via bilateral free trade agreements represents the

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<sup>15</sup> See Ikechi Mgbeoji, “TRIPS and TRIPS-Plus Impacts in Africa” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 259 at 224.

<sup>16</sup> See Mgbeoji, “TRIPS and TRIPS-Plus in Africa”, *ibid* at 290-291; Sumner La Croix & Ming Liu, “Patents and Access to Essential Medicines” in Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008) 423 at 439.

<sup>17</sup> Mohammed El-Said, “The Road from TRIPS-Minus, to TRIPS, to TRIPS-Plus: Implications of IPRS for the Arab World” (2005) 8 *Journal of World Intellectual Property* 53 at 55.

frontline of impeding access to affordable medicines in developing countries.<sup>18</sup> Worse still, the promises that induced the less developed world to sign up to TRIPS were backed by threats of alienation from the community of trading nations if a country failed to comply with the multilateral framework. Certainly, many SSA countries lack the economic wherewithal to resist such threats of alienation from global trade relations, hence their decision to subscribe to relatively strong patent standards under TRIPS.

Further, through technical assistance initiatives, many LDCs in SSA have suffered the unfortunate fate of enacting TRIPS-compliant and TRIPS-plus laws in spite of the moratorium under the WTO system for them not to do so. Bilateral assistance programs have steered LDCs in SSA to strengthen their patent laws in blatant disregard for TRIPS' transition rules.<sup>19</sup> Indeed, the TRIPS-based framework and its underlying theories have effectively secured standards of patents in SSA countries similar to those adopted in industrialized countries. Meanwhile, big pharma continues to push for longer patent terms to leverage market competition in the industry and to delay the entrance of generic drug makers to the market.<sup>20</sup> The consequence is that the prevailing international patent system has turned SSA countries into toll collectors for big pharma while their citizens remain impoverished and die from diseases such as HIV/AIDS, malaria, and TB.<sup>21</sup> The next part briefly analyzes some specific patent-related provisions under TRIPS that implicate public health and human development issues in SSA.

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<sup>18</sup> See Jean-Frederic Morin, "Tripping up TRIPS Debates: IP and Health in Bilateral Agreements" (2006) 1 *International Journal of Intellectual Property Management* 37.

<sup>19</sup> Tabaro, "Patent Law Reform in Uganda" *supra* note 10 at 589. The reality is that LDCs such as Benin, Burkina Faso, Burundi, Chad, Central African Republic, Democratic Republic of Congo, Gambia, Guinea, Guinea-Bissau, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Swaziland, Tanzania, Togo, Uganda, and Zambia all provide protection for pharmaceutical patents.

<sup>20</sup> Chidi Oguamanam, "Patents and Pharmaceutical R&D: Consolidating Private–Public Partnership Approach to Global Public Health Crises" (2010) 13 *Journal of World Intellectual Property* 556 at 558.

<sup>21</sup> Jagdish Bhagwati, *In Defense of Globalization* (New York: Oxford University Press, 2004) at 182–183.

### III. The TRIPS Agreement Patent Standards

TRIPS emerged as part of the Uruguay Round of multilateral trade negotiations that ushered into force the liberalized trade policies of the WTO in 1995. This Agreement sets the minimum threshold for IP rights protection and enforcement for all member states of the WTO. It declares that IP rights are private rights, which must be accorded an ‘effective and adequate protection’ in all WTO member states. Consequently, the TRIPS’ rules have, since their entry into force, become the foundation of legitimacy for patent systems across the globe. Needless to add that TRIPS’ rules also serve as the juridical foundations for the protection of other fields of IP rights such as copyright, trademarks, geographical indications, industrial designs, layout-designs of integrated circuits, and undisclosed information.<sup>22</sup>

Article 7 of TRIPS sets out the objectives of the Agreement as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and *in a manner conducive to social and economic welfare*, and to a balance of rights and obligations.

The governing principles of TRIPS provide that:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to *protect public health* and nutrition, and to promote *the public interest* in sectors of vital importance to their socio-economic and technical development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>23</sup>

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<sup>22</sup> See Part II of TRIPS – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights.

<sup>23</sup> Article 8 of the *TRIPS Agreement* (emphasis added).

The above objectives and principles serve as the guiding imperative for reading and implementing the provisions of TRIPS in domestic jurisdictions.<sup>24</sup> Indeed, paragraph 19 of the Doha Ministerial Declaration singles out Articles 7 and 8 of TRIPS as having a special significance in matters of interpretation within the WTO system. These objectives and principles of TRIPS demonstrate that the issue of accessibility to medicine is significant to the international patent law balance. As argued further in chapter 7, these objectives and principles of TRIPS should guide the TRIPS Council and policy-makers in SSA in incorporating human development and social justice-oriented principles into the design and interpretation of WTO patent rules.

Another key feature of TRIPS is that its rules confirm the commitment of the international community to “achieve uniformity as to the nature of the [IP] rights, combined enforceability and sanctions for breaches thereof.”<sup>25</sup> As a consequence, TRIPS rules do not differentiate between essential life-saving medicines and non-essential commodities in the area of patents, among others. TRIPS provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>26</sup> To this end, all nations subscribe to universal patent standards irrespective of any diversity in innovation cultures they may have.<sup>27</sup>

Additionally, under the TRIPS regime, patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.<sup>28</sup> The TRIPS regime obligates all WTO member states to comply with

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<sup>24</sup> See paragraph 5(a) of the Doha Declaration; paragraph 19 of the Doha Ministerial Declaration.

<sup>25</sup> Paul Faustin Kihwelo, “Intellectual Property Rights Jurisprudence in Tanzania: Turning an Eye to the Commercial Division of the High Court” (2006) 9 *Journal of World Intellectual Property* 673.

<sup>26</sup> Article 27.1 of the *TRIPS Agreement*.

<sup>27</sup> Assafa Endeshaw, “The Paradox of Intellectual Property Law-Making in the New Millennium: Universal Templates as Terms of Surrender for Non-Industrial Nations; Piracy as an Offshoot” (2002) 10 *Cardozo J Int’l & Comp L* 47 at 61 [Endeshaw, “The Paradox of IP Law-Making”].

<sup>28</sup> See Article 27.1 of the *TRIPS Agreement*.

the principles of national treatment and Most Favoured Nation (MFN) treatment. By the national treatment principle, “each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property.”<sup>29</sup> The MFN principle provides that “any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.”<sup>30</sup> These non-discriminatory rules serve as the bedrock of the globalized patent regime and its reflection in domestic jurisdictions.

Notwithstanding the above, the obligations under TRIPS are said to be ‘minimum standards of IPR protection’, and thus leave WTO Members with discretion to adopt higher standards. Thus, WTO members may implement in their laws “more extensive protection than is required” by TRIPS.<sup>31</sup> The fact that TRIPS sets minimum regulatory standards has emboldened developed countries to push for enhanced protection for patents, among others, across nations. For example, many SSA countries including Botswana,<sup>32</sup> Ghana,<sup>33</sup> and Uganda<sup>34</sup> grant protection to ‘inventions’ which do not meet the threshold for patent protection, otherwise known as ‘utility models’<sup>35</sup>, even though the need to protect such lower forms of invention is not explicitly mandated by TRIPS. The rationale for protecting utility models is that such protection will secure local incremental innovations (i.e., petty inventions) that may not meet the relatively high threshold of patentability as mandated by law. The converse is that protecting petty inventions may constrain the public domain. Also given that only 0.01 per cent of patent

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<sup>29</sup> Article 3.1 of the *TRIPS Agreement*.

<sup>30</sup> Article 4 of the *TRIPS Agreement*.

<sup>31</sup> See Article 1 of the *TRIPS Agreement*.

<sup>32</sup> See sections 34-38 of Botswana’s *Industrial Property Act* No. 14 of 1996.

<sup>33</sup> See sections 16-18 of Ghana’s *Patents Act*, 2003.

<sup>34</sup> Sections 41-44 of Uganda’s *Patent Act*, 1993.

<sup>35</sup> Utility patents are lower forms of inventions that are new and industrially applicable but do not involve an inventive step.

applications filed in 1997 in SSA belonged to local residents,<sup>36</sup> there is no guarantee that local innovators in SSA will benefit from the protection of utility models.

Further, the absence of ‘maximum standards’ under TRIPS has caused many SSA countries to institutionalize regional mechanisms for protecting traditional knowledge.<sup>37</sup> These domestic and regional arrangements are, therefore, examples of what are known as TRIPS-plus arrangements. TRIPS-plus arrangements may also involve compelling LDCs to implement and enforce patent standards under TRIPS before the end of its specified transition period. Currently, LDCs such as Benin, Burkina Faso, Burundi, Chad, Central African Republic, Democratic Republic of Congo, Gambia, Guinea, Guinea-Bissau, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, Swaziland, Tanzania, Togo, Uganda, and Zambia all provide protection for pharmaceutical patents. Nevertheless, the question as to whether the concept of patent law is relevant to these technologically deficient states remains a site for debate among scholars and commentators. The general lack of adequate indigenous capability to maximize the benefits of global patent rules in SSA should raise legitimate concerns for policy-makers in the African region.

In short, but of particular relevance to this study, TRIPS makes it obligatory for all members of the WTO to grant 20-years of patent protection to pharmaceutical products and processes, among others.<sup>38</sup> It also allows states to grant protection for medicinal test data, thereby creating an additional form of monopoly for data needed to obtain marketing approval for medicines.<sup>39</sup> Presently, the protection of clinical test data in places such as the US, Canada, and the EU lasts between 5 years and 11 years, thereby preventing technologically proficient countries, such as South Africa, from taking

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<sup>36</sup> World Bank, *World Development Indicators*, 2000.

<sup>37</sup> See *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore*, 2010.

<sup>38</sup> See Article 33 of the *TRIPS Agreement*.

<sup>39</sup> See Article 39.3 of TRIPS.

advantage of such data for the production of generics.<sup>40</sup> To this end, all new health-related products and processes, such as medicines, vaccines and diagnostics, are enclosed in the ‘fence’ of protection by the TRIPS-based patent framework.<sup>41</sup> The grant of such pharmaceutical patents confers exclusive rights on the owner to make, use, sell and/or import protected medicines.<sup>42</sup> The owner shall also have the right to assign, or transfer by succession, the rights over patents to a third party and to conclude licensing contracts thereto.<sup>43</sup>

There are also extensive provisions under TRIPS that oblige states to provide effective and adequate enforcement procedures against the infringement of IP rights.<sup>44</sup> The *TRIPS Agreement* also crucially insists on states’ compliance with standardized administrative rules and procedures. The protection of patents under TRIPS is fortified with dispute settlement mechanisms and trade sanctions to procure compliance. *Prima facie*, the exercise of these exclusive rights conferred by patents could serve as a barrier to access to medicines for the citizens of SSA who are the neediest consumers of pharmaceuticals. Given the spectre of epidemics in SSA, the grant of pharmaceutical patent rights can only be justified if the threshold of protection is commensurate with the deprivation.<sup>45</sup>

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<sup>40</sup> See US *Drug Price Competition and Patent Term Restoration Act* of 1984, Pub L No. 98-417, 98 Stat. 1585 [granting protection to marketing exclusivity for 5 years extends from the approval of the original drug to the approval of a generic version based on bioequivalence]; Canada Food and Drug Regulations (as amended) 2006 [granting clinical test data protection for 8 years. However, the generic companies are able to submit application for approval drug using such data after 6 years of protection]; Directive 2004/27/EC [granting protection to clinical data exclusivity for 11 years].

<sup>41</sup> Ellen FM ’t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) at 2.

<sup>42</sup> See Article 28.1 of TRIPS.

<sup>43</sup> See Article 28.2 of TRIPS.

<sup>44</sup> See Article 41 of TRIPS.

<sup>45</sup> See Margaret Llewelyn, “Schrodinger’s Cat: An Observation on Modern Patent Law” in Peter Drahos, ed, *Death of Patents* (London: Lawtext, 2005) 11 at 20 [Llewelyn, “Schrodinger’s Cat”].

### A. TRIPS-Based Patenting: Exclusions, Moratoriums and Exceptions

Besides TRIPS' requirements for a country to grant or enforce pharmaceutical patents, proponents of the globalized patent regime allude to the built-in flexibilities under TRIPS. In this regard, Article 27.2 of TRIPS allows states to exclude inventions from patentability on the basis of *ordre public* or morality, including protecting human life or health. Additionally, TRIPS allows states to exclude diagnostic, therapeutic and surgical methods for the treatment of humans from patentability.<sup>46</sup> It is however debatable whether a state can invoke the *ordre public* or the public interest exception to deny patent rights that interfere with the public right to have access to essential medicines. The answer to this debate is provided in chapters 4 and 6 of this study.

In particular regard to this study, Article 31 of TRIPS allows states to make provisions for pharmaceutical patent exceptions in cases of emergency and extreme urgency, public non-commercial use, and anti-competitive use. However, before Article 31 of TRIPS was amended, any such authorization without the consent of the right holder could only be used predominantly for the supply of medicines to the domestic market.<sup>47</sup> This meant that countries which lacked manufacturing capacities could not benefit from the use of compulsory licensing mechanisms under TRIPS to procure medicines for their citizens from abroad.

Importantly, the *TRIPS Agreement* also obliges patent applicants to disclose sufficient and clear information for the invention to be carried out by a person “skilled in the art.”<sup>48</sup>

That person ordinarily skilled in the art is

a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to

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<sup>46</sup> See Article 27.3 of the *TRIPS Agreement*.

<sup>47</sup> See Article 31(f) of the *TRIPS Agreement*. As I explain below, the amendment of Article 31 (which becomes Article 31*bis*) of TRIPS comes into force when two-thirds of WTO members ratify the amendment.

<sup>48</sup> Article 29.1 of the *TRIPS Agreement*.

understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the ‘reasonable man’ standard in negligence law. He is assumed to be a man who is not going to try to achieve success and not one who is looking for difficulties or seeking failure.<sup>49</sup>

Admittedly, the requirement of disclosure functions as an essential *quid pro quo* in the granting of patents. However, this requirement of disclosure which may inure to the benefit of a person skilled in the relevant art is a far cry from offering accessibility to the general public (particularly where one of the problems in SSA is a lack of capacity or training).<sup>50</sup> Further, this requirement of disclosure is often subverted by the arcane language in which patent claims are couched. Also the *modus operandi* of patentees, especially in highly competitive industries, is to reveal as little and to claim as much protection as possible in order to maintain their competitive edge.<sup>51</sup> Suffice it to say that patents can fulfill the goal of providing social benefit only if the disclosure is enabling.<sup>52</sup>

On the whole, when TRIPS came into force developing countries were given an extra five years to bring their laws into conformity with international law or, in default, face trade sanctions.<sup>53</sup> By this initial deadline, developing countries had up to January 1, 2000 to comply with TRIPS. This grace period was extended to the end of 2004, however. For LDCs (the majority of which are in SSA), the grace period from granting or enforcing pharmaceutical patents will last until 2016.<sup>54</sup> Besides pharmaceuticals, the protection for other forms of IP rights in LDCs was deferred until July 1, 2013. These grace periods,

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<sup>49</sup> *Free World Trust v Electro Santé Inc*, [2002] 2 SCR 1024, 2000 SCC 66 at para 44.

<sup>50</sup> Stamatia Tina Piper, “The Emergence of a Medical Exception from Patentability in the 20<sup>th</sup> Century” (D.Phil Thesis, University of Oxford, 2008) at 21.

<sup>51</sup> David Vaver, *Intellectual Property Law Copyright, Patents, Trademarks* (Concord, ON: Irwin Law, 1997) at 139.

<sup>52</sup> Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 67.

<sup>53</sup> An example of such a threat was issued in 1997 against Mandela’s government by the US for permitting the manufacture of generic versions of HIV/AIDS medicines.

<sup>54</sup> See Decision of the Council for TRIPS, *Extension of the Transition Period under Article 66.1 for Least-Developed Country Members* (29 November 2005); Paragraph 7 of the Doha Declaration. See also “The Doha Declaration Explained – TRIPS”, online: <[http://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm)>.

however, did not make an exception for the immediate application of the national treatment principle<sup>55</sup> and the MFN principle<sup>56</sup> in both developing and LDCs alike. Also, in seeking to utilize the transition periods, countries must accept the filing of pharmaceutical patent applications as well as create mechanisms for granting exclusive marketing rights for pharmaceuticals.<sup>57</sup>

To conclude, although LDCs have the option of not complying with TRIPS in its entirety until 2013 (and 2016 in the case of pharmaceutical patents), if a state commits to grant full patent protection, that protection must be TRIPS-compliant. This is intended to ensure that any patent laws, regulations, and practices during the transition period remain consistent with the provisions of TRIPS.<sup>58</sup> As I discuss further below, the reality is that a number of LDCs in SSA comply with the treaty, to the extent that some have been compelled to assume more obligations than the minimum standards required by TRIPS.<sup>59</sup> These countries have accepted that higher protection will better serve their interests in receiving increased investments and other support from developed countries.<sup>60</sup> Whatever the truth of this tale, complying with the strong patent standards under TRIPS may undermine the post-TRIPS mitigation measures under the Doha Declaration and the WTO ‘August 30’ Decision.

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<sup>55</sup> On the national treatment principle, Article 3 of the *TRIPS Agreement* (Part I) provides that each WTO member shall accord to nationals of other member states treatment no less favourable than it accords to its own nationals with regard to protection.

<sup>56</sup> On the most favoured nation principle, Article 4 of the *TRIPS Agreement* (Part I) stipulates that any advantage, favour, privilege or immunity granted by a WTO member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other member states.

<sup>57</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 52 at 74 [mandating members to provide what is called a ‘mailbox’ system for exclusive marketing of pharmaceuticals for five years in consonance with Article 70.8 & 70.9 of TRIPS].

<sup>58</sup> See Article 65.5 of the *TRIPS Agreement*.

<sup>59</sup> See S Hill & K Johnson, *Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries* (London: DFID Health System Resource Centre, 2004) at 7.

<sup>60</sup> See Richard D Smith et al, “Trade, TRIPS, and Pharmaceuticals” (2009) 373 *Lancet* 684 at 688.

## B. Post-TRIPS Mitigation Measures

Over the years, concern and outrage have been expressed about the rigidities associated with TRIPS. Critics contend that TRIPS makes it difficult for the less developed world to use automatic compulsory licenses that would allow easy access to life-saving medicines.<sup>61</sup> For Stiglitz, signing the *TRIPS Agreement* amounts to “signing the death warrants of thousands of people in sub-Saharan Africa and elsewhere in the developing countries.”<sup>62</sup> The general impression has been that pandemics in Africa have “reached such levels that entire nations may perish while the treatment, though available, is locked away through systematic patenting or becomes unaffordable as a result of the pricing strategies of the major pharmaceutical companies.”<sup>63</sup> These concerns, among others, attracted international attention, and efforts were made in the post-TRIPS negotiations at Doha, Cancún, and Hong Kong to address some of the inflexibilities associated with the global legal order.

In November 2001, efforts were made at the fourth WTO ministerial conference in Doha, Qatar to address the apparent rigidity in the global patent system. The Doha Round of negotiations sought to redesign and re-position the globalized patent regime to meet the health care needs of individuals in poor countries and thus promote development. At Doha, a group of developing countries “sought a legally binding declaration that would affirm an interpretation of TRIPS that would permit them to pursue policies affording access to essential medicines without fear of retribution from other WTO members.”<sup>64</sup> Eventually, Doha concluded that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.”<sup>65</sup> And that the *TRIPS*

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<sup>61</sup> See e.g. Joseph E Stiglitz, “Economic Foundations of Intellectual Property Rights” (2008) 57 Duke LJ 1693 at 1701.

<sup>62</sup> Stiglitz, “Economic Foundations of IPRs”, *supra* note 61 at 1701.

<sup>63</sup> Endeshaw, “The Paradox of IP Law-Making”, *supra* note 27 at 50.

<sup>64</sup> Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003) at 160.

<sup>65</sup> Paragraph 4 of the Doha Declaration.

*Agreement* should be “interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.”<sup>66</sup> Arguably, Doha introduced the most significant ‘humanitarian’ measure regarding public health and human development in poor countries.

The Doha Declaration also clarified the issue as to whether the *TRIPS Agreement* limits the use of the built-in flexibilities to particular diseases, such as HIV/AIDS, malaria, and TB. It noted that nothing in the *TRIPS Agreement* limits the use of compulsory licences or other ‘flexibilities’ to a narrow category of diseases.<sup>67</sup> Thus, in addition to HIV/AIDS, malaria, and TB, ‘other epidemics’ can form part of national emergency or other circumstances of extreme urgency in domestic jurisdictions, thereby necessitating the use of compulsory licensing mechanisms to tackle such epidemics.

Further, paragraph 5(c) of the Doha Declaration explained that domestic governments should determine the grounds upon which compulsory licences are granted to tackle health-related emergencies. States are also not required to consult patent right holders before issuing compulsory licences to address public health concerns.<sup>68</sup> Notice must be given of the use as soon as reasonably practicable, however. This waiver of prior consultation is aimed at avoiding inordinate delays in the issuance of compulsory licences in cases of national emergency, or in cases of public non-commercial use, or to remedy anti-competitive practice.

In addition, Doha explained that WTO members have the latitude to determine their own policies and rules on the subject of exhaustion of rights.<sup>69</sup> This doctrine of exhaustion is captured under Article 6 of TRIPS to the effect that nothing under the Agreement shall be

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<sup>66</sup> Paragraph 4 of the Doha Declaration.

<sup>67</sup> See Paragraphs 1 and 5 of the Doha Declaration; Kevin Outterson, “Should Access to Medicines and TRIPS Flexibilities be Limited to Specific Diseases?” (2008) 34 Am JL & Med 279 at 281.

<sup>68</sup> Article 31(b) of the *TRIPS Agreement*.

<sup>69</sup> Paragraph 5(d) of the Doha Declaration.

used to address the issue of the exhaustion of IP rights. The doctrine of exhaustion provides that the first sale of a patented drug exhausts the public law rights of the patent holder for that item. The exhaustion rule thus operates to remove patent law barriers to cross-border trade in patented and generic medicines.

Doha also recognized that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS.<sup>70</sup> The reason was that the production of medicines to alleviate human suffering was to “be authorized predominantly for the supply of the domestic market” of the country so licensed.<sup>71</sup> This meant that compulsory licences could not be granted to produce generic medicines for export. Having recognized this inequity, the Council for TRIPS was instructed to find an expeditious solution to such restrictions on access to medicines in places such as SSA, where there is a general lack of production capacity, and to report same to the General Council.

Subsequently, the WTO Council decided on August 30, 2003 to allow for the export of medicines manufactured under compulsory licences into countries that lack domestic production capacity. This ‘August 30’ Decision gives a temporary waiver to Article 31(f) of TRIPS, by allowing compulsory licenses to be used in producing generic medicines for export, provided approval is sought from the General Council. The ‘August 30’ Decision has culminated in the permanent amendment to Article 31 of TRIPS. This new amendment (i.e., Article 31*bis* of TRIPS) comes into force when two-thirds of all WTO members ratify the change. However, doubts still remain whether the implementation of the ‘August 30’ Decision or the permanent amendment will remove significant obstacles to access to medicines in places such as SSA. So far, “it is doubtful whether African countries have fared much better in terms of developing local industrial manufacturing capacity and thus significantly addressing the dire health challenges in Africa that

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<sup>70</sup> Paragraph 6 of the Doha Declaration.

<sup>71</sup> See Article 31(f) of TRIPS.

compelled the amendment of Article 31 of the TRIPS Agreement.”<sup>72</sup> As of 2011, only Rwanda has notified the TRIPS Council and in fact utilized the ‘August 30’ mechanism to import generic medicines, ApoTriAvir, from Canada. Even with this Rwandan experience, the rigid nature of the application procedures under Canada’s *Access to Medicines Regime* and the high cost of Canadian generics as compared with that of India made the entire deal unattractive.<sup>73</sup>

In conclusion, the WTO’s TRIPS provisions have laid the foundation for uniform patent rules across nations. As a consequence, SSA countries have adopted patent systems that are consistent with international standards, as stated and defined under the WTO system. Countries in SSA have also created domestic institutions, including specialized courts to enforce patent rights, among others.<sup>74</sup> Suffice it to say that the implementation of these WTO patent rules has far reaching consequences for access to medicine issues in SSA. Next I will analyze the implementation of these WTO-patent standards in domestic jurisdictions in SSA countries as well as point out any pitfalls and suggest ways to overcome these obstacles.

#### **IV. A Primer on the Patent Regimes in SSA and the Need for Patent Reforms**

Generally speaking, a patent is a right granted to an inventor by the state, or by regional office(s) acting for several states, to exploit an invention for commercial purposes. This protection is based on the assumption that patents facilitate pharmaceutical research and development (R&D) for the benefit of the public. The public benefit is supposed to be realized when the patent holder exploits the invention commercially. However, this commercial exploitation of patents allows the inventor to prevent the public from using,

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<sup>72</sup> Mgbeoji, “TRIPS and TRIPS-Plus in Africa”, *supra* note 15 at 274-275.

<sup>73</sup> Paige E Goodwin, “Right Idea, Wrong Result – Canada’s Access to Medicines Regime” (2008) 34 Am JL & Med 567 at 580.

<sup>74</sup> See Ghana’s *High Court (Civil Procedure) Rules*, 2004 (CI. 47); Tanzania’s *High Court Registries (Amendment) Rules* 1999 [all establishing Commercial High Courts to enforce IP rights].

making, selling or importing the patented product or process (or their hybrid) for a set period of time within a jurisdiction. Normally, this exploitation of patent rights subsists for a period of 20 years if the criteria for patentability are met in a particular jurisdiction.

The next task, therefore, is to describe the general patentability requirements for pharmaceutical protection in SSA countries. This discussion is linked with the practice(s) and/or administration(s) of patents in SSA countries in order to ascertain whether pharmaceutical patent applications are examined to ensure compliance with statutory provisions on patentability.

### **A. Patentability Criteria in SSA Countries**

This section does not intend to look at each of the patent-granting criteria in SSA countries. Rather, it stresses the commonalities among the patentability criteria in SSA countries. These commonalities have come about as a result of the fact that patent laws in SSA are modelled on the basis of TRIPS. Therefore, Article 27 of TRIPS should provide a starting point for this discussion. It requires that in order for an invention to be patentable, it must meet the granting criteria of ‘newness’, ‘inventive step’, and ‘industrial application’. Countries in SSA have included these patentability requirements in their patent legislation with somewhat insignificant variations.

For example, the patent legislation of Ghana employs the terms: ‘new’, ‘inventive step’, and ‘industrial applicability’.<sup>75</sup> Likewise, Uganda’s patent law uses the terms: ‘new’, ‘inventive step’, and ‘industrial applicability’.<sup>76</sup> That of Botswana provides that “an invention shall be patentable if it is new, involves an inventive step, and is industrially applicable.”<sup>77</sup> Equally, the patent law of South Africa provides that a patent may be granted for “any new invention which involves an inventive step and which is capable of

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<sup>75</sup> Section 3(1) of Ghana’s *Patents Act*, 2003 (Act 657).

<sup>76</sup> Section 8 of Uganda’s *Patents Act*, 1993.

<sup>77</sup> Section 8 of Botswana’s *Industrial Property Act No. 14* of 1996.

being used or applied in trade or industry or agriculture.”<sup>78</sup> Perhaps, South Africa’s somewhat different formulation of the requirement of industrial application nuances the country’s focus on inventions that can spur its economic growth and development. The patent law of South Africa limits protectable inventions to those that provide solutions to a specific problem in the field of trade, industry and/or agriculture. The salient point here is that the applications of these patentability standards (discussed in greater depth below) determine whether or not an invention is eligible for patent protection in a particular jurisdiction.

To be patentable, an invention must be industrially applicable. Thus, the invention must have a known and described utility.<sup>79</sup> This requirement of industrial application mandates the applicant to show that the invention is complete, that it does not require any further R&D, and that it is capable of being industrially used.<sup>80</sup> It follows that a patent will not be granted if the invention cannot perform its designated function. It should be an invention that works, or an invention capable of being reduced to practice, by providing a solution to a specific problem in the field of technology. It is for this reason that structured observations of natural phenomena (i.e., discoveries) are not protected by patents. This is not to say that an invention needs to demonstrate superiority to existing products or processes. Also, the invention does not necessarily need to demonstrate strict commercial viability in order to satisfy the utility or industrial applicability requirement. Utility only requires that an invention performs the functions specified in the patent-claim and that it achieves some beneficial results to society. In this regard, society will be assured of some positive benefits before granting an exclusive right to an applicant/inventor over a pharmaceutical product or process. It is, however, worth

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<sup>78</sup> Section 25(1) of South Africa’s *Patent Act No. 57 of 1978* (as amended).

<sup>79</sup> Bitu Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (England: Ashgate, 2009) at 50.

<sup>80</sup> Llewellyn, “Schrodinger’s Cat”, *supra* note 45 at 28.

stressing that the requirement of usefulness is a much lower threshold than the regulatory requirement that a drug be safe and effective.<sup>81</sup>

The second requirement of patentability is that an invention should be new or novel at the time of the application for patents. Generally, this novelty requirement is intended to ensure that the material being claimed as an invention has not been available to the public prior to making the patent application.<sup>82</sup> In other words, novelty in patent law requires that the subject matter of the invention has not previously been disclosed to the public anywhere in the world. In this vein, a publication of the inventor's research work before the filing of a patent application may destroy novelty. Therefore, in any patent application, a search of the prior art<sup>83</sup> is conducted to ensure that the application is in fact for a new invention and, that it does not infringe any other patented invention.<sup>84</sup> To mitigate the hardships of this patentability criterion, most patent systems in SSA countries assure patent applicants a one year grace period within which any disclosure made during the patent application process by the applicant will not cause the invention to lose its novel character. This one year moratorium (also known as the 'right of priority' rule) allows the applicant to designate other countries where they want to seek protection for the said invention. This exception relates to applications made in countries that are parties to the *Paris Convention*, however.

Finally, for an invention to be patentable, it must meet the requirement of inventive step. This requirement is also referred to as the requirement of non-obviousness. It requires that the invention must represent an improvement over the prior art before it can receive patent protection. This prior art may include any scientific and technical information that

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<sup>81</sup> Cynthia M Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (New York: Oxford University Press, 2011) at 18 [Ho, *Access to Medicine*].

<sup>82</sup> Llewelyn, "Schrodinger's Cat", *supra* note 45 at 23.

<sup>83</sup> Prior art consists of any oral or written disclosure, in connection with the invention, made anywhere to the public prior to the filing of the patent application.

<sup>84</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 79 at 50.

exist before the effective date of a particular patent application. Equally, the invention must not have been obvious to a person who is ordinarily skilled in the art. In effect, a product or process cannot be patented if a person of average skill in the relevant scientific/technical field can put together different pieces of known information and arrive at the same result. The invention must either involve a technical advance compared to the existing knowledge or should have an economic significance or both. States have the liberty to insist on meeting higher standards for the inventive step requirement, however.<sup>85</sup> The inventive step requirement is at the heart of the patent system, as it measures an invention's contribution to the technological progress. Preferably, SSA countries should grant patents to inventions that depart significantly from the prior art (rather than incremental development or minor improvements to prior art) in order to avoid the 'evergreening' of pharmaceutical patents.

On the whole, the above patentability requirements have been enacted as part of the patent legislation of many SSA countries. Once the patentability requirements are met, patent protection is granted to the claimed invention to commence from the date the application was filed. In many SSA countries, this protection is granted to the first person to file and not the first person to invent. In consequence, there is pressure to apply for patent protection as soon as possible in many SSA countries. Equally, the protection offered by patents in SSA countries is relatively broad: a person cannot legally use the same idea, even if he or she independently rediscovers it without permission from the patent holder.<sup>86</sup> Simply put, patents have become a state sanctioned anti-competition device in the hands of private companies, and their impact on access to medicine in parts of Africa is being felt across the board. Strict enforcement of the requirements of patentability by national patent institutions can prevent minor pharmaceutical inventions

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<sup>85</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 52 at 66.

<sup>86</sup> See Michele Boldrin & David Levine, *Against Intellectual Monopoly* (NY: Cambridge University Press, 2008) at 7.

(i.e., inventions that do not show significantly improved efficacy) from being patented in SSA.

It is however doubtful whether local patent offices in SSA countries scrutinize patent applications in order to ensure compliance with the above requirements of patentability before granting such monopolies. In order to ensure that patent rules serve the interests of SSA countries, the above patentability safeguards must be reflected in the patent administration(s) and practice(s) in SSA countries.

### **1. Tests of Patentability in SSA<sup>87</sup>**

As noted in chapter 2 (i.e., under the analysis of *patent practices*), the behaviour of patent administrators and examiners can be a more reliable indicator for measuring the extent of compliance with the formal requirements of patentability in SSA countries. Also, the efficient use of patent administration could help tailor pharmaceutical patent rules to redress some of the access to medicine challenges in SSA countries. The reason is that the grant of pharmaceutical patents is considered as a matter for domestic law. Equally, the definition of the regulatory scope and contents of the requirements of patentability is left to national patent granting institutions for determination and application. Countries have the freedom to examine whether the requirements for patentability under their national laws are fulfilled before granting the patent. It follows that a strict application of patentability standards may be employed to check patent quality and thus facilitate access to medicine.

More significantly, the threat posed by weak patents to access to medicine issues has not been lost on a number of intergovernmental organizations; UNCTAD has observed that

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<sup>87</sup> I rely on a research proposal submitted by Professor Ikechi Mgbeoji, Osgoode Hall Law School, York University, for an Open A.I.R. study in writing this section. I am also indebted to a number of patent examiners/administrators and practitioners in Ghana, ARIPO, Uganda, and South Africa for sharing pieces of information that helped in validating claims in the literature about patent administration in SSA countries.

“if a government grants patents without adequate attention to whether true novelty and inventive step are involved, it may create unjustified impediments to market entry for products both of local and foreign origin.”<sup>88</sup> The reality is that many SSA countries lack the institutional competence to scrutinize patent applications in order to ensure compliance with the above requirements of patentability before granting pharmaceutical patent monopolies. As stated earlier in this chapter, interpretations of patentability criteria by state agencies in SSA have followed approaches under international (i.e., the PCT) and regional (i.e., ARIPO/OAPI) arrangements such that the potency of any sovereign discretion is compromised. In particular, the instruments that establish OAPI and ARIPO vest both institutions with powers to grant regional patents in SSA. Such regional grants are enforceable across all member states irrespective of domestic regulatory and institutional lapses. In addition, SSA countries use the examination processes established by both ARIPO and OAPI in granting domestic patents. Thus, save South Africa, the patent offices in SSA countries lack the institutional competence to thoroughly examine pharmaceutical patent applications to ensure compliance with statutory provisions on patentability. Instead, countries have outsourced these key obligations of vetting patent applications to foreign institutions via the PCT/ARIPO/OAPI systems. Local patent offices are simply agents of an international system that is at best indifferent to the particular needs of the citizens of SSA countries.<sup>89</sup> The issue here is not that international or regional harmonization of the regime of patents is a bad idea. The point is that patent offices in SSA should develop institutional competencies to evaluate the merits of pharmaceutical patent applications as mandated by national laws.

Related to the above institutional quandary is the lack of qualified examiners in many SSA countries to scrutinize pharmaceutical patent applications in order to ensure strict

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<sup>88</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005) at 19.

<sup>89</sup> See Ruth L Okediji, “Africa and the Global Intellectual Property System: Beyond the Agency Model” (2004) 12 *Afri YB Int’l L* 207 at 250 [Okediji, “Africa and the Global IP System”].

compliance with the requirements of patentability. The practice of patent examination requires the examiner to first determine whether the product/process is a patentable subject matter. The second phase of the examination process is to determine whether the product/process meets the requirement of industrial application or usefulness. Once that hurdle is cleared, the examiner is required to ensure that the product/process is new and also that it meets the final test of inventive step: that someone with similar skill to the inventor would not have easily created the invention.

Perhaps, there is no task more difficult than that of examining and applying these patentability requirements in practice. To understand and apply these patentability requirements in the field of pharmaceuticals, the patent examiner requires an in-depth understanding of chemistry.<sup>90</sup> The examiner must also have background training in drug discovery; this training will enable the examiner to use the clinical data to identify slight variations on a microscopic level. However, such local expertise required to understand the intricacies of pharmaceutical patent claims as well as check for quality is generally not available in the patent offices in many SSA countries. The reality, as Mgbeoji points out, is that most patents filed in SSA are drafted by foreign patent lawyers, examined in foreign patent offices and mailed to patent offices in the capital cities for filing.<sup>91</sup> There is zero input from patent offices in SSA countries, except the collection of filing fees. In essence, the capacity of most SSA countries (save South Africa) to vet/check pharmaceutical patent quality remains largely utopian.

The above problems associated with patents administration in SSA is further exacerbated by the absence of a system in place to collate and make the technical and scientific information contained in patent applications accessible to local researchers. Also local innovators do not feel motivated to file for patent applications partly because many

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<sup>90</sup> Ho, *Access to Medicine*, *supra* note 81 at 19.

<sup>91</sup> Ikechi Mgbeoji, "A Promise Betrayed? Rethinking the Clerical Natures of IPRs Practice in the Third World", online: <<http://www.iposgoode.ca/2011/06/a-promise-betrayed-rethinking-the-clerical-natures-of-iprs-practice-in-the-third-world/>>.

lawyers in SSA lack the skill in drafting the requisite applications, without even considering prosecuting such applications in the patent offices in developed countries. Perhaps mirroring the general problems with patent law practice in SSA, many patent law practitioners in SSA serve as agents of foreign law firms by submitting ready-made patent applications to the domestic/regional patent offices with little or no local input, except the collection of professional fees.<sup>92</sup> Unsurprisingly, a World Bank report in 2000 confirmed that only 0.01 per cent of patent applications filed in 1997 in SSA belonged to local residents.<sup>93</sup> This disconsolate situation has not changed for the better in many SSA countries. The perverse result is that market monopolies are granted mostly to foreign pharmaceutical patent holders without a corresponding transfer or dissemination of scientific data to local innovators.<sup>94</sup> Presumably, the absence of local input in checking the merits of pharmaceutical patents hardly helps in ensuring that the social benefits of patents in promoting access to life-saving medicines for the citizens of poor countries is served.

To overcome these patent regulatory and institutional dysfunctions and make pharmaceutical patent regulation relevant to Africa, SSA countries need to build the capacity of patent examiners as well as develop the required infrastructure necessary to absorb, adapt and utilize technical scientific data for purposes of local innovation.<sup>95</sup> As in South Africa, countries in SSA need to develop their technological and institutional competences to: (i) evaluate the merits of patent applications; (ii) collate patent applications and assess whether the application has not been pre-empted by information in the public domain; and (iii) provide accessibility to information contained in patent

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<sup>92</sup> Mgbeoji, "A Promise Betrayed?", *ibid.*

<sup>93</sup> See World Bank, *World Development Indicators* (2000).

<sup>94</sup> Ikechi Mgbeoji, "Rethinking the Failure of African States to Examine and Collate Patent Applications" (2011) [unpublished, on file with the author].

<sup>95</sup> See Okediji, "Africa and the Global IP System", *supra* note 89 at 249.

applications to local researchers.<sup>96</sup> Developing domestic administrative and institutional competences will lead to the creation of a significant database that can promote dissemination of technical and scientific information to local innovators in SSA. Also, countries must enhance the capacities of domestic pharmaceutical companies, ministries of health and civil society to deal with the intricacies of patent law. That way, these institutions can act as important counter-weights to the grant as well as the exercise of pharmaceutical patent rights in SSA.

In addition, countries in SSA must determine their own ways of defining what constitutes a pharmaceutical invention as well as determining the criteria for judging patentability. This requires patent offices in SSA to develop their own public health sensitive regulations and guidelines indicating procedures for: (1) submission of patent applications, (2) publication of applications, (3) examination of applications, (4) opposition to the grant of patent to the applicant, (5) disclosure of the use of bio-resources, and (6) hearing the parties. In developing such examination guidelines, countries can get insights from other jurisdictions. At the international level, there are guidelines for ensuring public-health-sensitive approaches to examining pharmaceutical patent applications.<sup>97</sup> SSA countries could and should adapt these international guidelines to meet their domestic needs. The success of such ‘legal amalgamation’<sup>98</sup> will depend on comparing rules in different jurisdictions and being aware of the local conditions that need remedying.

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<sup>96</sup> These public interest considerations of patent protection were taken from Mgbeoji’s ongoing research proposal on “Rethinking the Failure of African States to Examine and Collate Patent Applications” (Open AIR Project proposal, unpublished, 2011).

<sup>97</sup> Carlos Correa *Guidelines for the examination of pharmaceutical patents: developing a public health perspective* (Geneva, ICTSD, UNCTAD, WHO, UNDP, 2007), online: <[http://www.emro.who.int/emp/media/pdf/patentability\\_guidelines.pdf](http://www.emro.who.int/emp/media/pdf/patentability_guidelines.pdf)>.

<sup>98</sup> This refers to importing certain elements of different legal systems, selected for their suitability. On this point see AW Bedner, “Amalgamating Environmental Law in Indonesia” in J Arnscheidt et al, eds, *Lawmaking for Development: Explorations into the Theory and Practice of International Legislative Projects* (Netherlands: Leiden University Press, 2008) 171.

Also, SSA countries can learn from India's adaptation of patent rules to local conditions. For instance, section 3(d) of India's *Patent Amendment Act*, 2005 provides that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance..." is not considered an invention. Indeed, there is evidence that this requirement for 'enhanced efficacy' under India's patent law has ensured that pharmaceutical patents are not issued for 'me too drugs'.<sup>99</sup> In consequence, adopting a similar approach can guide and/or assist patent offices in checking pharmaceutical patent quality in SSA.

It must suffice here to state that the problems relating to pharmaceutical patents in SSA are not only institutional. There are also provisions in the domestic statutes of SSA states that could serve as barriers to access medicines in SSA. Thus, even if the institutional and infrastructural challenges were to disappear, the state of existing laws in many SSA countries would hinder any meaningful access to medicines at affordable prices. In discussing some of the inhibiting-provisions below, I employ South Africa's patent regulatory framework as a model for pharmaceutical patent reforms across SSA.

## **B. Reforming Patent Laws in SSA Countries**

As earlier stated, SSA countries have enacted TRIPS-compliant rules on drug patenting as part of their legal and institutional frameworks on IP rights protection. In other instances, their compliance with international patent standards is procured through regional arrangements under the ARIPO and OAPI frameworks, and further reinforced through TRIPS-plus bilateral agreements. Though questionable, one of the perceived benefits for generalizing the application of patent rules is that patent exclusivity allows

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<sup>99</sup> See *Novartis AG & Another v Union of India & Others* (2007) 4 MLJ 1153, online: <[http://www.gnaipr.com/GNACaseLaws/Judgement\\_GliveCpdf](http://www.gnaipr.com/GNACaseLaws/Judgement_GliveCpdf)>; Chennai Patent Office order in the application for patent no. 1602/MAS/98 filed on 17 July 1998, online: <<http://www.gnaipr.com/Articles/Glivec%20Order.pdf>>.

private pharmaceutical companies to recoup their investment in research and development and to make profits. To this end, the patent statutes of SSA countries grant protection for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.<sup>100</sup> In SSA, the vast majority of such registered inventions are pharmaceutical patents, and the holders of those patent-grants are predominantly foreign nationals and big pharma.<sup>101</sup>

The grant of patent protection confers on the owner the right to exclude others from making, using, importing, or selling the patented product or process.<sup>102</sup> Further, patents allow the right holder to stock the patented product for purposes of offering it for sale or use.<sup>103</sup> The right holder can also grant a license or assign the whole or any part of his interest in the patent. Generally, this exploitation of pharmaceutical patent rights in SSA countries subsists for a period of 20 years from the date of the application.<sup>104</sup> And, the grant of patent exclusivity in African countries has similar effect against private persons and the state.<sup>105</sup> In essence, patent rights are enforceable in court against a third party, be it an individual, a company or a state agency.

However, as this study focuses on finding ways to maximize patent rules to scale up access to medicines in SSA, limitations, exceptions and/or exclusions under national

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<sup>100</sup> See section 25(1) of South Africa's *Patent Act No. 57* of 1978 (as amended). Other countries' formulation is a verbatim reproduction of the patentability requirements contained in the TRIPS Agreement: see section 3(1) of Ghana's *Patents Act*, 2003 (Act 657); section 8 of Uganda's *Patent Act*, 1993; Botswana's *Industrial Property Act No. 14* of 1996.

<sup>101</sup> See A Samuel Oddi, "The International Patent System and Third World Development: Reality or Myth?" (1987) 63 Duke LJ 831 at 843, 853; Mgbeoji, "TRIPS and TRIPS-Plus in Africa", *supra* note 15 at 292. The reality is that only 0.01 per cent of patent applications filed in 1997 were by residents in SSA. This reality calls into question whether these countries have derived any benefits from changing their IP laws and creating the institutions for the enforcement of patent rights.

<sup>102</sup> See section 45(1) of South Africa's *Patent Act No. 57* of 1978 (as amended); section 11 of Ghana's *Patents Act*, 2003 (Act 657).

<sup>103</sup> See section 11(2) of Ghana's *Patents Act*, 2003 (Act 657); section 25 of Uganda's *Patent Act*, 1993.

<sup>104</sup> See Section 46(1) of South Africa's *Patent Act No. 57* of 1978 (as amended); section 12(1) of Ghana's *Patents Act*, 2003 (Act 657).

<sup>105</sup> See Section 4 of South Africa's *Patent Act No. 57* of 1978 (as amended).

patent laws and beyond remain crucially important. Thus, pro-access legal mechanisms built into the patent legislative frameworks of SSA countries can be used to circumvent the monopoly conferred by patents. Therefore, SSA countries need to establish appropriate provisions in their national patent legislation to encourage the use of compulsory licenses, parallel imports, competition law, and other pro-access mechanisms to get medicines to their citizens. In this respect, I critique a number of extant statutory provisions contained in the patent laws of SSA countries and suggest that the South African patent regulatory regime (which reflects the country's social reality in promoting public health) provides a useful model for other countries in SSA desirous of improving access to medicine.

### **1. Patent-Related Rules on Compulsory Licensing**

Compulsory licensing is a regulatory mechanism that allows public authorities to authorize the use of patented pharmaceuticals by third parties without the consent of the right-holder. The use of a compulsory licensing mechanism in South Africa is one of the pressing issues that had occupied trade policy discourse in the last decade. Section 56 of South Africa's patent legislation allows a person to apply to the registrar of patents for a compulsory license on the grounds that the rights in a patent are being abused. The particulars of abuse of patents include the non-working of the patent on a commercial scale. Also, if the working of the invention on a commercial scale is being hindered by the importation of the patented article, it may amount to abuse.<sup>106</sup> Further, if the price charged for the patented article in South Africa as compared to the price on foreign markets is excessive or if the public interest would be prejudiced without the grant of a license, then a compulsory license could be granted for the exploitation of the patent.<sup>107</sup>

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<sup>106</sup> Section 56(2) of South Africa's *Patent Act No. 57 of 1978* (as amended).

<sup>107</sup> Section 56(2) of South Africa's *Patent Act No. 57 of 1978* (as amended).

Thus far, two NGOs have employed section 56 of the South African Act to obtain non-exclusive voluntary licenses to import generic nevirapine products.<sup>108</sup>

In addition, South Africa has adopted a National Drugs Policy with the goal of “ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa”.<sup>109</sup> Based on this Policy, South Africa amended its *Medicines and Related Substances Control Act* in 1997 to allow for the Minister of Health to abrogate patent rights for pharmaceuticals, to issue compulsory licenses and to allow parallel imports of pharmaceuticals. This legislation was invoked by the Minister to allow third parties to manufacture and/or import generic medicines in treating the HIV/AIDS menace in South Africa. In response, South Africa was placed on the United States Special 301 Watch List and 39 pharmaceutical companies filed a suit challenging the law. However, worldwide public outrage against the US and the drug companies caused them to reverse unjust courses. Based on this South African experience, proponents of global public health issues have succeeded in pushing for the moderation of WTO patent rules across jurisdictions. Indeed, the South African experience has influenced the outcomes of post-TRIPS patent discourses including the adoption of the Doha Declaration and the ‘August 30’ Decision. Now, these post-TRIPS flexibilities allow countries to use compulsory licensing and to determine the grounds on which to grant them. The Doha Declaration also allows countries to determine what constitutes a national emergency or urgency, which can ease the granting of compulsory licenses. Furthermore, the ‘August 30’ Decision allows for countries with manufacturing capacities to use compulsory licenses for the purposes of exporting generic medicines to poor countries in SSA.

Despite the opportunities provided by these post-TRIPS flexibilities, many SSA countries have not fully incorporated compulsory licensing flexibilities into their national legal

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<sup>108</sup> See TAC Electronic Newsletter: “Generic Antiretroviral Procurement Project (GARPP) and TAC Treatment Project Request Permission to Import Generic Nevirapine”, online: <[http://www.taCorg.za/newsletter/2003/ns28\\_09\\_2003.htm](http://www.taCorg.za/newsletter/2003/ns28_09_2003.htm)>.

<sup>109</sup> *National Drug Policy for South Africa* (1996) at 3.

frameworks. The patent laws of Botswana, Ghana, and Uganda have not embraced the post-TRIPS flexibilities under the Doha Declaration, the ‘August 30’ Decision, and the resultant amendment to TRIPS. In Botswana, for instance, the use of compulsory licensing on grounds of public health shall be predominantly for the supply of the domestic market.<sup>110</sup> Even when a person applies to the High Court for the grant of a license on grounds that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms, such authorization by the court shall be for the supply of the patented invention predominantly in Botswana. This requirement that the use of compulsory licenses shall be for the supply of the local market is not consistent with the post-TRIPS mitigation measures under the ‘August 30’ Decision and the subsequent amendment to TRIPS.

Equally, the patent law of Ghana places several restrictions on the use of compulsory licensing mechanisms by the Minister for Justice (instead of the Minister for Health, as in South Africa). First, before taking the decision to grant a compulsory license, the Minister must hear the owner of the patent.<sup>111</sup> Second, any request for a license (except in cases of national emergency or extreme urgency) must be accompanied by evidence that the patent holder has refused to grant such a license on reasonable commercial terms and conditions and within a reasonable time.<sup>112</sup> Third, like Botswana’s patent regime, the patent law of Ghana allows for compulsory licensing mechanisms to be used predominantly for the supply of the Ghanaian market.<sup>113</sup> Given the earlier analyses of the developments under the Doha Declaration, the ‘August 30’ Decision, and the resultant amendment to TRIPS, these restrictions on the use of compulsory license in Ghana are aberrations, and thus not needed in Ghana. In particular, prior consultation with the patent holder before the grant of compulsory license is not required in cases of national

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<sup>110</sup> Section 30(2) of Botswana’s *Industrial Property Act No. 14* of 1996.

<sup>111</sup> See Sections 13(3) of the Ghana’s *Patents Act*, 2003.

<sup>112</sup> See Sections 13(9)(10) of the Ghana’s *Patents Act*, 2003.

<sup>113</sup> Sections 13(11) of the Ghana’s *Patents Act*, 2003.

emergency or other urgent circumstances, or in cases of public non-commercial use, or when licenses are needed to remedy anti-competitive practices.

As compared to Ghana and Botswana, Uganda has the most restrictive provisions on the use of compulsory licensing in parts of Africa. First, in Uganda, the Minister responsible for patent registration has limited powers to authorize a third party to exploit a patented invention. Even before such authorization could be granted, the right holder must be given prior opportunity to be heard. Alternatively, the citizens can use the judicial system to approve the grant of such licenses.<sup>114</sup> Such applications could only be brought to court after four years from the filing date of an application or three years from the grant of a patent. It is, however, difficult to deny that using time conditionalities to constrain the use of compulsory licensing is not consistent with international norms on patent, particularly those dealing with the use of compulsory licensing to tackle public health concerns. Also, relying on the judicial system for the grant of compulsory licenses against giant pharmaceutical companies could be too costly for the ordinary citizen of Uganda. Moreover, inordinate delays in the administration of justice are common phenomena that cut across the entire SSA region. It follows that when the livelihoods of individuals are at stake, owing to the onslaught of the HIV/AIDS, malaria, and TB epidemics, any delays in accessing life-saving medication is unacceptable.

From the foregoing, it needs to be observed that implementing international and regional patent rules affecting pharmaceuticals in many SSA countries flies in the face of the flexibilities under the Doha Declaration and the ‘August 30’ Decision. LDCs such as Uganda and Botswana protect pharmaceuticals in spite of the moratorium under Doha which allows LDCs not to comply with patent rules until 2016. In so doing, national patent regulatory frameworks affect the space available to them to formulate patent and access policies of their choice. Accordingly, SSA countries need to amend their patent

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<sup>114</sup> Section 30 of Uganda’s *Patent Act*, 1993.

legislation to make it easier for compulsory licenses to be granted to third parties to produce and/or sell essential medicines. Such legislative reforms should take account of some of the post-TRIPS mitigation measures detailed earlier under this chapter. As I explain further below, such reforms should take into account local conditions and needs in matters of access to medicine. Additionally, countries need to build domestic technological capacities to manufacture generic medicines or attract foreign investment into the generic industry. Meanwhile, countries that lack the technological and economic capacity to manufacture drugs (as majority in fact lack such capacity in SSA) should explore alternative means of importing cheaper generics from abroad through parallel imports.

## **2. Patent-Related Rules on Parallel Imports**

The use of parallel imports allows for cross-border trade in patented medicines at reduced prices without the consent of the patent holder. Given that the pricing of medicines is not uniform across jurisdictions, a country with limited manufacturing capabilities can purchase patented and/or generic medicines from abroad at reduced prices, rather than buying it directly in its domestic market at the higher price.<sup>115</sup> Also, patent laws determine whether a patent owner could still exercise control over patented medicines after the sale of that item. The position is that a patent owner cannot use its IP rights to prevent resale of goods that it/he sells on the market. In legal terms, the patent owner is said to have exhausted its/his property rights in the products actually sold because the right holder is presumed to have received an adequate reward from that first sale.<sup>116</sup> This exhaustion rule is supported by Article 6 of TRIPS and it can operate at the domestic level or at the international level. It bears emphasizing however that the rule on international exhaustion provides more latitude for the resale of patented drugs without the permission of the right holder. As Outtersson opines, the international exhaustion rule

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<sup>115</sup> See UNAIDS, “Using TRIPS Flexibilities to Improve Access to HIV Treatment” in *AIDS at 30: Nations at the Crossroads* (2011) at 3, online: <<http://www.unaids.org/en/resources/unaidspublications/2011/>>.

<sup>116</sup> Ho, *Access to Medicine*, *supra* note 81 at 40.

removes patent law barriers to cross-border trade in patented and generic medicines.<sup>117</sup> On the flip side, domestic exhaustion limits the possibility for the resale of patented medicines to the domestic market in question.

In consequence, a country must have a flexible legal framework in place in order to make use of this doctrine of exhaustion. However, a nuanced reading of the patent laws of many SSA countries provides mixed signals. Whereas a number of countries have in place regimes for the application of the international exhaustion doctrine others follow the doctrine of domestic exhaustion. For example, the patent law of South Africa allows article put on the market anywhere by the patentee or his licensee to be imported into the country.<sup>118</sup> The application of the exhaustion rule under South Africa's patent law is further supported by the *Medicines and Related Substances Control (Amendment) Act*.<sup>119</sup> The Act: (1) promotes parallel imports of patented medicines in order to reduce drug prices, (2) compels pharmacists to dispense cheaper generics, unless otherwise requested by the doctor, and (3) establishes a pricing committee to supervise local drug pricing by big pharma. This South African law fits into the category of problem-solving legislation,<sup>120</sup> and is thus aimed at scaling up access to generic antiretroviral medicines to fight the HIV/AIDS menace in South Africa.

Likewise, Ghana's patent law allows for the application of the international exhaustion rule. It provides that when the product or process is put on the market in any country by the owner or with the owner's consent, then the owner's rights are exhausted.<sup>121</sup> This provides more latitude to source lower-priced medicines from abroad after comparing the prices in different markets. Thus far, in October 2005, the government of Ghana issued

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<sup>117</sup> Kevin Outterson, "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets" (2005) 5 Yale J Health Pol'y L & Ethics 193 at 209-210.

<sup>118</sup> See section 45 of South Africa's *Patent Act No. 57 of 1978* (as amended).

<sup>119</sup> No. 90 of 1997.

<sup>120</sup> I discuss below how to use problem-solving or evidence-based methodology to improve patent lawmaking in SSA.

<sup>121</sup> Section 11(4)(a) of Ghana's *Patents Act, 2003* (Act 657).

one government use order to import generic antiretrovirals from India to treat HIV/AIDS patients; and, this reduced the cost of treatment from US\$495 to US\$235 for one year's treatment.

The mode of application of the exhaustion doctrine in Uganda and Botswana is different, however. Both countries follow the doctrine of domestic exhaustion. In Botswana, the exploitation of patent rights shall not extend to "acts in respect of articles which have been put on the market in Botswana by the owner of the patent or with his consent."<sup>122</sup> Likewise, Uganda's patent law provides that acts done in respect of articles that have been put on the market in Uganda by the owner of the patent or with his consent do not constitute a violation.<sup>123</sup> It bears emphasizing that following the doctrine of domestic exhaustion in Botswana and Uganda is unnecessarily restrictive since articles put on foreign markets are not allowed to be imported without the consent of the patent owner. Agreeing to relinquish rights to permit parallel importation of cheaper medicines from abroad restricts the options available to local distributors as well as consumers who may be in need of essential medication.

In learning from the South African experience, countries need to amend their laws to give more latitude to third parties to import patented and generic articles from foreign markets. In reforming their rules on exhaustion, SSA countries should focus on encouraging parallel imports in order to enhance the competitiveness of local pharmaceutical companies. Without that, the competitiveness of such local companies may be jeopardized as a result of being restricted to buy solely from a local distributor whose prices may be higher than those charged elsewhere.<sup>124</sup> The reforms must also have general provisions on parallel imports as well as specific provisions on parallel importation of medicines

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<sup>122</sup> Section 24(3) of Botswana's *Industrial Property Act No. 14 of 1996*.

<sup>123</sup> See section 28(b) of Uganda's *Patents Act*, 1993.

<sup>124</sup> See Carlos M Correa, "Intellectual property rights and public health: the general context and main trips compliant flexibilities" in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 11 at 15, online: <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)>.

from abroad to tackle epidemics such as HIV/AIDS, malaria, and TB. Further, as in South Africa, SSA countries need to introduce mechanisms for checking medicine pricing abuses in the domestic markets via competition law.

### 3. Competition Laws in SSA

The use and enforcement of competition law in South Africa has proven effective in checking pharmaceutical pricing abuses and ensuring access to affordable medicines. Equally, the experience of South Africa in using competition law to increase access to medicines for the treatment of pandemics provides helpful insights into the potential benefits of exploiting competition law and policy in other SSA countries.<sup>125</sup> For instance, South Africa's *Competition Act No. 89 of 1998* provides distinct oversight mechanisms to check anti-competitive practices in its marketplace. The South African Act is implemented by an independent competition authority vested with strong investigative powers. The Competition Commission, as the regulatory authority, is mandated to investigate any matter that is in the public interest simply on the basis of a third party complaint. The Commission is also required to implement measures to increase market transparency and to develop public awareness of the provisions of the Act, among others. The South African Competition Act also establishes a Competition Tribunal to adjudicate over matters of unjust restrictions, abuse of dominant positions, and mergers.<sup>126</sup> The work of the Competition Tribunal complements that of the Commission.

Thus far, two important cases that touch on access to medicines have come up for consideration by the Competition Tribunal established under the law. First, in 2002, a group of concerned individuals and organizations launched a complaint against

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<sup>125</sup> Tenu Avafia, et al, "Using Competition Law and Policy to Increase Access to a Sustainable Supply of Affordable Medicines" in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 191 at 192, online: <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)> [Avafia, et al, "Using Competition Law and Policy"].

<sup>126</sup> See the Preamble to the Competition Act No. 89 of 1998 (assented to on 20 October 1998) online: <[http://www.saflii.org/za/legis/num\\_act/ca1998149.pdf](http://www.saflii.org/za/legis/num_act/ca1998149.pdf)>.

GlaxoSmithKline (GSK) and Boeringer Ingelheim (BI) at the South African Competition Bureau.<sup>127</sup> The complaint was that the companies engaged in excessive pricing of antiretroviral medicines to the detriment of consumers. On October 16, 2003, the Competition Commission found that the respondents had contravened the *Competition Act*, 1998 of South Africa by abusing their dominant positions. In particular the respondents were held to have hindered competitors from having equal access to the markets and engaged in excessive pricing and in an exclusionary act. In further reference to the Competition Tribunal, the Competition Commission recommended: (1) the use of compulsory licenses to allow third parties to market generic versions of GSK's and BI's patented medicines, in return for the payment of a reasonable royalty, and (2) a 10 per cent penalty on GSK's and BI's annual turnovers in South Africa for each year that they are found to have violated the Act. These measures forced the two companies to the negotiating table. Eventually, GSK and BI granted voluntary licenses to both private and public sector marketers in return for royalties below 5 per cent. A similar approach to using and enforcing competition law in South Africa resulted in a voluntary settlement in the matter of *Treatment Action Campaign v Bristol-Myers Squibb* in July 2005; this settlement reduced the price of amphotericin B by more than 80 per cent.<sup>128</sup>

Second, in 2005, the Competition Tribunal had to consider an application to sanction a merger between two health care groups in the administration of 'capitated managed care options', which sought to provide low-income earners with access to private health care services. In refusing to sanction the merger, the Tribunal reasoned that the horizontal dimensions of the merger (including possible price fixing among competitors) were likely to lead to a substantial lessening of competition in the relevant market. It opined that "the general state of healthcare provisioning in South Africa, the policy objectives of the South African Government in the realm of healthcare provision, the mechanisms whereby

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<sup>127</sup> See *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, online: <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf>

<sup>128</sup> Avafia, et al, "Using Competition Law and Policy, *supra* note 125 at 199.

government intends achieving those objectives, and the place and role of the private sector” worked against the merger.<sup>129</sup> For the Tribunal, the merger would serve to increase concentration, and in effect reduce the three viable competitors to two, being the first and second appellants and Carecross. However, on 31 January 2006, the Competition Appeal Court overturned the ruling of the Competition Tribunal and approved the merger unconditionally.<sup>130</sup> It noted that the Tribunal misdirected itself by adopting a ‘cautious and circumspect approach’ to the merger and over-relying on public interest considerations before reaching its decision. Further, the Competition Appeal Court noted that there is evidence that the proposed merger would allow other competitors with sound financial and administrative networks to compete on the market.

Whatever the outcome of the above noted cases, the South African experience shows that competition law and policy instruments can be employed to great effect, particularly in a context where governments are unwilling or unable to act. The point is that access to medicine will be enhanced by relying on the normative values from other disciplines such as competition law and reforms. In addition to the legal reforms, countries must also have in place a legal culture that supports resolving disputes through the courts as done in South Africa. The South African experience and how it supports the litigation of public health right issues through the court system is addressed in chapter 6 of this study. Suffice it to say that in South Africa, civil society’s involvement in promoting competition has increased access to affordable medicines that are sorely needed in other SSA countries. Therefore, based on this South African experience, countries in SSA such as Ghana that do not have competition legislation and institutions to check anti-competitive practices need such regulatory frameworks. The established bodies under the

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<sup>129</sup> *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd* (Competition Tribunal, case no: 11/LM/Mar05, 13 October 2005).

<sup>130</sup> *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd v The Competition Commission*, 55/CAC/Sep05, online: <<http://www.comptribco.za/assets/Uploads/Case-Documents/Medicross%2055CACSep05.pdf>>.

competition law would have to be independent from governmental control and must be given powers to enforce the law. Also, SSA countries that have competition legislation need to strengthen their enforcement mechanisms.

Overall, the use of competition law should aim at providing adequate remedies in the form of statutory limitations or compulsory licences if: (a) the use of the patented product/process is indispensable for competition in the relevant market; or (b) the use of an IP right results in the abuse of a dominant position on the relevant market.<sup>131</sup> The use and enforcement of competition law should also empower citizens to become active players in the discourse on pharmaceutical patents and access to medicine issues. Thus, in checking anti-competitive practices, resources should be made available to complainants, including providing them with access to certain information held by industry that will ordinarily not be accessible.<sup>132</sup> That way, the use and enforcement of competition law would work to complement other pro-access rules such as compulsory licensing and parallel imports that were earlier discussed.

#### **4. Patent-Related Rules on Biopiracy**

The quest for recognition of the contribution of indigenous communities in the inventive processes is increasingly gaining attention in global trade relations. At least from 1992 when the UN' framework *Convention on Biological Diversity*<sup>133</sup> was concluded to date, there has been a movement to create regional and national regimes to govern access to indigenous resources and to share in the benefits of modern scientific endeavours.<sup>134</sup> Equally in SSA, proactive efforts have been made through regional and national

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<sup>131</sup> This suggestion is taken from: Jens Schovsbo, "Fire and Water Make Steam – Redefining the Role of Competition Law in TRIPS" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 308 at 352.

<sup>132</sup> Avafia, et al, "Using Competition Law and Policy", *supra* note 125 at 200.

<sup>133</sup> 31 ILM 818 (1992).

<sup>134</sup> Chidi Oguamanam, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (Toronto: University of Toronto Press, 2006) at 4.

arrangements to recalibrate patent rules to take account of the use of indigenous resources. For example, ARIPO members have concluded a Protocol<sup>135</sup> to deal with traditional-knowledge-based inventions. This Protocol seeks to empower the custodians and holders of traditional knowledge and expressions of folklore to utilize their knowledge for socio-economic development and wealth creation. The implementation of this Protocol is intended to curtail ongoing misappropriation and bio-piracy, and prevent illicit claim of traditional knowledge-based inventions and patent applications.<sup>136</sup> Since SSA countries are rich in indigenous resources including traditional medicines, the implementation of this Protocol in national legislation promises to give recognition to indigenous rights over genetic resources in modern biomedical and patenting endeavours.

Again, South Africa has taken a lead by amending its patent law to insist that all patent applications should be accompanied by a statement disclosing whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.<sup>137</sup> After the required disclosure, the registrar of patents shall call upon the applicant to furnish proof as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use. This regulation will attach some sort of communal encumbrance to the private rights over indigenous-resource-based patents. Complying with the obligation to disclose the use of traditional knowledge should form the basis for states and communities to negotiate effective benefit sharing and use agreements, and to institute appropriate mechanisms for enforcement.<sup>138</sup> For

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<sup>135</sup> See the *Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore*, 2010. This Protocol was adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia) on 9 August 2010. This Protocol was adopted by the ARIPO member states and signed by nine States comprising: Botswana, Ghana, Kenya, Lesotho, Liberia, Mozambique, Namibia, Zambia, and Zimbabwe.

<sup>136</sup> See ARIPO website <<http://www.aripo.org/>>.

<sup>137</sup> See South Africa's *Patents Amendment Act No. 20* of 2005.

<sup>138</sup> See Jacques de Werra, "Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?" (2009) 42 *Vand J Transnat'l L* 143.

Cann, the failure to disclose material information, such as the source of biological resources contained in an invention, for purposes of an application should be considered as an inequitable conduct to warrant the revocation of the patent in question.<sup>139</sup> To support it all, South Africa has a database of traditional medicinal knowledge that can aid in tracking and scrutinizing inventions that are derived from genetic resources. This South African experience also provides a useful model for other SSA countries desirous of benefiting from traditional knowledge-based inventions.

However, despite the suggestions for SSA countries to learn from the South African approach to patent regulation of pharmaceuticals, the South African regime is not without problems. As one commentator has observed, there are instances when South Africa has been unable to do a thorough substantive examination of patents because of the lack of a sufficiently qualified pool of examiners to perform examinations.<sup>140</sup> Further, the right to oppose a patent application before it is granted is lacking in South African law. However, once a patent is granted in South Africa, the public can apply to inspect the patent and the application and all its supporting documents in the patent office.<sup>141</sup> Preferably, avenues should be provided for pre-grant opposition proceedings during patent application processes because the court processes tend to be more expensive and cumbersome. As noted in chapter 4, the use of patent opposition proceedings aided the Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People successfully to oppose GlaxoSmithKline's patent application for zidovudine and lamivudine in 2006 on the grounds that the patent claim in question was not for a new invention.<sup>142</sup> Without

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<sup>139</sup> See Michael A Carrier, "Cabining Intellectual Property through a Property Paradigm" (2004) 54 Duke LJ 1 at 110.

<sup>140</sup> See Chan Park, "Challenging pharmaceutical patents: the case of India" in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 107 at 108, citing MacDonald Netshitenze, *South Africa Department of Trade and Industry*, online: <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)>.

<sup>141</sup> Section 43(1) of South Africa's *Patent Act No. 57* of 1978 (as amended).

<sup>142</sup> See Hoen, *The Global Politics*, *supra* note 41 at 78; MANU/TN/1217/2008.

such public interest safeguards in the patent application processes, erroneous patents are more likely to issue.<sup>143</sup>

South Africa's problem-solving approach to patent regulation coupled with its strong industrial base has positioned the country as an important player in the global trading system. Given its technological capacity, South Africa could spearhead efforts to maximize access to patented and generic medicines through South-South collaborative initiatives among SSA countries.<sup>144</sup> Indeed, paragraph 6 of the 'August 30' Decision supports such collaborative initiatives for "harnessing economies of scale for purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products." Also, while South Africa may differ in terms of its technological capacity and innovativeness, the lessons in using patent law and other regulatory instruments to promote compulsory licensing, parallel imports, competition, and anti-piracy, can and should apply broadly to other SSA countries. The need for legislative reforms in other SSA countries should begin with the amendment to national patent laws in order to optimally incorporate the flexibilities under the international patent system. The reforms must take into account the technologically deficient status of many SSA countries and the high incidence of epidemics in these countries. There should also be mechanisms for monitoring and evaluating the social impact of patent rules once implemented. As followed in South Africa, this problem-solving approach would provide deeper insights into building the factual basis required to revise and improve patent legislation.

## **5. Towards an Evidence-based Approach to Patent Lawmaking**

The problematic of patent regulatory and institutional frameworks in SSA countries has become far too glaring to ignore. Patent laws and institutions have been enacted and/or

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<sup>143</sup> Ho, *Access to Medicine*, *supra* note 81 at 225.

<sup>144</sup> For a comprehensive study on how to undertake such south-south cooperation see Sisule F Musungu et al, "Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks", *South Perspectives Report* (Geneva: South Center, 2004).

adopted as part of the legal systems of many SSA countries without adequate consideration of their impacts on local innovativeness. It is also difficult to deny that the implementation of international norms on patents has not succeeded in scaling up access to medicines in SSA. To a significant degree, patent rules have not resulted from a study of the conditions in SSA countries; the rules have been enacted based upon questionable property rights and/or efficiency-based utilitarian justifications, and have thus failed to respond accurately to social needs.<sup>145</sup> The prescription for making patent rules fit the social conditions in SSA countries is to adopt evidence-based approaches to implementing international norms on patents. An evidence-based approach rests on the proposition that, before enacting or revising patent legislation in SSA countries, law- and policy makers should consider real evidence and the actual environment in which the law will operate. In the particular case of SSA countries, it implies revising patent rules and policies with a pro-poor and pro-health emphasis so that medicines will be more affordable and accessible to their citizens. It also implies bringing an end to the use of faith-based approaches to pharmaceutical patent protection in SSA. This proposed evidence-based approach to patent lawmaking draws insights from the work of Seidman & Seidman on how legislation can be improved in African countries.<sup>146</sup>

Generally, Seidman & Seidman have theorized about the importance of drafting or revising laws based on the social conditions that prevail in the country concerned. They advocate a problem-solving methodology in enacting quality legislation and dealing with

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<sup>145</sup> See Roscoe Pound, "Mechanical Jurisprudence" in Ray D Henson, ed, *Landmarks of Law* (Boston: Beacon Press, 1960) 101 at 107. Pound criticizes the blind application of law without regard to the consequences; according to him, law is bound to fail if it does not respond accurately to social needs or standards.

<sup>146</sup> See AW Seidman & RB Seidman, "Lawmaking, Development and Rule of Law" in J Arnscheidt et al, eds, *Lawmaking for Development: Explorations into the Theory and Practice of International Legislative Projects* (Netherland: Leiden University Press, 2008) 91; Ann Seidman & Robert B Seidman, "Law in Aid of Development: 'Hasty Legal Transplants' and the Fatal Race" (2006) 1:2 *Journal of Comparative Law* 282.

the effects of legal transplantation in parts of Africa.<sup>147</sup> This problem-solving methodology advances the use of country specific evidence to influence legislative change in order to help solve a targeted social problem. Seidman & Seidman urge policy makers to adopt a fact-finding approach that can induce the desired social change necessary to promote local development. For them, legislative drafters should be equipped with training in gathering and organizing local available evidence to demonstrate that their proposed bill will likely achieve the desired social impact. Thus, proponents of patent legislative reforms should be able to justify the law with arguments supported by evidence that a reasonable person will accept. For Seidman & Seidman, the use of a problem solving methodology should bring about legislative changes that advance the public interest, rather than appealing to a section of society.

In an effort to show how their legislative theory's problem-solving methodology works in practice, the Seidmans have developed a manual for drafters working in developing contexts.<sup>148</sup> This manual provides models for designing and drafting laws based on facts and/or grounded on reasoned choice in the context of the lawmakers' own country-specific experience. In particular, the Seidmans indicate that Zambia has successfully employed this problem-solving methodology to do country-level research leading to the passage of legislation to maximize the use of natural resources to enhance development.<sup>149</sup> This Zambian law has also established a Law and Development Commission with a duty to conduct research and draft legislation based on empirical evidence, and to submit their results to Parliament for legislative action. Based on the

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<sup>147</sup> See Seidman & Seidman, "Lawmaking, Development and Rule of Law", *ibid*; Seidman & Seidman, "Law in Aid of Development", *ibid*; A Seidman & RB Seidman, *State and Law in the Development Process: Problem-Solving and Institutional Change in the Third World* (Basingstoke: Macmillan, 1994). Other theories of lawmaking discussed by the Seidmans include: the ends-means methodology that defines an end and looks for the most efficient means to achieve such end, and incrementalism, which suggests gradual but minimal changes in lawmaking.

<sup>148</sup> See Ann Seidman et al, *Legislative Drafting for Democratic Social Change: A Manual for Drafters* (The Hague: Kluwer Law International, 2001).

<sup>149</sup> Seidman & Seidman, "Lawmaking, Development and Rule of Law", *supra* note 146 at 105-116.

sector for which laws are made, this commission is encouraged to employ qualified experts and to follow legislative procedures that are transparent and accountable. The work of such law reform commissions should allow for public participation and realistic empirically founded lawmaking.

The use of an independent law reform commission to design and draft key pieces of legislation also proved effective in Ghana in the 1970s. The law reform commission system allowed for a much wider public scrutiny of legislative processes in the past, and this enhanced the quality of key Ghanaian legislation such as the *Limitations Act*, 1972 (NRCD 54) and the *Evidence Act*, 1975 (NRCD 323). More importantly, these Ghanaian laws were passed after broad-based consultations and public participation, at least among members of the legal community; and, the laws were/are accompanied by detailed memoranda explaining and justifying the provisions in light of the Ghanaian context. Such quality-control mechanisms are also needed in revising patent laws in many SSA countries. Perhaps, by following the law reform commission system (which is also evidence-based), domestic patent rules could be re-structured along human development lines, thus taking into account the impact-in-fact of such rules on access to medicine issues.

Admittedly, although the law reform commission system still operates in Ghana (as in many SSA countries), its importance has diminished for reasons including lack of financial and human resources. Besides arguments to establish and adequately resource law reform commissions in SSA countries, it is time for such independent commissions to be employed to design and draft patent laws based on empirically gathered evidence from the citizens and institutions. The commissions in SSA countries should conduct local assessment needs to ascertain the capability of domestic patent *institutions*, and draw from experiences or *practices* of countries such as India and Brazil in designing pro-access patent regulatory and institutional mechanisms in SSA. To cap it all, the legal and regulatory reforms must be backed by strong *political* will and commitments from

governments in SSA to supply essential medicines to their citizens. Countries should also give greater recognition to the fact that patent grants have “significantly different public welfare implications depending on their field of application and the level of development of the implementing country.”<sup>150</sup> Like Paul Simon’s famous lyrics, ‘One man’s ceiling is another man’s floor.’ Therefore, an approach to gathering local evidence by an independent law reform commission and considering local opinions before drafting patent legislation could make patent laws more useful in their domestic contexts. Without such quality-control mechanisms to patenting in SSA countries, WTO patent rules could become deadweight losses to many countries in Africa.<sup>151</sup>

Indeed, as explained in chapter 3, the need to adopt evidence-based consultations that allow for public participation in enacting crucial health-related statutes is followed in South Africa.<sup>152</sup> Also, this suggestion for taking account of real evidence and socio-economic conditions in reforming global patent rules is increasingly gaining root in the post-TRIPS era. For almost a decade, evidence of the failures arising from the implementation of WTO patent rules played a pivotal role in the launch of the Doha Round of trade negotiations, which have sought to emphasize the public health/interest dimension of global trade governance. Moreover, international documents such as the ICCPR assert that no trade or investment agreements should be concluded in the absence of a public debate and local content.<sup>153</sup> Using an evidence-based approach to lawmaking would facilitate the implementation and subsequent monitoring of patent legislation in order to suggest further reforms, if needed. This approach also holds the promise of enabling SSA countries to stay closest to the current and emerging situation on pharmaceutical patent regulation in the global economy. As I elaborate in chapter 7, this

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<sup>150</sup> Frederick M Abbott, “Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism” (2005) 8 J Int’l Econ L 77 at 77-78.

<sup>151</sup> See Okediji, “Africa and the Global IP System”, *supra* note 89 at 236.

<sup>152</sup> See *Doctors for Life International v The Speaker of the National Assembly & Others* 2006 (12) BCLR 1399 (CC) (SA).

<sup>153</sup> See *International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 171 (entered into force on 23 March 1976), Article 25(a).

claim to adopt evidence-based approaches to implementing global patent standards in SSA countries must be supported by an international legal framework in order to make it more effective.

## **V. Conclusions**

This chapter has stressed that TRIPS-compliant rules on drug patenting have become part and parcel of the legal and institutional frameworks of many SSA countries. In many instances, countries such as Ghana, Uganda, and Botswana have been ‘aided’ to adopt far more stringent patent rules than TRIPS actually requires. The implementation thus far of global patent standards in SSA countries has failed to fully utilize existing TRIPS-related flexibilities that can scale up access to essential medicines to treat epidemics. Further, some of the patent rules in SSA countries, owing to the lack of fine-tuning, provide robust protections to pharmaceuticals and have thus become drawbacks to access to essential medicines. Worse still, many SSA countries lack the institutional and human capability, which can absorb technology through the process of technology transfer, adaptation and diffusion.

Viewed this way, this chapter has urged the need for SSA countries to adopt evidence-based approaches to implementing international norms on patents. Such a broad-based approach to patenting holds the promise of taking account of the national context and making pharmaceutical patent regulation relevant to the citizens of SSA countries. It must, however, be admitted that an evidence-based approach to patent regulation that only utilizes the existing built-in flexibilities under TRIPS cannot fully address the gargantuan challenges facing the governments of SSA countries in supplying essential medicines to their citizens. A more sustainable approach, therefore, is to incorporate human development-oriented and human rights principles into the design, interpretation and implementation of WTO patent rules. The proposed blend of the concept of patent law with human development concepts would enrich the public interest objective of patent law in promoting access to essential medicines in poor countries. Put differently,

the concept of patent law will be relevant to the citizens of SSA countries if the globalized patent framework is reconstructed to be responsive to the health needs of individuals by incorporating human development concepts into the design of patent rules. Chapters 6 and 7 of this study analyze in detail these prescriptions for incorporating human rights/development-oriented concepts into the design, interpretation and implementation of WTO patent rules.

## Chapter 6

### Pharmaceutical Patents, the Right to Health, and Constitutional Supremacy in Sub-Saharan Africa

#### I. Introduction

The last half-century has spawned a considerable debate about human rights and its regime complex.<sup>1</sup> This regime complex consists of a web of interlocking national laws, constitutions, customs and practices, judicial decisions, and international and regional agreements regarding human rights. Also prominent in the human rights rhetoric is a growing body of academic literature describing human right norms as: *jus cogens*, global morality, obligations *erga omnes*, universal entitlements, the ‘veritable Magna Carta’ of humanity, and the inherent dignity and worth of humans.<sup>2</sup> In legal circles, the concept of human rights has attained a high priority status in the hierarchy of international legal norms as compared to private interests in pharmaceuticals. Indeed, human rights norms are universal ideals that transcend any limitations and inadequacies associated with the western concept of property ownership. Equally, the concept of human rights is immune to the criticisms levelled at the globalized patent regime. In consequence, this chapter aims to emphasize that access to medicine will be enhanced by relying on the universal ideals/norms from other disciplines such as human rights law to regulate the grant of pharmaceutical patents.

However, despite the superior legal status of human rights norms and the frequent use of pro-human rights metaphors in policy and academic discourse, the realization of the

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<sup>1</sup> See Stephen D Krasner, “Structural Causes and Regime Consequences: Regimes as Intervening Variables” in Stephen D Krasner, ed, *International Regimes* (Ithaca: Cornell University Press, 1983) 2 [defining regime complex as sets of implicit and explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area].

<sup>2</sup> For a plethora of pro-human right metaphors see generally: Wesley A Cann, “On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism” (2004) 25 U Pa J Int’l Econ L 755.

fundamental right to health,<sup>3</sup> which includes the right to access medicine, treatment and prevention measures, still faces significant challenges in SSA. The lack of adequate healthcare arises partly because patents make the cost of access to life-saving medicines prohibitively expensive for the sick population in less developed countries.<sup>4</sup> The preference for patents as a regulatory tool does not encourage efforts to develop other regulatory policies aimed at promoting the affordability of and/or access to essential life-saving medicines in SSA. In consequence, access to medicine as a human right<sup>5</sup> is constrained by the grant of pharmaceutical patent rights to private corporations, which regulate the prices of patented medicines on the market. Worse still, the public health crises epitomized by the HIV/AIDS, malaria, and TB epidemics add another layer of complexity to the already fragile healthcare services in SSA. Conceivably, the incidences of HIV/AIDS, malaria, and TB epidemics have outpaced governments' treatment capacities, and millions of people in SSA are deprived of their fundamental right to health.<sup>6</sup>

The goal of this chapter is to explore the intersections between human rights law and patent law in light of the access to medicine challenges in SSA. It proceeds on the

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<sup>3</sup> Other terms commonly used in the literature to describe health as a human right include 'the right to healthcare', 'the right to medical care', and 'the right to health protection'. In this study, I use the terms: 'right to health' and 'right to healthcare' interchangeably to describe the protection of health as a human right. Whereas the former term is mostly used in international human rights treaties, the latter term is more realistic in terms of implementation. The right to health also encapsulates the right to access to medicines.

<sup>4</sup> See Carlos Correa, "Trade Agreements on Intellectual Property and Public Health in Developing Countries" in *Globalization and Access to Drugs* (Geneva: WHO, 1999). At 82, Correa notes: "there is no doubt that patents lead to prices higher than those prevailing without protection. The generation of monopolistic rents is, in fact, the very purpose and essence of the patent system."

<sup>5</sup> The UN has put it beyond doubt that access to medication in the context of epidemics is an essential human right: see, UN Commission of Human Rights, *Access to Medication in the Context of Pandemics Such as HIV/AIDS*, UN Doc E/CN.4/RES/2001/33 (2001). Essential medicines are defined by the WHO as those medicines that satisfy the priority healthcare needs of the majority of the population. Such medicines must be available at all times, in adequate amounts and at an affordable price. See WHO, *The World Medicines Situation* (Geneva: WHO, 2004).

<sup>6</sup> Riadh Quadir, "Patent Stalemate? The WTO's Essential Medicines Impasse between Pharmas and Least Developed Countries" (2009) 61 Rutgers L Rev 437 at 444.

premise that HIV/AIDS, malaria, and TB epidemics raise fundamental human rights issues both in terms of the rights of persons infected and the lack of access to medicines to treat these pandemics in SSA.<sup>7</sup> It argues that the protection of the fundamental right to health should serve as a corrective measure against excessive exploitation of pharmaceutical patent rights in SSA. Human rights offer a framework for action to compel governments to provide healthcare services to their citizens and to alter the conditions, including unfair industry practices, which create, exacerbate, and perpetuate deprivation and marginalization in SSA.<sup>8</sup> Indeed, adopting a human rights-based approach to patent law-making will provide specific guidance to policy-makers to create exceptions to private pharmaceutical patent rights in SSA. In addition, a rights-based paradigm justifies trumping rigid pharmaceutical patent rules in favour of the right to health guaranteed in transnational human rights instruments and national constitutions in SSA. The salient point here is that human rights norms, with particular emphasis on the right to health, have a higher normative and constitutional value than WTO patent law.<sup>9</sup>

Against the backdrop of this introduction, part II of this chapter discusses the general intersections between patent law and human rights law. In recent years, the use of patents as instruments to promote public health has attracted significant attention and recognition in international patent polity. This part contributes to that debate and also responds to controversies surrounding the role of patents in promoting access to medicines in SSA. From this account, I adopt the perspective that a functioning patent system will play a key role in resolving the access-to-medicine problems in SSA. Thus, increasing access to effective, safe and affordable medicines is considered to be a crucial element of healthcare delivery in SSA.

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<sup>7</sup> See Cann, "IP Rights and Less Developed Countries", *supra* note 2 at 756.

<sup>8</sup> See Sofia Gruskin, "Rights-Based Approaches to Health: Something for Everyone" (2006) 9 Health and Hum Rts 5.

<sup>9</sup> See Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 203.

Part III details the provisions in international instruments, which oblige states to respect, protect and fulfil their obligations regarding health and healthcare. Specifically, I discuss the scope of the provisions on the right to health guaranteed in international documents, such as the *Universal Declaration of Human Rights*, 1948 (UDHR),<sup>10</sup> the *International Covenant on Economic, Social and Cultural Rights*, 1966 (ICESCR),<sup>11</sup> and the *International Covenant on Civil and Political Rights*, 1966 (ICCPR).<sup>12</sup> In addition, I analyze the normative content of the right to health in human rights discourse.

Part IV discusses the obligations of SSA countries to protect the fundamental right to health under the *African Charter*.<sup>13</sup> Here, I discuss how the right to health guaranteed under the *African Charter* has been interpreted by the African Commission on Human and Peoples' Rights (African Commission) in human rights jurisprudence. The African Commission has the mandate to promote and ensure the protection of human rights throughout the African continent.<sup>14</sup> This part also alludes to other sub-regional instruments in Africa that mandate SSA states to protect the fundamental right to health of their citizens. I conclude by discussing some states' practices that support the proposition that the right to health has become a general principle of international law.

Part V moves the discourse from the realms of transnational law into the field of domestic protection of the right to health in SSA. It posits that the fundamental right to health has been enshrined in many national constitutions in SSA and this trend gives especial significance to the right to health in human rights discourse at the domestic level. As a consequence, I employ the twin concepts of constitutional supremacy and the

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<sup>10</sup> Adopted by the UN General Assembly on 10 December 1948: UNGA Res 217A (III). As a General Assembly Resolution the UDHR is hortatory. Nevertheless, scholars agree that the UDHR exerts a binding effect of customary international law.

<sup>11</sup> Adopted on 16 December 1966, 993 UNTS 3 (entered into force on 3 January 1976).

<sup>12</sup> *International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 171 (entered into force on 23 March 1976).

<sup>13</sup> *African Charter on Human and Peoples' Rights*, 27 June 1981, 21 ILM 58 (entered into force on 21 October 1986) [*African Charter* or *Banjul Charter*].

<sup>14</sup> See Articles 30, 31 & 41 of the *African Charter*.

primacy of human rights to justify why the right to health should trump any patent limitations in order to facilitate access to medicines for the masses affected by epidemics in SSA. Here, I employ the South African constitutional jurisprudence on the protection of the right to health to inform this discussion. Part VI concludes this chapter.

## II. On the Intersections between Patents and Human Rights

Historically, patent law and human rights law evolved as relatively distinct concepts. Whereas patents are considered to be strict private property rights and thus not deserving unwarranted public interference, the right to health is viewed as human aspirations for which a state should endeavor to provide. Perhaps, patent law and human rights practitioners failed in the past to fully appreciate how either body of law could aid or threaten each other's sphere of influence or opportunities for expansion.<sup>15</sup> For Koopman, what accounts for this jurisprudential separation is that patent law is not rooted in morality, but rather in economic instrumentality.<sup>16</sup> On his part, Mgbeoji has remarked that "patents are not founded on human rights, global morality, or obligations *erga omnes*."<sup>17</sup> This assumed dichotomy between patents and human rights law has historically manifested in the legal community: few patent lawyers got involved with human rights law, and few human rights specialists dealt with patent issues.<sup>18</sup> Nevertheless, as noted in chapter 4, the influence of natural law theory in the design of the globalized patent rules highlights [or should have heightened] this interplay between patents, the price of essential medicines, and human rights law.

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<sup>15</sup> Laurence R Helfer, "Human Rights and Intellectual Property: Conflict or Coexistence?" (2003) 5 Minn Intell Prop Rev 47 at 51 [Helfer, "Human Rights and IP"].

<sup>16</sup> See Jerzy Koopman, "Human Rights Implications of Patenting Biotechnological Knowledge" in Paul LC Torremans, ed, *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights* (New York: Wolters Kluwer, 2008) 533 at 541.

<sup>17</sup> Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Vancouver: UBC Press, 2006) at 42.

<sup>18</sup> See Audrey Chapman, "A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to Benefits of Science" (1998) at 3, online: <<http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/chapman.pdf>>.

Today, the grant of patents and its broader impact on society in terms of access to life-saving medicines is increasingly being articulated in academic and policy discourse. Several factors coalesced to accentuate this synergy between patents and the right to access medicine. Most notably, the threat of the HIV/AIDS epidemic and the efforts in the late 1990s by the South African government to provide antiretroviral medicines to its citizens and the resulting trade dispute with pharmaceutical corporations and the US government was a significant factor in stressing this interface between patents and human rights. The South African experience drew significant attention to the effects of strong patent rights for pharmaceuticals on the citizens of SSA; it also made pharmaceutical companies accountable for their actions and inaction towards people threatened with pandemics, such as HIV/AIDS.<sup>19</sup> Further, the adoption of the Doha Declaration and the ‘August 30’ Decision, and the recent amendment to TRIPS highlight this overlap between patents and access to medicine issues, especially as it pertains to less developed countries. These ‘humanitarian’ initiatives sought to mitigate the hardships associated with the implementation of the *TRIPS Agreement* in order to promote public health in less developed countries. The point here is that the use of human rights rhetoric in connection with patent regulation emphasized the idea that the dignity of individuals must be central to the grant of pharmaceutical patent rights in domestic jurisdictions.

The concept of patent law intertwines with human rights law in three significant respects. The first intersection is based on the idea that patent rights should be treated as a basic human right. This notion of treating patents as a human right is rooted in the natural law rationale for patent protection and also shares experience with traditional (Eurocentric) human rights theory.<sup>20</sup> The second intersection between patents and human rights appears in the form of a conflict: the grant of exclusive patent rights in pharmaceuticals tends to

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<sup>19</sup> Ruth L Okediji, “The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual System” (2003) 7 *Sing JICL* 315 at 345.

<sup>20</sup> Daniel J Gervais, “Intellectual Property and Human Rights: Learning to Live Together” in Paul LC Torremans, ed, *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights* (New York: Wolters Kluwer, 2008) 3 at 4 [Gervais, “IP and Human Rights”].

undermine the realization of the right to access medicine. And, the third intersection between patents and human rights law involves efforts to reconcile both concepts in legal and policy discourse. This third approach thus seeks to promote a synergy between patent concepts and human rights law since both serve a common purpose in promoting human development. The following sections analyze these intersections in turn.

### A. Patents-as-Human-Rights

Proponents of the patents-as-human-rights view employ natural law arguments to justify and expand their claims for strong IP protection.<sup>21</sup> They assert that patent rights must be recognized as a basic human right and must thus be introduced as part of the fundamental bill of rights in domestic jurisdictions.<sup>22</sup> This argument for patents to be protected as a basic human right is further grounded on the need to foster security, protect individual autonomy, prevent piracy/theft, and protect other human rights such as the right to privacy.<sup>23</sup> On that score, proponents rely on international documents, which assert that the grant of exclusive patent rights over pharmaceuticals will eliminate trade barriers and foster international trade.<sup>24</sup> For them, the state has an obligation to respect, protect and enforce patents as private property rights of inventors against theft.<sup>25</sup> In light of these arguments, some scholars have even ventured to (mis-)characterize the *TRIPS Agreement*

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<sup>21</sup> Laurence R Helfer, “Toward a Human Rights Framework for Intellectual Property” (2007) 40 UC Davis L Rev 971 at 1017 [Helfer, “Toward a Human Rights Framework for IP”].

<sup>22</sup> Tom Giovanetti & Merrill Matthews, “Intellectual Property Rights and Human Rights” (2005) 34 IDEAS 1, quoted in Peter K Yu, “Reconceptualizing Intellectual Property Interests in a Human Rights Framework” (2006-2007) 40 UC Davis L Rev 1039 at 1084 [Yu, “Reconceptualizing IP Interests”].

<sup>23</sup> Philippe Cullet, “Human Rights and Intellectual Property Protection in the TRIPS Era” (2007) 29 Hum. Rts Q 403 at 406.

<sup>24</sup> See the Preamble to the World Trade Organization’s (WTO’s) *Agreement on Trade Related Aspects of Intellectual Property Rights* (adopted on 15 April 1994 and entered into force on 1 January 1995) 33 ILM 81.

<sup>25</sup> This view is influenced by the US patent jurisprudence; the US Constitution protects inventions under its Article 1 s 8 cl 8.

as a ‘charter of rights’ for patent holders,<sup>26</sup> thereby re-enforcing the ideals of the western concept of property ownership.

In addition, proponents of patents-as-entitlement thesis rely on both the UDHR and ICESCR in support of their claims for patents to be recognized as a human right. In particular, Article 27(2) of the UDHR provides that “everyone has the right to the protection of the moral and material interests resulting from any scientific...production of which he is the author [or inventor].” In a somewhat identical language, Article 15(1)(c) of the ICESCR requires each state party to “recognize the right of everyone...to benefit from the protection of the moral and material interests resulting from any scientific...production of which he is the author [or inventor].” The Committee on Economic, Social and Cultural Rights (which monitors implementation of the ICESCR) interprets Article 15(1)(c) of the ICESCR as granting regulatory discretion to states to implement IP systems in a manner that takes account of their economic, social and cultural conditions.<sup>27</sup> Thus, the implementation of the above knowledge-protection provisions is expected to be balanced against the need to promote the public right to enjoy the benefits of scientific progress and access to inventions.<sup>28</sup>

Critics on several fronts have assailed this approach of treating patents as human rights. According to Drahos the ‘instrumental’ character of the regime for protecting patent rights established by the provisions in the UDHR and ICESCR cannot rightly be said to

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<sup>26</sup> On this mischaracterization see Bitu Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (England: Ashgate, 2009) at 261, citing BK Keyala, *TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All* (New Delhi: CSGTSD, 1998) at 263.

<sup>27</sup> Committee on Economic, Social and Cultural Rights, General Comment No.17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author (Art. 15(1)(c)), para 18, 22-24 & 47, 12 January 2006, UN Doc E/C12/GC/17 [ESCR Committee or CESCR].

<sup>28</sup> See Article 15(1)(a)(b) of the ICESCR.

be a ‘fundamental’ human rights regime.<sup>29</sup> Besides the nebulous and permissive character of the above provisions, a careful and nuanced analysis of the drafting history of Article 27(2) of the UDHR and Article 15(1)(c) of the ICESCR confirms that the knowledge protection-related provisions are strictly not ‘fundamental’ human rights provisions.<sup>30</sup> While these provisions allow states to design IP protection systems in a manner that meet local needs, interests and goals, they do not oblige states to adopt a patent system that is exclusive for twenty years, as is presently the case under TRIPS.

Indeed, unlike classic human rights which are vested in natural persons and thus inalienable, the bulk of pharmaceutical patent rights are vested in artificial entities. The true character of patent rights is that they are creatures of statute and cannot rightly fit any notion of fundamental human rights. As private property rights, patents can be assigned, licensed, sold, or revoked; patent rights have thus been reduced to the status of trade law, a move that does not dovetail well with the notion of human rights.<sup>31</sup> Human rights can neither be granted nor repealed by any legislator.<sup>32</sup> Worth emphasizing is that the presence of the knowledge protection-related provisions in human rights instruments, such as the UDHR and the ICESCR, cannot change the nature of patents as temporary property interests.

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<sup>29</sup> See Peter Drahos, “The Universality of Intellectual Property Rights: Origins and Development” in *Intellectual Property and Human Rights* (Geneva: WIPO, 1999) 13; Peter Drahos, “Intellectual Property and Human Rights” (1999) 3 *Intellectual Property Quarterly* 349.

<sup>30</sup> For a thorough discussion of the drafting history of the UDHR and ICESCR, see: Yu, “Reconceptualizing IP Interests”, *supra* note 22.

<sup>31</sup> See e.g. Committee on Economic, Social and Cultural Rights, General Comment No.17: *The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author* (Art. 15(1)(c)), paras 2 & 7, 12 January 2006, UN Doc E/C12/GC/17. See generally Peter K Yu, “Challenges to the Development of a Human-Rights Framework for Intellectual Property” in Paul LC Torremans, ed, *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights* (New York: Wolters Kluwer, 2008) 77. Gervais, “IP and Human Rights”, *supra* note 20 at 7.

<sup>32</sup> Jakob Cornides, “Human Rights and Intellectual Property: Conflict or Convergence?” (2004) 7 *Journal of World Intellectual Property* 135 at 138.

Another possible objection to the patents-as-human-rights thesis is that the *TRIPS Agreement* does not describe patent rights as ‘human rights’ or ‘fundamental human rights’; rather, it refers consistently to the rights over inventions as: ‘rights’, ‘private rights’, and ‘exclusive rights’. Based on the basic rule of interpretation, *generalia specialibus non derogant* [the universal shall not detract from the specific], there is support for the argument that the phrasing of TRIPS prevails over that contained in any general human rights document on matters of IP. This approach to interpretation is in line with the *Vienna Convention*,<sup>33</sup> which codifies customary international law on treaty law. The *Vienna Convention* allows TRIPS’ provisions to take priority in matters of patents due to its specific character.<sup>34</sup>

Notwithstanding these lines of argument, chapter 4 has shown that the rhetorical significance of the natural law/human rights rationale in patent discourse has not yet diminished. Yu predicts that IP rights will be elevated to the status of human rights in *rhetoric* even if that status will not be elevated in *practice* as fundamental human entitlements.<sup>35</sup> Again, treating patent rights as fundamental human entitlements, whether in theory or practice, could hamper access to essential medicines in less developed countries. As Ostergard put it, the obligation to give priority to the well-being of the citizens of a country militates against any notions of treating patent rights as human rights.<sup>36</sup> This perceived conflict between patents and human rights is discussed next.

## **B. Conflict between Patents and Human Rights**

The second intersection between patents and human rights law is that the former severely undermines the realization of the fundamental human right to healthcare in poor

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<sup>33</sup> *Vienna Convention on the Law of Treaties*, 1155 UNTS 331 (23 May 1969) (entered into force on 27 January 1980) [Vienna Convention].

<sup>34</sup> See Articles 30 & 31 of the *Vienna Convention*.

<sup>35</sup> Yu, “Reconceptualizing IP Interests”, *supra* note 22 at 1127.

<sup>36</sup> Robert L Ostergard, *The Development Dilemma: The Political Economy of Intellectual Property Rights in the International System*, Eric Rice, ed (New York: LFB Scholarly, 2003) at 28-29; Robert L Ostergard, “Intellectual Property: A Universal Human Right?” (1999) 21 Hum Rts Q 156.

countries. According to Helfer, strong patent protection undermines – and is therefore incompatible with – a broad spectrum of human rights obligations, especially in the area of economic, social, and cultural rights.<sup>37</sup> Take, as an example, Article 8 of TRIPS and fundamental human rights provisions of national constitutions that mandate countries to adopt measures necessary to protect public health. On the flip side, Article 27 of TRIPS and national patent laws protect the right of patentees to exploit their inventions. Also, chapter 4 has demonstrated that patent law interferes with the right to health by creating regulatory dysfunctions such as excessive pricing of life-saving medicines and monopoly rents. The complaint brought before the South African Competition Bureau against GlaxoSmithKline and Boeringer Ingelheim for excessive pricing of antiretroviral medicines exemplifies this. Evidence also suggests that patent protection does not encourage research into diseases prevalent in less developed countries. Moreover, the globalized patent regime does not discourage the surge of biopiracy, but rather disdains matters of traditional knowledge.<sup>38</sup> Safe to say, trade restrictions affect the pursuit of non-trade objectives, including respect for the right to health.<sup>39</sup>

This conflicting view is confirmed by UN Sub-Commission Resolution 2000/7, which indicates that “actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, cultural and social rights.”<sup>40</sup> Accordingly, efforts are being undertaken to resolve this supposed conflict between patents and human rights law. For Helfer, the prescription for resolving this conflict is to recognize the normative primacy of human rights law over IP law in areas where specific

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<sup>37</sup> Helfer, “Human Rights and IP”, *supra* note 15 at 48.

<sup>38</sup> Chidi Oguamanam, “Local Knowledge as Trapped Knowledge: Intellectual Property, Culture, Power and Politics” (2008) 11 *Journal of World Intellectual Property* 29 at 32.

<sup>39</sup> See Joost Pauwelyn, “The Role of Public International Law in the WTO: How Far Can We Go?” (2001) 95 *Am J Int’l L* 535 at 539 [Pauwelyn, “Role of International Law in WTO”].

<sup>40</sup> UN Economic and Social Council, Sub-Commission on Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights*, Res 2000/7 UN Doc E/CN.4/SuB2/RES/2000/7, para 11 (17 August 2007) [UN Sub-Commission Resolution 2000/7 or Sub-Commission Resolution].

treaty obligations conflict.<sup>41</sup> Amani notes that “states should not be discouraged by the threat of trade sanctions in giving human rights obligations priority over trade in domestic law and policy.”<sup>42</sup> For her, this universal trumping of human rights norms over WTO patent rules will maximize states’ comparative advantage and lead to greater welfare.<sup>43</sup> It needs to be mentioned that these conclusions draw support from the UN Charter, which many classify as the Constitution of the international community and thus contains binding and universally accepted human right norms.<sup>44</sup> The UN Charter provides that in the event of a conflict between obligations under the UN Charter and obligations under any other international agreement, the obligation under the Charter shall prevail.<sup>45</sup>

The resolution of this patents/human rights conflict by the UN supports the approach that primacy should be given to human rights obligations over “economic policies and agreements”<sup>46</sup> and that “governments and national, regional and international economic policy forums [must] take international human rights obligations and principles fully into account in international economic policy formulation.”<sup>47</sup> This prescription is also supported by the Report of the UK Commission on Intellectual Property Rights: “there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection.”<sup>48</sup> Therefore, less developed countries

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<sup>41</sup> See Helfer, “Human Rights and IP”, *supra* note 15 at 48.

<sup>42</sup> Bita Amani, “Merchants and missionaries: Patenting life, competing international obligations and the proselytization of a Realistic Utopia” (SJD Dissertation, University of Toronto, 2007) at 1 (abstract).

<sup>43</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 330.

<sup>44</sup> See generally, Bardo Fassbender, “The United Nations Charter as Constitution of the International Community” (1998) 36 Colum J Transnat’l L 529; Ronald Macdonald, “The Charter of the United Nations in Constitutional Perspective” (1999) 20 Aus YB Int’l L 205; W Michael Reisman, “The Constitutional Crisis in the United Nations” (1993) 87 Am J Int’l L 83; Bernhard Schluter, “The Domestic Status of the Human Rights Clauses of the United Nations Charter” (1973) 61 Cal L Rev 110.

<sup>45</sup> See Article 103 of the UN Charter.

<sup>46</sup> Resolution 2000/7, para 3.

<sup>47</sup> Resolution 2000/7, para 4.

<sup>48</sup> *Integrating Intellectual Property Rights and Development Policy: Report of the UK Commission on Intellectual Property Rights*, (London, September 2002) at 7, online: <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)>.

can interpret human rights norms to impose limits on the grant of strong patent rights.<sup>49</sup> As I explain further below, the right to access medicine had become a norm of general international law and constitutional law. As such, the right to health can serve as a justification for states threatened with epidemics to limit pharmaceutical patent rights in order to cater to the needs of their citizens. That way, state agencies can correct some of the regulatory imbalances discussed in chapter 4. A human rights-based patent paradigm will also promote co-existence (i.e., a measured balance) between the protection of patent rights and the protection of the fundamental right to health in SSA.

### **C. Co-existence between Patents and Human Rights**

The third intersection between patent law and human rights adopts a co-existence approach. This co-existence approach is based on the axiom that every human right has an economic substratum. Without that economic substratum the right cannot possibly exist in practical terms, no matter how grounded its theory might be.<sup>50</sup> Likewise, patent law is relevant to the realization of the right to health because it provides the economic/juridical substratum for regulating pharmaceuticals, which grease the wheels of life. In this sense, patent law and human rights law share a common social goal of promoting access to medicines and enhancing human development. Thus, resolving the patent/human rights conflict in a manner which enhances access to essential medicines at prices affordable to the poor will promote coexistence between both concepts. In this regard, policy-makers must seek to achieve human rights ends through the instrumentality of patents.<sup>51</sup>

This notion that patents serve the social benefit goal of promoting access to medicines and public health has wide acceptance in international law, especially under Articles 7

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<sup>49</sup> Anupam Chander & Madhavi Sunder, "Is Nozick Kicking Rawls' Ass? Intellectual Property and Social Justice" (2007) 40 UC Davis L Rev 563 at 578.

<sup>50</sup> See Christopher G Weeramantry, "Human Rights and the Global Marketplace" (1999) 25 Brook J Int'l L 27.

<sup>51</sup> Helfer, "Toward a Human Rights Framework for IP", *supra* note 21 at 1017.

and 8 of the *TRIPS Agreement*. Both provisions stress the need to maintain a balance between the public interest in access to medicines and the private interest in reaping pecuniary benefits from innovations. Although I will discuss the scope of the objectives (Article 7) and principles (Article 8) of TRIPS in chapter 7 of this study, TRIPS must be read as permitting states to give priority to public health and human development concerns in the design of domestic patent policies. A functioning patent regime must help to improve the living conditions and standard of health of persons in a manner consistent with the ‘curative goals’ of human rights. For Amani, patents should exist as “rights of inclusion, participation and access that reasonably complement, rather than undermine, the realization of other human rights.”<sup>52</sup> That way, the *TRIPS Agreement* will not only be seen as trade-related, but also health-related.<sup>53</sup>

More importantly, the WTO favours this co-existence approach. For instance, the Appellate Body has ruled that the WTO Agreement should not be read in isolation from public international law.<sup>54</sup> This decision is congruent with suggestions that the WTO should apply the entire *corpus* of international law, including human rights norms in its dispute resolution mechanism.<sup>55</sup> The drawback in the WTO’s approach, however, is that the organization tends to limit itself to the use of the built-in ‘flexibilities’ under TRIPS to promote public health. As I will elaborate in chapter 7 of this text, this limited worldview of the WTO distorts the organization’s understanding of the public health debacle confronting countries in SSA, the region worst affected by the HIV/AIDS,

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<sup>52</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 14.

<sup>53</sup> See Frederick M Abbott, “Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism” (2005) 8 J Int’l Econ L 77 at 85.

<sup>54</sup> *United States – Standards for Reformulated and Conventional Gasoline*, WTO DoC WT/DS2/AB/R, para III (B) 1996.

<sup>55</sup> On this point see Pauwelyn, “Role of International Law in WTO”, *supra* 39 at 577.

malaria, and TB epidemics. For Stiglitz, the WTO's notion of flexibilities is tantamount to a blind appreciation of the "inflexibilities in [the] flexibilities" under TRIPS.<sup>56</sup>

From a different perspective, the Report of the UN Secretary General has concluded that "the TRIPS Agreement also promotes other values deemed essential for the realization of human rights."<sup>57</sup> Those values include TRIPS' rules against discrimination and the requirement of due process. This supposed complementarity between human rights and trade law has emboldened scholars to posit that violators of human right are also WTO rule violators.<sup>58</sup> A less radical proposition, however, is that WTO law must be interpreted consistently with universally recognized human rights. The interactions between human rights law and patent law would generate promising results if each were viewed as complementary to the other. However, the issue is not only that we must protect public health, but also how to go about it in order not to stifle innovation and research into epidemics afflicting the masses in SSA.

#### **D. The Role of Patents in the Access Landscape**

The above analysis of the intersections between patents and human rights law only represents the general story. The specific aspect of the story comes from scholars who contend that the problem of access to medicines to combat HIV/AIDS, malaria, and TB epidemics in SSA cannot be attributed to patents.<sup>59</sup> The thrust of this argument is that "the impact of patents is de minimis: 95 per cent of the WTO's essential drugs have never

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<sup>56</sup> Joseph E Stiglitz, "Economic Foundations of Intellectual Property Rights" (2008) 57 Duke LJ 1693 at 1717.

<sup>57</sup> Intellectual Property Rights and Human Rights: Report of the Secretary-General, Commission on Human Rights, Committee on Economic, Social and Cultural Rights Sub-Commission on the Promotion and Protection of Human Rights, UN Doc E/CN.4/SuB2/2001/12 (2001) 8.

<sup>58</sup> Robert Howse & Makau Mutua, "Protecting Human Rights in a Global Economy: Challenges for the World Trade Organization" in Hugo Stokke & Anne Tostensen, eds, *Human Rights in Development Year Book* (Millennium Edition, 2000) 51.

<sup>59</sup> See Amir Attaran & Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" (2001) 286 *Journal of the American Medical Association* 1886 [Attaran & Gillespie-White, "Access to AIDS Treatment in Africa"]; Gervais, "IP and Human Rights", *supra* note 20 at 20.

been or are no longer patented and most AIDS, malaria, or tuberculosis medication is not patented in the countries that are hardest hit.”<sup>60</sup> For example, a study by Attaran & Gillespie-White in 2001 concluded that since most antiretrovirals were not patented in Africa (except South Africa) patent protection was not a major barrier to access.<sup>61</sup> This study is often (mis)-interpreted as supporting claims that patents do not hinder access to medicines in SSA.<sup>62</sup> Further, the argument goes that in several African countries essential medicines are not patented. Alternatively, some pharmaceutical companies do not enforce patents on their essential medicines in SSA.<sup>63</sup> For his part, Gervais contends that since many countries in SSA need not adopt pharmaceutical patents until 2016, such countries have the latitude to utilize the flexibilities within the WTO system to supply medicines to their citizens.<sup>64</sup> Thus, the problems of access to medicines in SSA are exacerbated mainly by the lack of manufacturing capacity, non-existent distribution and delivery networks, and the absence of political will in less developed countries.

The assertion that patents are a de minimis contributor to the lack of sufficient access to medicines to alleviate human suffering in SSA is misplaced, however. First, the Doha Ministerial Declaration, the Doha Declaration, and the ‘August 30’ Decision confirm that patents on pharmaceuticals are a key factor in the lack of access to medicines in less developed countries.<sup>65</sup> These post-TRIPS developments acknowledge the inhibiting effects of patents on access to medicines and also urge states to place the public health interests of their citizens above the private interests of pharmaceutical companies. As net

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<sup>60</sup> See Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 150.

<sup>61</sup> Attaran & Gillespie-White, “Access to AIDS Treatment in Africa”, *supra* note 59 at 1890.

<sup>62</sup> On this point see Kevin Outterson, “Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets” (2005) 5 *Yale J Health Pol’y L & Ethics* 193 at 255.

<sup>63</sup> On this point see Eric Noehrenberg, “The Realities of TRIPS, Patents and Access to Medicines in Developing Countries” in Meir Perez Pugatch, ed, *The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy* (MA: Edward Elgar, 2006) 170 at 173, 183. It bears emphasizing that Noehrenberg is a Director at the International Federation of Pharmaceutical Manufacturers & Associations.

<sup>64</sup> Gervais, “IP and Human Rights”, *supra* note 20 at 20.

<sup>65</sup> See e.g. para 3 of the Doha Declaration; Para 17 of the Doha Ministerial Declaration.

importers of patented and generic medicines, SSA countries, like other less developed countries, spend as much as 70 per cent of their health budgets on medication as compared to 15 per cent spending on medication by the developed world.<sup>66</sup> Yet still, millions of people in SSA do not have access to medications due to the high prices of medicines.

The WHO, for instance, cites the high cost of medicines as a major hurdle that countries face in obtaining access to medication.<sup>67</sup> This viewpoint is confirmed by the WHO-Health Action International survey which has predicted that essential medicines will be very expensive and not universally available due to the prevailing patent regime.<sup>68</sup> Thus, on the preponderance of the empirical evidence, the major impediments to access to essential life-saving medicines are the strong global patent rules and the new trade-related barriers that are being erected to stifle the pipeline of drugs to African countries.<sup>69</sup> Accordingly, proposals have been made to the Council for TRIPS to extend the list of exceptions to patentability in Article 27.3(b) of TRIPS to include the WHO's essential drugs list in order to enhance the public health principles established in Article 8 of the *TRIPS Agreement*.<sup>70</sup>

Second, a number of strategies that hitherto allowed states to scale up access to medicines are no longer an option under TRIPS. As Hestermeyer aptly puts it, "cheap generics can only be manufactured where the medication is not protected by patents."<sup>71</sup> The fact that all countries with manufacturing capacity have become TRIPS-compliant since 2005 has significantly altered the access landscape. Major generic suppliers such as India, Brazil,

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<sup>66</sup> US Government Accountability Office, *Intellectual Property: US Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification* (GAO, 2007) at 8.

<sup>67</sup> See US GAO, *ibid* at 13.

<sup>68</sup> On this point see ZUD Babar et al "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia" (2007) 4 PLoS Med 467.

<sup>69</sup> S Srivastava & K Satyanarayana, "Universal Access to HIV/AIDS Treatment: Challenges Ahead" (2009) Indian J Med Res 671 at 672.

<sup>70</sup> See Venezuela's 6 August 1999 Communication to the TRIPS Council, WT/GC/W/282.

<sup>71</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 11.

and China now comply with TRIPS, a post-2005 development that renders the continuing validity of the study by Attaran & Gillespie-White questionable. The trend, according to Stiglitz, is that big pharma have resorted to a vigorous campaign to impede generic companies from manufacturing drugs that drive down the prices of brand name medicines.<sup>72</sup> Illustrative of this new protectionism is the recent seizure of generic medicines bound for developing countries by the Netherlands government, a move that incurred the displeasure of the governments of India and Brazil.<sup>73</sup> Another seizure affected the shipment of 49 kg of abacavir sulphate – a generic antiretroviral drug – by Dutch customs officials on the grounds that the drug was counterfeit and infringed patent rights.<sup>74</sup> The medicines in question were intended to be used for treating HIV/AIDS patients in Nigeria.

Closely related to the common seizure of medicines-in-transit is the establishment of an anti-counterfeiting body called the International Medical Product Anti-Counterfeit Taskforce (IMPACT) to police cross-border shipment of IP materials.<sup>75</sup> It needs to be mentioned that the operations of the IMPACT have come under severe criticism for its inability to distinguish between counterfeit and generic medicines. The argument is that such seizures may violate Articles 41 and 42 of TRIPS, which prohibit acts that create barriers to trade, permit abuse of rights conferred on patentees, are unfair and inequitable, and create unwarranted delays. For Outterson, the work of IMPACT forms part of a new secret anti-piracy agenda that is being used to delay global access to generic medicines.<sup>76</sup>

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<sup>72</sup> Stiglitz, “Economic Foundations of IPRs”, *supra* note 56 at 1701.

<sup>73</sup> William New, “International Health Groups Warn WHO, WTO on Medicines Seizure”, online <<http://www.ip-watch.org/weblog/2009/02/21/international-health-groups-warn-who-wto-on-medicines-seizures/>>.

<sup>74</sup> See “Dutch Seizure of HIV Drugs Highlights Patent Friction” Financial Times Thursday 5 March 2009. <[http://www.ft.com/cms/s/0/0a0a0a9e-0928-11de-b8b0-0000779fd2aChtml?ncllick\\_check=1](http://www.ft.com/cms/s/0/0a0a0a9e-0928-11de-b8b0-0000779fd2aChtml?ncllick_check=1)>.

<sup>75</sup> For information on this anti-counterfeiting partnership see online: <<http://www.who.int/impact/en/>>.

<sup>76</sup> Kevin Outterson, “Import Safety Rules and Generic Drug Markets” in C Coglianese, AM Finkel & D Zaring, eds, *Import Safety: Regulatory Governance in the Global Economy* (Philadelphia, PA: University of Pennsylvania Press, 2009) 110.

Third, and as a corollary, many SSA countries lack the capacity to manufacture drugs needed to combat epidemics. As such, the reluctance to patent drugs (as claimed by Attaran & Gillespie-White) in SSA countries is misleading and in fact inconsequential. Pharmaceutical companies need only obtain patents in countries with the manufacturing capacity to monopolize the world market.<sup>77</sup> And, in reality this approach of seeking pharmaceutical patent protection in countries with the manufacturing capacities has become the *modus operandi* of the pharmaceutical companies. By strategically obtaining patents in all countries that have the capacity to manufacture drugs, pharmaceutical companies inhibit efforts by less developed countries to procure cheaper generics from abroad.

Fourth, the reality in SSA is that many countries have in place patent regimes for protecting pharmaceuticals, to the extent that some have been compelled to assume more obligations than the minimum standards required by TRIPS.<sup>78</sup> This reality is not lost on some commentators who have confirmed that all but three of Africa's LDCs have implemented laws for pharmaceutical patents as of 2004.<sup>79</sup> Countries in SSA have acquired patent laws and patent offices as a result of processes of colonization or more recently globalization.<sup>80</sup>

Indeed, chapter 5 of this text shows that many countries in SSA comply with TRIPS, a fact that renders Gervais' contention that many SSA countries need not be TRIPS-compliant merely academic. Even SSA countries that do not have patent regimes are mandated to provide what is called a 'mailbox' system for exclusive marketing of pharmaceuticals for five years in consonance with TRIPS.<sup>81</sup> Presently, there are also in

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<sup>77</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 297.

<sup>78</sup> S Hill & K Johnson, *Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries* (London: DFID Health System Resource Centre, 2004) at 7.

<sup>79</sup> See e.g. Outtersson, "Pharmaceutical Arbitrage", *supra* note 62 at 257.

<sup>80</sup> Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (New York: Cambridge University Press, 2010) at 2.

<sup>81</sup> See Article 70.8 and 70.9 of the *TRIPS Agreement*.

force patent rules on non-discrimination, such as the national treatment and MFN principles, to which all countries must adhere. Finally, and again, SSA countries such as South Africa that have the capacity to manufacture drugs and possibly supply medicines to other countries in the African region do not enjoy a supposed patent-free regime of pharmaceuticals. Also India, which is the leading supplier of generic drugs to the world, is TRIPS-compliant. Needless to say, the existence of strong patent systems in places where countries in SSA can procure medicines crucially affects the realization of the right to access medicine.

In short, the discussion so far drives home the point that patents and human rights are not mutually exclusive; they share similar social functions and goals. In addition, the patent system, which is the most widely used form of juridical control of pharmaceuticals, plays a significant role in matters of access to medicines in SSA. The pharmaceutical industry would not spend huge resources promoting the globalization and influencing the content of patent rules, if they did not matter.<sup>82</sup> A strong patent system can perpetuate high prices for medicines and also hinders access to essential life-saving medicines in SSA. Conversely, a flexible patent system should thus be employed to achieve human rights ends by providing avenues for citizens to receive medical treatment. This goal can be achieved if policy-makers in SSA countries and the developed world understand their obligations to provide essential medicines to the masses affected by epidemics. The next task, then, is to provide a synthesis of the right to health obligations guaranteed in international human rights documents. Knowledge of the right to health obligations of states is not only important for the protection and enforcement of the right to health, but also crucial for patent law-making in SSA.

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<sup>82</sup> Peter Drahos, “‘Trust Me’: Patent Offices in Developing Countries” (2008) 34 *Am JL & Med* 151.

### III. The Right to Health in International Human Rights Instruments

Many international human rights instruments protect the right to health. This protection is justified on the grounds that human beings have an inherent dignity that is inviolable.<sup>83</sup> The major sources of authority for the international human right to health include the UDHR, the ICESCR, and the ICCPR. These human rights documents form the core of the International Bill of Human Rights; the trio obliges states to respect, protect, and fulfil their obligations to provide healthcare services to their citizens. The obligation to respect requires states to refrain from interfering indirectly or directly with the right to health. The obligation to protect requires states to take measures that prevent third parties from interfering with the right to health. And, finally, the obligation to fulfil requires states to adopt appropriate legislative, administrative, budgetary, and other measures that ensure the full realization of the right to health.<sup>84</sup>

The UDHR, though not a treaty, remains a key human rights document that guarantees the right to health at the international level. In particular, Article 25(1) of the UDHR explicitly proclaims the universal right of every person “to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.” This declaration is complemented by other provisions in the UDHR that guarantee the right to life,<sup>85</sup> the right to social security,<sup>86</sup> and the right to share in scientific advancement and its benefits.<sup>87</sup> Generally, the provisions of the UDHR serve as the model for codifying human rights protection in multilateral human rights treaties.<sup>88</sup>

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<sup>83</sup> See Sheetal B Shah, “Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India” (1999) 32 Vand J Transnat’l L 435 at 442 [Shah, “Guaranteeing the Human Right to Health”].

<sup>84</sup> See CESCR General Comment No. 14, paras 33 & 35.

<sup>85</sup> See Article 3 of the UDHR.

<sup>86</sup> See Article 22 of the UDHR.

<sup>87</sup> See Article 27(1) of the UDHR.

<sup>88</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 185.

Subsequent to the UDHR, the international health-related provisions have been solidified in the ICESCR in an effort to accord the right to health more normative force. In particular, Article 12 of the ICESCR obliges states to “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” States must achieve the full realization of the right to health by adopting measures for “the prevention, treatment and control of epidemic, endemic...and other diseases.”<sup>89</sup> They must also create “conditions which would assure to all medical service and medical attention in the event of sickness.”<sup>90</sup> In all this, access to essential medicines in situations of epidemics forms part of a state’s minimum core obligations towards the right to health.<sup>91</sup> The minimum core obligations should thus be understood as mandating SSA states to adopt patent regulatory standards that are tailored to meet the access-to-medicine needs and goals of their citizens.

Recently, the ESCR Committee has significantly clarified and fleshed out the scope of the obligations attendant to the fundamental right to health guaranteed in the ICESCR.<sup>92</sup> For instance, the ESCR Committee has interpreted the constitutive elements of the right to health to include: (a) the availability of the medication in sufficient quantity; (b) the accessibility of the medication to everybody; (c) the acceptability of treatment with respect to the culture and ethics of the individual; and (d) the appropriate quality of the medication.<sup>93</sup> According to the ESCR Committee, a state is in violation of Article 12 of the ICESCR if it adopts “legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.”<sup>94</sup>

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<sup>89</sup> See Article 12(2)(c) of the ICESCR.

<sup>90</sup> See Article 12(2)(d) of the ICESCR.

<sup>91</sup> See Cann, “IP Rights and Less Developed Countries”, *supra* note 2 at 839.

<sup>92</sup> See *The Nature of States parties Obligations*, General Comments.

<sup>93</sup> See Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000). The contents of these elements have received further elaborations in paragraph 12 of this General Comment [General Comment No. 14].

<sup>94</sup> See General Comment No. 14, para 48.

The adoption of strong patent laws constitutes such incompatible legislation.<sup>95</sup> Also, a state is in violation of international law if that state fails to take into consideration its legal obligations regarding the right to health when entering into bilateral or multilateral agreements.<sup>96</sup> It follows that bilateral TRIPS-plus agreements that limit the ability of governments in SSA to make use of compulsory licensing and parallel import flexibilities violate international human right obligations regarding health.

As a consequence, the ESCR Committee advises that health facilities, goods and services must be affordable for all and that poorer households should not be disproportionately burdened with health care costs as compared to richer households.<sup>97</sup> Further, the ESCR Committee provides that a state in which any significant number of individuals is deprived of essential primary health care is, *prima facie*, in violation of its international obligations.<sup>98</sup> The legal obligations regarding health require the adoption of patent systems that facilitate the supply of essential medicines to the population at affordable prices. The above interpretations should serve as a guide and a focal point for change among national legal systems in the design of patent policies that affect access to essential medicines. According to Helfer, the interpretation by the ESCR Committee has imbued the right to health, among other socio-economic rights, with greater prescriptive force.<sup>99</sup>

Furthermore, the WHO envisions that the attainment of the highest available standard of health for all people is integral to human survival. The Constitution of the WHO defines health as “a state of complete physical, mental and social well-being and not merely the

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<sup>95</sup> Sarah Joseph, “Pharmaceutical Corporations and Access to Drugs: The ‘Fourth Wave’ of Corporate Human Rights Security” (2003) 25 Hum Rts Q 425 at 438-439 [Joseph, “Pharmaceutical Corporations and Access to Drugs”].

<sup>96</sup> See General Comment No. 14, para 50.

<sup>97</sup> See General Comment No. 14.

<sup>98</sup> See General Comment No. 14, para 10.

<sup>99</sup> Helfer, “Toward a Human Rights Framework for IP”, *supra* note 21 at 988.

absence of disease or infirmity.”<sup>100</sup> The WHO emphasizes that human health is “the most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.”<sup>101</sup> Accordingly, “governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.”<sup>102</sup> For Amani, a state thus has an obligation to adopt patent policies that take cognizance of issues of need, access and production of healthcare services within its jurisdiction.<sup>103</sup> It thus follows that a state should not fear WTO complaint in adopting measures necessary to protect public health by promoting access to essential medicines.

Progressively, human rights advocates have linked the enjoyment of socio-economic rights to the enjoyment of civil and political rights. For example, the right to health has been linked with the fundamental right to life as enshrined in the ICCPR.<sup>104</sup> The emerging thinking is that access to life-saving medicines is part of the right to life. As I show below, the constitutional jurisprudence of South Africa adopts this approach of treating the right to health as a right to life. According to the Human Rights Committee (which monitors compliance with the ICCPR), the right to life requires that states “take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measure to eliminate malnutrition and epidemics.”<sup>105</sup> Without access to life-saving medicines for the citizens of SSA, where epidemics are rampant, the right to life is somewhat meaningless. As Nnamuchi aptly notes, “to contend that an individual possesses the right to life in the absence of the ingredients necessary for its

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<sup>100</sup> Constitution of the WHO, 14 UNTS 185, Preamble, online at <<http://www.who.int/about/en/>>.

<sup>101</sup> See *Declaration of Alma-Ata: Health for All*, Series 1 (Geneva: WHO, 1978).

<sup>102</sup> See Preamble of the WHO Constitution.

<sup>103</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 219.

<sup>104</sup> Rajshree Chandra, *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Rights* (New Delhi: Oxford University Press, 2010) at 186.

<sup>105</sup> UN Human Rights Committee, *General Comment No. 6/16*, para 5 (27 July 1982).

sustenance (such as health care) is, on many levels, vacuous.”<sup>106</sup> A related point is that the right to life is so recognizable by the international community that it has become *jus cogens*, a peremptory norm of international law.<sup>107</sup> Therefore, interpreting the right to life to include access to life-saving medicines imbues the latter with especial normative value from which no derogation must be permitted in situations of epidemics. These interpretations thus re-affirm the notion that the concept of human rights is indivisible, interrelated and interdependent.

Finally, there are also other international human rights documents that recognize the right to health. These human rights instruments include, *inter alia*, the UN Charter (Articles 1, 55 and 56), the UN *Convention on the Rights of the Child* (Article 24), *International Labour Organization Convention No 169* (Article 25), and the *International Convention on the Elimination of All Forms Racial Discrimination* (Article 5).<sup>108</sup> A detailed analysis of these human rights documents fall outside the parameters of this study. Suffice it to say that they re-enforce the emerging thinking that states must protect and enforce the social rights of individuals. Moreover, the recent adoption of the *Optional Protocol to the International Covenant on Economic, Social and Cultural Rights*,<sup>109</sup> when in force, will allow persons to petition the ESCR Committee about the violation of the right to health under the ICESCR. The procedure for challenging an alleged violation of the right to

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<sup>106</sup> Obiajulu Nnamuchi, “Kleptocracy and Its Many Faces: The Challenges of Justiciability of the Right to Health Care in Nigeria” (2008) 52 J Afr L 1 at 10.

<sup>107</sup> See Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 116; Denis Borges Barbosa et al, “Slouching towards Development in International Intellectual Property” (2007) Mich St L Rev 71 at 132. Article 53 of the *Vienna Convention* defines *jus cogens* as “a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.”

<sup>108</sup> For a discussion of these other human rights documents, see Eleanor D Kinney, “Recognition of the International Human Right to Health and Health Care in the United States” (2008) 60 Rutgers L Rev 335 at 342-344; Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 121;.

<sup>109</sup> This Optional Protocol is annexed to the UN General Assembly Resolution A/RES/63/117 (10 December 2008). Although the Protocol is opened for signature, it is not yet in force [ICESCR Protocol].

health via the ICESCR Protocol is similar to that of the ICCPR Protocol.<sup>110</sup> This latter Protocol has long been used to investigate alleged violations of civil and political rights of individuals. The ICESCR Protocol will likely contribute to resolving some of the controversies surrounding the justiciability of socio-economic rights in human rights jurisprudence.

#### IV. The Right to Health in the African Context

Regional human rights instruments, such as the *African Charter*, provide additional impetus for SSA countries to protect the right to health. The *African Charter* states that “every individual shall have the right to enjoy the best attainable state of physical and mental health.”<sup>111</sup> This Charter also provides that state parties shall take the necessary measures “to protect the health of their people and to ensure that they receive medical attention when they are sick.”<sup>112</sup> As I show below, the right to health obligations under the *African Charter* are interlinked with other supervisory and monitoring mechanisms to ensure compliance by states.

Presently, fifty-three countries, including those in SSA, are parties to the *African Charter*. These countries have thus undertaken to adopt legislative or other measures to give effect to the right to health, among other fundamental rights, guaranteed under the *African Charter*.<sup>113</sup> The *African Charter* also implores states to pay particular attention to the basic right to development.<sup>114</sup> Given the strong links between improving the basic health of a country’s people and improving its developmental prospects, SSA countries are required to provide life-saving medicines to their citizens. Conversely, a state is in

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<sup>110</sup> See *Optional Protocol to the International Covenant on Civil and Political Rights*, G.A. res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 59, UN Doc A/6316 (1966), 999 UNTS 302, *entered into force* 23 March 1976 [ICCPR Protocol].

<sup>111</sup> Article 16(1) of the *African Charter*.

<sup>112</sup> Article 16(2) of the *African Charter*.

<sup>113</sup> See Article 1 of the *African Charter*.

<sup>114</sup> Preamble to the *African Charter*.

violation of its obligations under the *African Charter* if it adopts patent regulatory and institutional frameworks that stifle access to life-saving medicines for its citizens.

The right to health obligations guaranteed in the *African Charter* has recently become a subject matter of litigation before the African Commission, which has the mandate to interpret the *African Charter* to protect and promote human rights. In *Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria*<sup>115</sup> a communication was filed by the applicants on behalf of the people of Ogoniland, citing, alleged violations of the right to health and the right to a healthy environment through oil exploration activities by Shell Petroleum Development Corporation with the connivance of the Government of Nigeria. The African Commission found, *inter alia*, that the government of Nigeria had violated the right to health and the right to life of the people of Ogoniland by not insisting on environmental impact studies prior to allowing an oil exploration and by failing to monitor the project.<sup>116</sup> The African Commission observed in paragraph 53 of its decision that,

Government compliance with the spirit of Articles 16 [right to health] and 24 [right to clean environment] of the African Charter must also include ordering or at least permitting independent scientific monitoring of threatened environments, requiring and publicising environmental and social impact studies prior to any major industrial development, undertaking appropriate monitoring and providing information to those communities exposed to hazardous materials and activities and providing meaningful opportunities for individuals to be heard and to participate in the development decisions affecting their communities.

Subsequent to the SERAC decision, the government of the Gambia was found to have violated human rights norms for protecting persons who are mentally ill or disabled under the *Mental Health Acts* of the Republic of the Gambia.<sup>117</sup> In paragraph 80 of its ruling, the African Commission noted that the enjoyment of the right to health is vital to all

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<sup>115</sup> Communication No. 155/1996, ACHPR/COMM/A044/1 (27 May 2002) [*SERAC Case*].

<sup>116</sup> See paras 53-67 of the *SERAC Case*.

<sup>117</sup> Communication Submitted Against The Gambia 241/01 Purohit and Moore/The Gambia 16th Annual Activity Report, ISBN 9983-9907-1-7.

aspects of a person's life and well-being, and is crucial to the realisation of all the other fundamental human rights and freedoms. Without doubt, both decisions demonstrate that socio-economic rights under the *African Charter* are justiciable and for that matter enforceable against governments.<sup>118</sup> Further, the recent coming into force of the *Protocol on the Establishment of an African Court on Human and Peoples' Rights*<sup>119</sup> will provide additional avenues for individuals to seek remedies for alleged violations of the right to health, among others socio-economic rights, in SSA.

Finally, several other sub-regional instruments touch on the right to health in SSA. These human rights-supportive instruments include: the constitutive treaties of ECOWAS,<sup>120</sup> SADC,<sup>121</sup> and the EAC.<sup>122</sup> The constitutions of these sub-regional bodies make specific references to the promotion and protection of human rights as the foundations for the enhancement of economic integration. In addition, SSA countries have adopted specific Protocols to strengthen and enhance the right to health in domestic jurisdictions. For example, the *Charter of Fundamental Social Rights in SADC*, 2003,<sup>123</sup> the *SADC Protocol on Health*,<sup>124</sup> and the *Protocol Establishing the ECOWAS Community Court*,<sup>125</sup> all in various forms mandate SSA countries to protect the right to health, by combating HIV/AIDS and other epidemics. However, it remains to be seen whether these measures

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<sup>118</sup> See also Justice C Nwobike, "The African Commission on Human and Peoples' Rights and the Demystification of Second and Third Generation Rights under the African Charter: Social and Economic Rights Action Center (SERAC) and the Center for Economic and Social Rights (CESR) v. Nigeria" (2005) 1 Afr J Legal Stud 129.

<sup>119</sup> This Protocol was adopted by the Assembly of Heads of State at its 34th session in June 1998 in Ouagadougou, Burkina Faso and came into force on 25 January 2004.

<sup>120</sup> See *Treaty of the Economic Community of West African States* (ECOWAS Treaty). ECOWAS members are implementing a West African Regional Programme for Health (PRSAO) to build national capacities for the fight against epidemics and also coordinate health policies.

<sup>121</sup> See *Treaty of the Southern African Development Community* (SADC Treaty), Article 4: [SADC and its member states shall act in accordance with the principles of human rights], Article 5: [The objectives of SADC shall be to combat HIV/AIDS and other deadly or communicable diseases].

<sup>122</sup> See *East African Community Treaty* (EAC Treaty), Articles 81(2), 117, and 118.

<sup>123</sup> See Article 12 of the *Charter of Fundamental Social Rights in SADC*, 2003.

<sup>124</sup> Entered into force 14 August 2004.

<sup>125</sup> Protocol A/P1/7/91 (amended by Supplementary Protocol A/SP.1/01/05) [granting mandate to the ECOWAS court to determine cases of human rights violation that occur in ECOWAS member states].

will be sufficient to tackle the threats posed by the HIV/AIDS, malaria, and TB epidemics in SSA.

#### **A. Global Commitments to HealthCare and the Status of the Right to Health**

The foregoing discussion of the right to health in transnational law demonstrates that a state's obligation to respect, protect and fulfil the right to health is not only morally imperative but also legally enforceable. In implementing WTO patent rules, governments bear a strong responsibility to guarantee healthcare to their citizens. Without purporting to lessen the responsibility of governments to provide healthcare to their citizens, a trend is emerging toward recognizing the responsibilities of private actors in the health sector (including pharmaceutical companies) to adopt policies that promote access to medicines for the public.<sup>126</sup>

Furthermore, global commitments with respect to access to life-saving medicines in national health emergencies support the point that the right to health has become a general principle of law from which no derogation is encouraged.<sup>127</sup> Hestermeyer chronicles a number of measures by states and international agencies across the globe to combat epidemics, namely, HIV/AIDS, malaria, and TB, as supportive of the claim that the right to health has attained the character of general principle of law.<sup>128</sup> For instance, there is presently in place a UN Global Fund to Fight AIDS, Tuberculosis and Malaria, a public/private partnership designed to attract, manage and distribute resources to mitigate the impact of these pandemics.<sup>129</sup> The WHO has also canvassed support for increased research into tropical diseases such as the HIV/AIDS, malaria, and TB epidemics, and

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<sup>126</sup> Brigit Toebes, "The Right to Health and the Privatization of National Health Systems: A Case of the Netherlands" (2006) 9 Health & Hum Rts 103 at 108.

<sup>127</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 135.

<sup>128</sup> Hestermeyer, *Human Rights and the WTO*, *ibid* at 131-132.

<sup>129</sup> See The Global Fund to Fight AIDS, Tuberculosis & Malaria, online: <<http://www.globalfundatm.org/index.html>>.

has further highlighted the role of patents in global health inequity.<sup>130</sup> In addition, the World Bank, the US President's Emergency Plan for AIDS Relief (PEPFAR), the Clinton Foundation, and the European Union (EU), have all financed the procurement of health related products to treat epidemics in Africa. To some degree, these access support initiatives show the willingness of western governments and other philanthropic organisations to contribute to the provision of medicines to countries in need. Nonetheless, giving aid to provide medicines to SSA countries is different from revising patent rules and policies with a pro-poor and pro-health emphasis so that medicines will be more affordable and accessible in the future.<sup>131</sup>

Also, there is an ongoing initiative by the international drug agency UNITAID<sup>132</sup> to establish a patent pool to boost innovation in and access to antiretroviral medicines. This initiative involves bringing a number of patent rights together so that they become available on a nonexclusive basis to manufacturers and distributors of medicines, in return for the payment of royalties. Patent pools facilitate generic competition and access, by allowing voluntary licences from two or more patent holders so that third parties do not have to go to all patent holders individually.<sup>133</sup> Pools also serve as an effective mechanism for financing research and development of medicines. Indeed, co-funding medicine research and development costs, through a patent pool, will make it easier for generic manufacturers to enter the market and also give sufficient voice to governments in matters pertaining to drug pricing to promote access.<sup>134</sup> Patent pools can also provide

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<sup>130</sup> See World Health Organization, *Global Public Goods for Health*, online at <<http://www.emro.who.int/cbi/pdf/Global%20Public%20Goods%20for%20Health.pdf>>.

<sup>131</sup> Germán Velásquez, "Trade Agreements, Intellectual Property and Access to Medicines: An Introduction" in *Intellectual Property and Access to Medicines: Papers and Perspectives* (Geneva: WHO, 2010) 1 at 8 <[http://203.90.70.117/PDS\\_DOCS/B4552.pdf](http://203.90.70.117/PDS_DOCS/B4552.pdf)>.

<sup>132</sup> UNITAID is a 2006 collaborative initiative under the aegis of the World Health Organization to scale up access to treatment for HIV/AIDS, Malaria and tuberculosis.

<sup>133</sup> Beirne Roose-Snyder & Megan K Doyle, "The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level" (2009) 35 Am JL & Med 281 at 292.

<sup>134</sup> E Richard Gold et al, *Preliminary Legal Review of Proposed Medicines Patent Pool* (2008), online: <<http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf>>.

mechanisms for free sharing of technical information relating to pharmaceutical patents and lead to a more effective and efficient allocation of limited resources.<sup>135</sup>

In the specific case of SSA countries, there are several domestic initiatives to combat HIV/AIDS, malaria and TB epidemics. Some of these measures include but are not limited to: South Africa's policy to supply antiretrovirals to pregnant women to prevent mother-to-child transmission of HIV. In the South African situation, the government was even compelled by the Constitutional Court to make the program available in all public health institutions.<sup>136</sup> Also, the South African *Medicines and Related Substances Control (Amendment) Act*, 1997: (1) promotes parallel imports of patented medicines in order to reduce drug prices, (2) compels pharmacists to dispense cheaper generics, unless otherwise requested by the doctor, and (3) establishes a pricing committee to supervise local drug pricing by big pharma.<sup>137</sup> The South African government has also successfully negotiated and signed voluntary licenses with GlaxoSmithKline and Boehringer Ingelheim for increased availability of pharmaceutical products. As Yu has remarked, South Africa has been "instrumental in putting the access-to-medicines issue on the human rights and public health agendas."<sup>138</sup>

Another domestic initiative is Botswana's National Policy on HIV/AIDS (1998) and the National Strategic Framework for HIV/AIDS, which support (1) the initiation of Isoniazid Tuberculosis Preventive Therapy (ITP) for HIV-positive patients, (2) the introduction of a Prevention of Mother to Child Transmission (PMTCT) program,<sup>139</sup> and (3) the prevention of HIV infection. There is also a joint initiative program – the African

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<sup>135</sup> Irina Haracoglou, *Competition Law and Patents: A Follow-on Innovation Perspective in the Biopharmaceutical Industry* (Cheltenham, UK: Edward Elgar, 2008) at 52.

<sup>136</sup> See *Minister of Health & Others v Treatment Action Campaign & Others* (2002) (5) SA 721 (CC).

<sup>137</sup> See Joseph, "Pharmaceutical Corporations and Access to Drugs", *supra* note 95 at 442.

<sup>138</sup> Peter K Yu, "Access to Medicines, BRICS Alliances, and Collective Action" (2008) 34 Am JL & Med 345 at 355.

<sup>139</sup> UN Human Rights Committee, "Consideration of Reports Submitted by States Parties under Article 40 of the Covenant: Initial Report of States Parties Due in 2001: Botswana" CCPR/C/BWA/1 (2007), online: <<http://www.unhcr.org/refworld/docid/46b9b7752.html>>.

Comprehensive HIV/AIDS Partnership – between the government of Botswana, the Bill & Melinda Gates Foundation and Merck & Co Inc that seeks to support and enhance Botswana’s response to the HIV and AIDS epidemic through a comprehensive approach to HIV/AIDS and TB prevention, treatment, care and support and impact mitigation.<sup>140</sup>

Kenya has also initiated a project to produce generic medicines.<sup>141</sup> This initiative, when implemented, will permit Cosmos Pharmaceuticals to supply cheaper generics to the East African market, which includes Burundi, Rwanda, Tanzania and Uganda. This comes against the backdrop of the fact that Boehringer Ingelheim has pre-empted the Kenyan process by entering into a voluntary license with Cosmos to produce generic versions of medicines in question. Further, despite the challenges to the use of compulsory licensing mechanisms in SSA, countries such as Ghana, Zambia, Mozambique and Zimbabwe have all resorted to compulsory licensing or government use for purposes of scaling up access to life-saving medicines for their citizens.<sup>142</sup>

Ghana also operates a national health insurance scheme under its *National Health Insurance Act*, 2003 (Act 650). This scheme seeks to provide basic healthcare services to persons resident in Ghana through a mutual and private health insurance schemes. The public option allows poor households to buy into a mutual health scheme in order to have access to medications, including some of the medicines described by the WHO as essential. Presently, an adult pays about US\$100 and children pay about US\$30 per annum as fees for access to basic healthcare. It must however be pointed out that the scheme does not cover access to antiretroviral medicines. Also, recent developments have

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<sup>140</sup> See online: <<http://www.achap.org>>.

<sup>141</sup> On this initiative see Tenu Avafia et al, “The Ability to Utilize TRIPS Flexibilities in sub-Saharan African Countries” in Ricardo Melendez-Ortiz & Pedro Roffe, eds, *Intellectual Property and Sustainable Development: Development Agendas in a Changing World* (Cheltenham, UK: Edward Elgar, 2009) 175 at 182.

<sup>142</sup> See Avafia et al, “The Ability to Utilize TRIPS Flexibilities”, *ibid* at 185.

doubted the sustainability of the Ghana health insurance scheme.<sup>143</sup> There are also national treatment programs in Burkina Faso, Central African Republic, Malawi, and Swaziland that rely heavily on generic medicines from India.<sup>144</sup> It must suffice here to say that several studies have well documented the existence of national health programs in SSA countries that are geared towards scaling up access to essential medicines and combating pandemics, namely, HIV/AIDS, malaria, and TB.<sup>145</sup>

The evidence thus far supports the emerging thinking that essential medicines must be made available to the poor in situations of epidemics. Given the threat posed by the escalating HIV/AIDS, malaria, and TB epidemics, access to essential medicines has become a worldwide priority. And, recent states' practices and global strategies to combat epidemics suffice to support a customary international law norm guaranteeing access to life-saving medicines in the face of national health emergencies, such as HIV/AIDS, malaria, and TB epidemics.<sup>146</sup> Collectively, human rights instruments, state practice and global initiatives to combat epidemics have arguably propelled the right to health into the category of general international law norm, a clear manifestation of the global recognition of the right to health.<sup>147</sup> As I elaborate below, this global recognition of the right to health has given additional boost to the content and status of the right to health in national constitutions in SSA.

## V. The Right to Health in Domestic Contexts

Given the global recognition of the right to health coupled with the threats posed by HIV/AIDS, malaria, and TB to the citizens of SSA, this part makes a case that the right to

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<sup>143</sup> See "President Mills urges pharmacists to make NHIS sustainable", online: <<http://news.myjoyonline.com/health/201008/50684.asp>>.

<sup>144</sup> See Chandra, *Knowledge as Property*, *supra* note 104 at 219.

<sup>145</sup> See *Human Rights Protected? Nine Southern African Country Reports on HIV, AIDS and the Law* (Pretoria: Pretoria University Law Press, 2007).

<sup>146</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 131.

<sup>147</sup> See Cann, "IP Rights and Less Developed Countries", *supra* note 2 at 879; Hestermeyer, *Human Rights and the WTO*, *ibid.*

access medicine in SSA trumps the enforcement of rigid pharmaceutical patent rules. In this vein, section A briefly analyzes the right to health provisions in some constitutions in SSA countries and concludes that the right to health has acquired constitutional status in many SSA countries. In so doing, I rely on the jurisprudence of the South African Constitutional Court, which has interpreted the right to health as a right to life. This South African jurisprudence provides significant lessons to aid other agencies of SSA countries in developing local jurisprudence on the enforcement of health rights. In building on this jurisprudence, sections B and C urge state agencies to employ the twin concepts of constitutional supremacy and primacy of human rights to justify why the right to health should trump strict patent limitations in order to facilitate access to medicines for the masses affected by epidemics in SSA.

### **A. The Right to Health in National Constitutions**

Empirical studies have found that over two thirds of all national constitutions have provisions that protect the right to health and healthcare in national jurisdictions.<sup>148</sup> Equally, health rights are entrenched in the national constitutions of many SSA countries as part of the bill of rights and/or directive principles of state policy.<sup>149</sup> Even, SSA countries that do not expressly guarantee the right to health in their national constitutions do protect the right to life, which, as earlier stated, has been interpreted by the Human

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<sup>148</sup> Eleanor D Kinney & Brian Alexander Clark, “Provisions for Health and Health Care in the Constitutions of the Countries of the World” (2004) 37 Cornell Int’l L J 285 at 287, 291 [Kinney & Clark, “Health Care Provisions in the Constitutions of the World”].

<sup>149</sup> On the right to health as part of justiciable fundamental human rights: see Article 18 & 26 of the Constitution of Burkina Faso, 1991; Article 8 of the Benin Constitution, 1990; Article 68 of the Constitution of Cape Verde, 1992; Articles 54 & 94 of the Constitution of Mozambique, 1990; Article 8 of the Constitution of Senegal, 2001; Article 41 of the Constitution of Rwanda, 2003; Articles 42 & 47 of the Constitution of the Democratic Republic of Congo, 2005; Article 19 of the Constitution of Burundi, 2005; Article 17 of the Mali Constitution, 1992; Article 14 of the Constitution of Togo, 1992; Article 77 of the Constitution of Angola, 2010. The right to health as part of the directive principles of state policy: see Article 34(2) of the Constitution of Ghana, 1992; Article 36(e) [assuring basic necessities of life for the citizens as a fundamental duty]; Article 30 of the Constitution of Congo, 2002; Article 27 of the Lesotho Constitution 1993; Sections XIV of the Ugandan Constitution, 1995; Section 17(3)(d) of the Constitution of Nigeria, 1999; Article 13(c) of the Constitution of Malawi, 1994; Section 8 (3)(d) of the Constitution of Sierra Leone, 1991; Article 112 (d) of the Constitution of Zambia, 1991.

Rights Committee to include the provision of life-saving medicines in the event of epidemics. Furthermore, given the above analysis of the treaty obligations of SSA countries, many countries have thus agreed to be bound by the core minimum obligations to provide essential medicines to their citizens in situations of epidemics. Countries are also obliged to ensure that private corporations do not interfere with the right to access medicine, and that patents on pharmaceuticals do not constitute a threat to availability, accessibility, acceptability or quality of healthcare.<sup>150</sup>

In contrast, there is no protection of patents as a human right in national constitutions in SSA. In support of this point, the Constitutional Court of South Africa has held that there is no provision protecting IP rights in the *African Charter* as well as in national constitutions in SSA.<sup>151</sup> It follows that by constitutionally guaranteeing the right to health, countries in SSA have imbued the substantive content of the right to health with normative supremacy and greater enforcement powers. Thus, constitutionalizing health rights empowers the citizens of SSA countries to sue their governments for violations of the right to access to essential medicines or to have violating legislation struck down.<sup>152</sup> In this vein, the Constitutional Court of South Africa has taken an activist position in upholding the right to health as a justiciable right.

Next is to analyze how the Constitutional Court of South Africa has conceptualized the right to health as a right to life in its domestic constitutional jurisprudence. By this analysis, courts in other SSA countries can learn from the South African jurisprudence on

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<sup>150</sup> Cann, “IP Rights and Less Developed Countries”, *supra* note 2 at 853; Haracoglou, *Competition Law and Patents*, *supra* note 135 at 81.

<sup>151</sup> See e.g., *In re Certification of the Constitution of the Republic of South Africa* 1996 (4) SA 744 (CC), para 75. This somewhat unprecedented approach of judicially certifying the provisions of the South African Constitution, before coming into force, was intended to test the provisions against what the Court referred to as ‘stated Constitutional Principles’. This case also held that socio-economic rights are justiciable.

<sup>152</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 191.

the protection of health rights, which significantly implicate patents and access to medicine issues.

### **1. South Africa as an Example of Enforcing the Right to Health**

In treating the protection of health rights as a right to life, South African constitutional jurisprudence provides an important model for other countries in SSA desirous of improving access to medicine. To start with, the South African Constitution, 1996 guarantees the right to healthcare services and also provides citizens with the right to institute legal proceedings to vindicate their rights when violated. It formulates the state's responsibility for health by stipulating that "everyone has the right to have access to... health care services, including reproductive health care."<sup>153</sup> As such, an individual can seek redress in court when the right to health is infringed or threatened.<sup>154</sup> It also bears noting that in interpreting the Bill of Rights under the South African Constitution, the Constitution obliges the courts to consider international law.<sup>155</sup> For many, South Africa's constitutional experience should serve as a global benchmark in terms of the constitutional protection and judicial enforcement of socio-economic rights across nations.<sup>156</sup> The salient point here is that the inclusion of justiciable socio-economic rights in the South African Constitution is a mark of the Constitution's extraordinary status.<sup>157</sup> Yet still, it remains to be seen whether/how state agencies in other SSA countries can overcome ideological claims that socio-economic rights are not justiciable.

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<sup>153</sup> Article 27(1) of the South African Constitution, 1996.

<sup>154</sup> See Article 38 of the South African Constitution, 1996.

<sup>155</sup> See Article 39(1)(b) of the South African Constitution, 1996.

<sup>156</sup> See generally, Eric C Christiansen, "Exporting South Africa's Social Rights Jurisprudence" (2007-2008) 5 *Loy U Chi Int'l L Rev* 29; John Cantius Mubangizi, "The Constitutional Protection of Socio-Economic Rights in Selected African Countries: A Comparative Evaluation" (2006) 2 *Afr J Legal Stud* 1 at 3; Jeanne M Woods, "Justiciable Social Rights as a Critique of the Liberal Paradigm" (2003) 38 *Tex Int'l LJ* 763 at 767 [Woods, "Justiciable Social Rights"].

<sup>157</sup> Heinz Klug, "South Africa's Constitutional Court: Enabling Democracy and Promoting Law in the Transition from Apartheid" (2008) 3:2 *Journal of Comparative Law* 174 at 181.

Thus, one of the most pressing issues in human rights discourse today is whether socio-economic rights, such as the right to health, are justiciable. Justiciable means the ability of a court to adjudicate or pronounce on the right to health and provide a legal remedy for the alleged violation. Despite the constitutional and the general international law norm status of the right to health, critics of social rights enforcement argue that the right to health is not justiciable. The arguments of critics take multiple shapes and sizes: that the right to health is not justiciable because it is a mere aspiration, that the right to health imposes a mere programmatic obligation on states and that its realization is subject to the availability of resources.<sup>158</sup> In essence, critics argue that the courts are ill-equipped to decide on the prioritization of the resources needed for implementing socio-economic rights.<sup>159</sup> In other words, policy-makers, rather than the judiciary, should be granted the leeway to allocate resources for purposes of national development.

Furthermore, critics of social rights enforcement draw a distinction between civil and political rights on the one hand and economic and social rights on the other. They argue that, unlike economic and social rights, civil and political rights are enforceable against governments because they are negative rights and that their realization does not involve expending financial resources.<sup>160</sup> In effect, the chief focus of this distinction is on the remedies designed to prevent governmental interference with civil and political rights as against remedies designed to force a government to provide a particular service.<sup>161</sup> This ideological separation between civil rights and social rights is reflected in the difficulties surrounding the justiciability of the right to health, especially in situations where the provisions regarding health and healthcare form part of the directive principles of the constitution.<sup>162</sup> This distinction is also reflected in Dworkin's articulation of rights as

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<sup>158</sup> Maurice Cranston, *What are Human Rights?* (London: Bodley Head, 1973) at 66.

<sup>159</sup> See Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 89.

<sup>160</sup> See Hestermeyer, *Human Rights and the WTO*, *ibid* at 89.

<sup>161</sup> Kinney & Clark, "Health Care Provisions in the Constitutions of the World", *supra* note 148 at 299.

<sup>162</sup> See Nnamuchi, "Kleptocracy and Its Many Faces", *supra* note 106.

“political trumps held by individuals.”<sup>163</sup> In consequence, the conception of rights as individualistic, adversarial and negative underlies the contention that the right to health is non-justiciable.<sup>164</sup>

However, it bears emphasizing that the above distinction between social/economic rights and civil/political rights flies in the face of numerous documents confirming the indivisibility and interdependence of all human rights.<sup>165</sup> Also, the distinction between social/economic rights and civil/political rights does not appreciate the reality that every human right may contain positive and/or negative obligations. As Shah rightly notes, “every human right, even the most privileged civil or political right, requires state intervention and expenditure for realization of the right.”<sup>166</sup> For instance, civil and political rights such as the right to a fair trial and presumption of innocence contain positive components. In administering justice, states expend resources to improve the court system. In addition states expend financial resources to feed and transport prisoners to and from the courts. On the flip side, socio-economic rights such as the right to health and the right not to be prevented from joining a labour union contain negative obligations. The negative component of the right to health prohibits governments from adopting patent policies that interfere with their citizens’ right to health.<sup>167</sup> Accordingly, inadequate resources can never be a viable justification for not complying with the content of a constitutionally guaranteed right to health.<sup>168</sup> For Fuller, the polycentric character of socio-economic rights necessitates that they are made amenable to adjudication.<sup>169</sup> As in South Africa, state agencies must overcome ideological claims that

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<sup>163</sup> See Ronald Dworkin, *Taking Rights Seriously* (Cambridge Mass.: Harvard University Press, 1977) at ix.

<sup>164</sup> Woods, “Justiciable Social Rights”, *supra* note 156 at 771.

<sup>165</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 90.

<sup>166</sup> Shah, “Guaranteeing the Human Right to Health”, *supra* note 83 at 447-448.

<sup>167</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 26 at 321.

<sup>168</sup> Even the United States that is generally reluctant to enforce socio economic rights see *Hamilton v Love*, 328 F. Supp. 1182, 1194 (1971) [State must provide adequate resources to cater for conditions of persons detained during trial] ; *Bishop v Jackson*, 404 F. 2d 571, 580 (8<sup>th</sup> Cir, 1968) [constitutional requirements are not to be measured or limited by dollar considerations].

<sup>169</sup> See Lon L Fuller, “The Forms and Limits of Adjudication” (1978) 92 Harv L Rev 353 at 394-400.

socio-economic rights are non-justiciable in order to make the content of the right to health meaningful in SSA.

In practice, the Constitutional Court of South Africa has indicated that the appropriate question is not whether socio-economic rights are justiciable, but rather how to enforce them in a given case.<sup>170</sup> Accordingly, the South African court has shown in a number of cases that the socio-economic rights guaranteed under national constitutions are enforceable.<sup>171</sup> For our purposes, one such relevant case is discussed here as evidence of the fact that domestic courts have taken affirmative positions to enforce the right to health against governments in SSA. In the South African case of *Minister of Health & Others v Treatment Action Campaign (TAC) & Others*,<sup>172</sup> the applicants sought to challenge the government's policy on accessibility to antiretroviral medicines that prevented the risk of mother-to-child transmission of HIV. The policy allowed the drugs to be administered at designated locations, thereby making it unavailable at other public health institutions. In deciding whether the policy fell short of the government's obligation under the South African Constitution, the Constitutional Court found that this was indeed the case, and ordered the government to remove the said restrictions. This ratio in the *TAC* decision has been followed in the case of *Republic v Chief Administrative Officer, La Polyclinic; Minister of Health; Attorney General*.<sup>173</sup> Here, a High Court in Ghana ordered the release of a 25 year old woman who had delivered a baby at a polyclinic but was being detained at the clinic due to her inability to pay her medical bill of about \$150.

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<sup>170</sup> *Government of the Republic of South Africa & Others v Grootboom & Others* 2000 (11) BCLR 1169 (CC), para 20.

<sup>171</sup> On this point see *In re Certification of the Constitution of the Republic of South Africa* 1996 (4) SA 744 (CC); *Soobramoney v Minister of Health, KwaZulu-Natal*, 1997 (12) BCLR 1696 (CC) (SA); *Government of the Republic of South Africa v Grootboom*, 2000 (11) BCLR 1169 (CC) (SA); *Minister of Health & Others v Treatment Action Campaign & Others*, 2002 (5) SA 721 (CC) (SA); *Republic v Chief Administrative Officer, La Polyclinic; Minister of Health; Attorney General* (High Court, 2003) [unreported]; *Khosa v Minister of Social Development*, 2004 (6) SA 505 (CC) (SA). Even though much of the socio-economic rights jurisprudence here originates from South Africa, the principles underpinning them are exportable to other African jurisdictions.

<sup>172</sup> 2002 (5) SA 721 (CC) [*TAC Case*].

<sup>173</sup> High Court, 2003 [unreported].

According to Flood, the *TAC* decision shows that judicial interpretation of the right to access medicine is powerful enough to cut through governmental intransigence to supply antiretroviral medicines in situations of an HIV/AIDS epidemic.<sup>174</sup> It also exemplifies the dilemma of some African governments: the globalized pharmaceutical patent regime holds them to ransom for bringing down the cost of access to health care, while their domestic constitutional obligations are being enforced against them at the behest of the domestic courts. In what follows, I urge state agencies in SSA to resolve this patent/access dilemma in favour of the right to health guaranteed under their national constitutions. Thus, in matters of access to medicines, the constitutional status of the right to health should provide justifications for non compliance with rigid pharmaceutical patent rules. To hold otherwise would be to undermine the supremacy of the constitution, a matter which I address next.

## **B. Constitutional Supremacy and the Right to Health in SSA**

This section takes up the argument that the right to health has attained the character of a constitutional norm in many SSA countries. In keeping with the doctrine of constitutionalism, the preambles to the written constitutions of countries in SSA declare the national constitution as the supreme law of the land,<sup>175</sup> and that any act or omission found to be inconsistent with the provisions of the constitution shall to the extent of the inconsistency be void.<sup>176</sup> National constitutions also guarantee the sovereignty of the state and vest the powers of governance in the people.<sup>177</sup> By inference, the superior character of the national constitution clothes the right to health with a higher normative and

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<sup>174</sup> Colleen M Flood et al, "Introduction: Legislating and Litigating Health Care Rights around the World" (2005) 33 *J L Med & Ethics* 636 at 639.

<sup>175</sup> See e.g. Section 1(1) of the Constitution of Nigeria, 1999; Article 1(2) of the Constitution of Ghana, 1992; Section 4 of the Constitution of the Gambia, 1997.

<sup>176</sup> *Marbury v Madison*, 5 US (1 Cranch) 137 at 176-177 (1803); Section 1(5) of the Constitution of Malawi, 1994; Article 1(2) of the Constitution of Ghana, 1992; Section 2(1)(4) & 77 of the Kenyan Constitution, 2010.

<sup>177</sup> See *McCulloch v Maryland*, 17 US (4 Wheat.) 316 (1819) [the government proceeds directly from the people; it is 'ordained and established' in the name of the people]; *Tuffour v Attorney General*, [1980] GLR 637 at 647.

constitutional status over patent rights. It follows that based on the concept of the supremacy of the constitution states agencies can justify trumping a right to health over interests in pharmaceuticals.

It is axiomatic in legal scholarship and in judicial pronouncements that the concept of the supremacy of the written constitution is traced to Chief Justice Marshall's reasoning in *Marbury v Madison*.<sup>178</sup> Justice Marshall reasoned that any law in conflict with the constitution is void and that the court is the ultimate expositor of the constitutional text. This reasoning is also to the effect that among the hierarchy of legal norms in domestic jurisdictions, national constitutions rank supreme; constitutional rules specify how legal norms are to be produced, applied, and interpreted.<sup>179</sup> The constitution has objective characteristics such that any law repugnant to the constitution is void and that all departments of the state are bound by the constitution.<sup>180</sup> This concept of the supremacy of the constitution thus implies that patent legislation ranks lower, that no person or body can interfere with a constitutionally guaranteed right, and that the judiciary has the responsibility to check the unconstitutionality of governmental acts.<sup>181</sup> In effect, the concept of the supremacy of the constitution has become part and parcel of the constitutional jurisprudence of many countries in SSA; the concept thus provides a legal basis to review the constitutionality of governmental acts and omissions in parts of Africa.<sup>182</sup>

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<sup>178</sup> See *Marbury v Madison*, 5 US (1 Cranch) 137 (1803).

<sup>179</sup> Alec Stone, "What is a Supranational Constitution? An Essay in International Relations Theory" (1994) 56 *Review of Politics* 441 at 444.

<sup>180</sup> See *Marbury v Madison*, 5 US (1 Cranch) 137 at 180 (1803).

<sup>181</sup> See Jutta Limbach, "The Concept of the Supremacy of the Constitution" (2001) 64 *Mod L Rev* 1.

<sup>182</sup> See *Tuffour v Attorney General* [1980] GLR 637; Richard Frimpong Oppong, *Legal Aspects of Economic Integration in Africa* (Cambridge: Cambridge University Press, 2011) at 207-208.

Furthermore, the place of a treaty in the internal legal order of a state is determined by constitutional law.<sup>183</sup> Thus, constitutions as the *grundnorm* determine how treaties are received in domestic jurisdictions. Indeed, many countries in SSA share the view that the reception of international law into domestic law is subject to the constitution.<sup>184</sup> The reason is that the eventual beneficiaries or otherwise of the dictates of international law is the people who constitute the state, as an institution of governance. As a founding text made morally legitimate by virtue of an original act of consent by the people,<sup>185</sup> national constitutions oblige governments to conduct international relations in accordance with the supreme interest of the people. The relevance of national constitutions in international relations is particularly true with respect to WTO law: most national constitutions in SSA require domestic legislation to be passed to implement WTO treaty obligations. Yet, as argued in chapter 2, the depth of harmonization under TRIPS has blurred the lines between domestic legislation and international economic law, such that both function in the same manner. Accordingly, the ubiquitous international patent regime should not be immune from the checks and balances inherent in the rule of constitutionalism.<sup>186</sup> It goes without saying that the supremacy of the constitution has attained the status of *jus cogens*, a peremptory norm whose enforcement cannot be impeded by any rules of international economic law.<sup>187</sup>

In reality, several judicial decisions in SSA countries have upheld the supremacy of the national constitution over transnational law. In *Sani Abacha v Fawehhinmi*,<sup>188</sup> the

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<sup>183</sup> See Quincy Wright, “The Legal Nature of Treaties” (1916) 10 Am J Int’l L 706; Mgbeoji, *Global Biopiracy*, *supra* note 17 at 46. This point rejects any proposition that international law prevails over national constitutions.

<sup>184</sup> See e.g. Article 232 of the South African Constitution, 1996; Article 211(3) of the Malawian Constitution, 1994; Article 2(5) of the Kenyan Constitution, 2010; Articles 73 & 75 of 1992 Constitution of Ghana.

<sup>185</sup> Luc B Tremblay, “*Marbury v Madison* and Canadian Constitutionalism: Rhetoric and Practice” (2004) 36 Geo Wash Int’l L Rev 515 at 517.

<sup>186</sup> See Alec Stone, “What is a Supranational Constitution?”, *supra* note 179 at 448.

<sup>187</sup> See *Attorney General v Faroe Atlantic Co Ltd* [2005-2006] SCGLR 271 at 298.

<sup>188</sup> (2000) 6 NWLR 228.

Supreme Court of Nigeria had to decide whether to ascribe to the *African Charter* superiority over the Nigerian Constitution. The Court held that to elevate the *African Charter* above the Constitution of Nigeria would be a violation of the provisions of the supremacy of the Constitution. Likewise, in *Sikunda v Government of the Republic of Namibia*, a High Court held that a UN Security Council resolution is subservient to the Namibian Constitution, which is the supreme law of that country.<sup>189</sup> Similar approaches have been adopted in other jurisdictions including the Gambia,<sup>190</sup> Ghana,<sup>191</sup> Kenya,<sup>192</sup> and South Africa.<sup>193</sup> It follows that this judicial stance on the doctrines of sovereignty and supremacy of national constitutions is very much a feature of the common law countries in parts of Africa. For Bimpong-Buta, these decisions are consistent with the constitutional imperative that treaties must be ratified, via implementing legislation, before they become operative at the domestic level in most SSA states.<sup>194</sup> The adjudication of claims that prioritize access to medicine issues over innovators' rights brings into focus the right of a sovereign country to grant, uphold or delimit supranational law in consonance with its socio-economic imperatives.<sup>195</sup>

Closely allied to the concept of the supremacy of the constitution is the use of a purposive-interpretive methodology in construing the constitution as a living organic document capable of growth and development.<sup>196</sup> This concept of organic growth resonates with the idea that a constitution goes beyond mere positive laws and should

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<sup>189</sup> (2001) NR 85 at 86.

<sup>190</sup> *Jammeh v Attorney General* (1997-2001) GR 839.

<sup>191</sup> See e.g. *Attorney General v Faroe Atlantic Co Ltd* [2005-2006] SCGLR 271 at 298, *Ghana Bar Association v Attorney General (Abban Case)* [1995-96] 1 GLR 598; *Mensima v Attorney General* [1996-97] SCGLR 676 at 712-713.

<sup>192</sup> *Kenya v Okunda* (1969) 91 ILM 556 at 558, *Anyang' Nyong'o v AG* [2007] Eklr 1 (HC).

<sup>193</sup> See *Mohamed & Another v President of the Republic of South Africa & Others*, 2001 (3) SA 893 (CC) (SA).

<sup>194</sup> Seth Yeboa Bimpong-Buta, "The Role of the Supreme Court in the Development of Constitutional Law in Ghana" (Doctor of Laws Dissertation, University of South Africa, 2005) at 75.

<sup>195</sup> Chandra, *Knowledge as Property*, *supra* note 145 at 223.

<sup>196</sup> *Tuffour v Attorney General* [1980] GLR 637 at 647.

thus not be viewed in a purely legalistic fashion.<sup>197</sup> Therefore, in interpreting the constitution, a broad and liberal spirit is required; a doctrinaire approach to constitutional interpretation would not do.<sup>198</sup> As a result, one could argue that a constitution gives priority to the greater social interest such as public access to life-saving medication over interests in pharmaceuticals.<sup>199</sup> Cann suggests that national constitutions create a hierarchy of values in which the right to health prevails over interests in intellectual creations, such as patents.<sup>200</sup> As such, in implementing international obligations on trade-related IP rights, domestic agents have a duty to ensure that WTO patent rules do not interfere with the protection and advancement of the fundamental right to health.

Particularly, in situations of national health emergencies, a state's obligation to protect the right to health is said to be immediate.<sup>201</sup> That said, claims of 'progressive realization' of the right to health cannot be a defence, but rather an obligation on states to use all the means at their disposal to give effect to the right to health. Since many national constitutions in SSA guarantee protection and enforcement of the right to health, the concept of constitutional supremacy can provide a foundation on which to ground the primacy of the right to health over patents in pharmaceuticals. Furthermore, the doctrine of human rights primacy provides another justification for prioritizing the right to health over patent rights. This doctrine of human rights primacy should also clothe domestic courts with institutional competence to grant legal remedies for alleged violations of the right to health in SSA. This primacy-of-human-rights thesis is intended to complement the above constitutional-supremacy argument that the right to health must override pharmaceutical patent rights in SSA.

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<sup>197</sup> Cann, "IP Rights and Less Developed Countries", *supra* note 2 at 882.

<sup>198</sup> *Tuffour v Attorney General* [1980] GLR 637 at 647-648 [Justice Sowah].

<sup>199</sup> Cann, "IP Rights and Less Developed Countries", *supra* note 2 at 881.

<sup>200</sup> Cann, "IP Rights and Less Developed Countries", *ibid* at 881.

<sup>201</sup> Cann, "IP Rights and Less Developed Countries", *ibid* at 839.

### C. Primacy of Human Rights and the Right to Health

The concept of human rights primacy provides another justification for the right to health to override pharmaceutical patent rights in SSA.<sup>202</sup> This concept of human rights primacy is founded on the idea that human rights are universal and inalienable. Human rights norms have an inherent legal value that is superior to positive rules of law, such as patent legislation; human rights thus provide the foundation needed for human development.<sup>203</sup> Hence, despite the lack of consensus about the scope and content of these rights, countries adhere to universally accepted standards of human rights.<sup>204</sup> Also, from the perspective of liberal philosophy, health rights have a higher moral claim than patent rights. To this end, Chandra has surmised that the right to health is particularly crucial to life and liberty, which are regarded as ‘originating’ or ‘source’ rights in Lockean liberal philosophy.<sup>205</sup> On the other hand, the right to higher profits or returns on innovation cannot be considered as particularly crucial to human survival and liberty as patents are based on want-fulfilment.<sup>206</sup>

In light of the primary character of human rights norms, the right to access medicine has become a globally accepted norm which states adhere to in situations of epidemics. The earlier discussion in part IV about the status of the right to health in light of the global fight against HIV/AIDS, malaria, and TB epidemics aptly illustrates this point. The classification of the right to health as a general principle of law or general international law norm empowers governments to provide essential medicines to their citizens irrespective of WTO and national patent rules.<sup>207</sup> Indeed, giving priority to international

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<sup>202</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 152.

<sup>203</sup> John O’Manique, “Development, Human Rights and Law” (1992) 14 Hum Rts Q 383 at 384.

<sup>204</sup> Burns H Weston, “Human Rights” (1984) 6 Hum Rts Q 257 at 262-267.

<sup>205</sup> Chandra, *Knowledge as Property*, *supra* note 145 at 338-339.

<sup>206</sup> Chandra, *Knowledge as Property*, *ibid* at 188.

<sup>207</sup> Cann, “IP Rights and Less Developed Countries”, *supra* note 2 at 888.

human right norms at the domestic level is consistent with the social functions and goals of constitutional law.<sup>208</sup>

Most importantly, prioritizing the right to health obligations over private interests in pharmaceuticals is supported by a number of international policy considerations. These human rights-friendly initiatives include: the UN Sub-Commission Resolution 2000/7 that primacy should be given to human rights obligations over economic policies and agreements.<sup>209</sup> There are also annual resolutions by the UN Commission on Human Rights to ensure “Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria.”<sup>210</sup> In addition, the UN High Commissioner for Human Rights has mounted a trenchant critique of the *TRIPS Agreement*’s negative impact on the right to health and has thus recommended that the globalized patent system should promote access to affordable medicines to treat epidemics.<sup>211</sup>

As mentioned earlier, the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, the WTO General Council’s ‘August 30’ Decision, and the amendment to TRIPS show global commitments to integrate human rights law into the WTO system. For example, the language of the Doha Declaration provides that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health,”<sup>212</sup> and that the Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>213</sup> This Declaration is consistent with the argument that the protection of the right to health should not be undermined by the grant of strong

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<sup>208</sup> Yuval Shany, “How Supreme is the Supreme Law of the Land? Comparative Analysis of the Influence of International Human Rights Treaties Upon the Interpretation of Constitutional Texts by Domestic Courts” (2006) 31 *Brook J Int’l L* 341 at 342-343.

<sup>209</sup> UN Resolution 2000/7, para 3.

<sup>210</sup> For a list of these Resolutions see Helfer, “Toward a Human Rights Framework for IP”, *supra* note 21 at 986.

<sup>211</sup> Helfer, “Toward a Human Rights Framework for IP”, *ibid* at 986.

<sup>212</sup> Para 4 of the Doha Declaration.

<sup>213</sup> Para 4 of the Doha Declaration.

patent rights in domestic jurisdictions. In addition, the implementation of the WIPO Development Agenda supports the adoption of human rights-friendly patent standards in national laws. The common denominator here is that these human rights-friendly measures limit the adoption of expansive patent standards while supporting efforts to give primacy to the right to healthcare in national legislation. Those initiatives make it clear that the private rights of big pharma should not be allowed to frustrate the greater social good of global public health.<sup>214</sup>

Recognizing that human right norms have primacy over WTO patent rules is one thing. But, as Hestermeyer notes, it may be quite another thing when ‘soft-enforced’ human rights norms meet ‘hard-enforced’ WTO law, resulting in states succumbing to the latter.<sup>215</sup> A solution for this scenario comes down to political will: state agencies should not undermine their ability to affirm the normative supremacy of human rights law over rigid WTO rules. The governments of SSA countries need to work in ways that do not lead to the sacrifice of human health (life) on the altar of increased trade. A while ago, Stiglitz advised developing countries to assume responsibility for their well-being themselves and make choices over their needs and rights.<sup>216</sup> Similarly, SSA countries must look to higher legal principles in human rights as a way to forge a humane policy that accounts for the human development needs of their citizens. Also, since WTO rules form part of the rules of public international law, non-WTO rules (especially human rights norms) can be employed as justifications for the breach of WTO rules, even if the WTO treaty itself does not offer such justification.<sup>217</sup> Alternatively, as happened during the dispute between the Pharmaceutical Industry and South Africa, a state should be able to raise the obligation to protect its citizens’ right to health as justification for non-

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<sup>214</sup> Cann, “IP Rights and Less Developed Countries”, *supra* note 2 at 899.

<sup>215</sup> See Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 197, 205-206.

<sup>216</sup> Joseph E Stiglitz, *Globalization and Its Discontents* (New York: W.W. Norton & Co., 2002) at 251.

<sup>217</sup> Pauwelyn, “Role of International Law in WTO”, *supra* 39 at 577.

compliance with strong patent rules. That is the essence of *politics* in global trade relations.

Finally, scholars agree that the WTO is bound by general international law standards on human rights to the extent that those standards are necessary to promote public health under Article 8 of TRIPS.<sup>218</sup> Promoting human rights norms, through the WTO system, will serve the objective of promoting development which generally accompanies the realization of human rights.<sup>219</sup> A more radical proposition is that no individual or corporation should have the right to sue if the lawsuit violates the public right to access life-saving medicines, especially in situations of epidemics.<sup>220</sup> Further, the democratic deficit that characterized the design of TRIPS gives additional impetus for universally recognized human rights obligations to override WTO patent rules.

To sum up, an emerging trend supports the argument that the fundamental right to health transcends WTO treaty obligations. When international human rights and development-friendly initiatives are combined with the constitutional character of the right to health, it is undeniable that the right to access to medicine should trump patent limitations in WTO law, especially in situations of national health emergencies. To be effective, this would require domestic mechanisms at the constitutional level to give priority to the right to health over patent rights in SSA. Also, since TRIPS has moved into the domestic arena as if it is a national legislation, it is only natural that the implementations of TRIPS' patent rules in SSA countries are subjected to the superior and constitutional functions of human

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<sup>218</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 101; Pauwelyn, "Role of International Law in WTO", *ibid*.

<sup>219</sup> Cann, "IP Rights and Less Developed Countries", *supra* note 2 at 919.

<sup>220</sup> Margaret B Kwoka, "Vindicating the Rights of People Living with AIDS under the Alien Tort Claims Act" (2009) 40 Loy U Chi L J 643 at 647.

rights norms.<sup>221</sup> To hold otherwise would be to deny the right to health its content as an enforceable human right in SSA.

## VI. Conclusions

SSA countries are confronted with public health crises of gargantuan proportions. As a consequence, this chapter has made a case for giving primacy to the right to health over patent rights on pharmaceuticals. It has stressed that giving priority to the fundamental right to health over patents in pharmaceuticals in SSA finds support from treaties, customary law, state practices, judicial decisions, constitutional norms, and other international actions. Progressively, the Constitutional Court of South Africa has interpreted the right to health as a right to life; this jurisprudence provides significant lessons to aid other agencies of SSA countries in developing local jurisprudence on the enforcement of health rights. In addition, where the fundamental right to health is guaranteed in a constitution – declared to be supreme – any law which interferes with the ability of citizens to have access to medicines can be challenged as contrary to the constitution.<sup>222</sup>

Alternatively, as I articulate further in chapters 7 and 8 of this text, in jurisdictions where socio-economic rights are not frequently litigated or enforced, the prescriptions made in this chapter could be implemented in national health and access policy guides. That way, the right to health can be employed as a corrective instrument against the excessive exploitation of pharmaceutical patent rights in SSA.<sup>223</sup> Such an approach is also essential to achieving human development which generally hinges on the health of the population. Indeed, the objectives and the principles that underpin the globalized patent system can

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<sup>221</sup> Hestermeyer, *Human Rights and the WTO*, *supra* note 9 at 298.

<sup>222</sup> See Loke Kit Choy, “Constitutional Supremacy in Malaysia in the Light of Two Recent Decisions” (1969) 11 *Malaya L Rev* 260 at 267.

<sup>223</sup> On this point see: Helfer, “Toward a Human Rights Framework for IP”, *supra* note 21 at 1017-1018; Christophe Geiger, “Fundamental Rights, a Safeguard for the Coherence of Intellectual Property Law?” (2004) 35 *Int’l Rev Intell Prop & Competition L* 268 at 278.

be realized if human development principles are incorporated into the design and interpretation of the WTO patent rules, a matter which I address in the next, penultimate, chapter.

## Chapter 7

### Pharmaceutical Patents and Human Development in Sub-Saharan Africa

#### I. Introduction

The analyses in the preceding chapters have shown that law is integral to development. Yet laws do not themselves give rise to development unless they are properly situated within their social context and realities. Fuller once observed that, “for a given social context one form of law may be more appropriate than another, and that the attempt to force a form of law upon a social environment uncongenial to it may miscarry with damaging results.”<sup>1</sup> This idea that laws must reflect social realities is equally germane in the implementation of international norms on patents in SSA. The patent system is the most widely used form of juridical control of pharmaceuticals in the global marketplace. As Oguamanam aptly explains, “of all the regimes of IP, patent is the most relevant to pharmaceutical research both in terms of the subject matter of pharmaceutical innovation and in consideration of the imperative in that industry for a stronger and more exclusive protective regime.”<sup>2</sup> And private pharmaceutical companies employ the globalized patent regime and its domestic prototypes to regulate the prices of medicines on the market. This private regulation of pharmaceuticals reduces the availability of and/or access to medicines to alleviate human suffering, which in turn affects human survival and development.

On the other hand, development is a cardinal component of the international trading system within which the present patent regime operates.<sup>3</sup> As Fisher & Syed have noted,

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<sup>1</sup> Lon L Fuller, “Human Interaction and the Law” (1969) 14 Am J Juris 1 at 27.

<sup>2</sup> Chidi Oguamanam, “Patents and Pharmaceutical R&D: Consolidating Private–Public Partnership Approach to Global Public Health Crises” (2010) 13 Journal of World Intellectual Property 556 at 558 [Oguamanam, “Patents and Pharmaceutical R&D”].

<sup>3</sup> Denis Borges Barbosa et al, “Slouching towards Development in International Intellectual Property” (2007) Mich St L Rev 71 at 72 [Barbosa et al, “Slouching towards Development”].

there are strong links between improving the basic health of a country's people and improving its development prospects.<sup>4</sup> Given this inextricable link between trade, development, and human rights, scholars have made a case to calibrate the international intellectual property (IP) balance to achieve global human development goals.<sup>5</sup> For her part, Robinson urges the pursuit of equitable development and fair trade in order to foster human rights concerns.<sup>6</sup> Needless to say, providing medications to the citizens of SSA who are worst affected by the HIV/AIDS, malaria, and TB epidemics would help sustain the human resources needed to develop.

Similarly, international instruments suggest that development is a basic human right.<sup>7</sup> Achieving the right to development entails the pursuit of a comprehensive social, economic, *legal*, cultural and political process, which aims at the constant improvement of the well being of individuals. Ordinarily, this comprehensive process is supposed to recognize the human person as the 'central subject' of development as well as its primary beneficiary.<sup>8</sup> Of equal importance is the UNDP's definition of development as a "process of enhancing human capabilities – to expand choices and opportunities so that each person can lead a life of respect and value."<sup>9</sup> This capability view thus emphasizes not

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<sup>4</sup> William W Fisher & Talha Syed, "Global Justice in Healthcare: Developing Drugs for the Developing World" (2007) 40 UC Davis L Rev 581 at 589.

<sup>5</sup> See Barbosa et al, "Slouching towards Development", *supra* note 3; Margaret Chon, "Intellectual Property and the Development Divide" (2006) 27 Cardozo L Rev 2821 [Chon, "IP and the Development Divide"].

<sup>6</sup> Mary Robinson, "Making the Global Economy Work for Human Rights" in Gary P Sampson, ed, *The Role of the World Trade Organization in Global Governance* (Tokyo: United Nations University Press, 2001) 209 at 210.

<sup>7</sup> See e.g. Preamble to the *UN Declaration on the Right to Development*, UN DoC A/RES/41/128 (1986); World Conference on Human Rights, *Vienna Declaration and Programme of Action*, UN DoCA/CONF.157/23, Vienna, 25 June 1993, para 10; *African Charter on Human and Peoples' Rights*, 27 June 1981, 21 ILM 58 (entered into force on 21 October 1986), Article 22. The right to development is increasingly being recognized as *ius cogens*, a peremptory norm of international law.

<sup>8</sup> Wesley A Cann, "On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism" (2004) 25 U Pa J Int'l Econ L 755 at 924.

<sup>9</sup> UNDP, *Human Development Report 2000: Human Rights and Human Development* (New York: Oxford University Press, 2000) at 2.

just the innovation aspect of the patent system, but also the policy objective of the patent system to promote social benefits, public health and development.<sup>10</sup> It is within this understanding that development entails the realization of the right to access medicine required for human functioning that the discussion of the globalized patent regime takes place in this chapter. So defined, a patent-driven approach to human development should promote access to essential medicines at prices affordable to the masses in poor regions such as SSA.

### A. On Development Rhetoric

Traditionally, much of the development rhetoric has been confined to economic development and encouraging an increase in gross national income.<sup>11</sup> It is alleged that increase in gross national incomes and industrialization is central to national development and poverty alleviation.<sup>12</sup> Further, proponents of a ‘development as growth’ model contend that economic growth provides the material base upon which many aspects of human life depend.<sup>13</sup> Thus, achieving economic growth has the potential to enhance human capabilities and enlarge people’s choices.<sup>14</sup> This development as growth model has also been linked with international trade. As Boutros-Ghali has noted, the “expansion of international trade is essential to economic growth and is an integral part of the economic dimension of development.”<sup>15</sup> In consequence, the primary focus of this

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<sup>10</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 77.

<sup>11</sup> On this point see Ray Bush, *Poverty & Neoliberalism: Persistence and Reproduction in the Global South* (London: Pluto Press, 2007); Barbosa et al, “Slouching towards Development”, *ibid* at 77; Amartya Sen, *Development as Freedom* (New York: Anchor Books, 1999) at 1; Jeremy de Beer, “Defining WIPO’s Development Agenda” in Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization’s Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009) 1 at 5 [De Beer, “Defining WIPO’s Development Agenda”].

<sup>12</sup> See Gerald M Meier, *Leading Issues in Economic Development*, 5<sup>th</sup> ed (New York: Oxford University Press, 1989) at 6.

<sup>13</sup> See Kwame Gyekye, “Taking Development Seriously” (1994) 11 *Journal of Applied Philosophy* 45 at 49.

<sup>14</sup> UNDP, *Human Development Report 1996: Economic Growth and Human Development* (New York: Oxford University Press, 1996) at 86.

<sup>15</sup> Boutros Boutros-Ghali, *An Agenda for Development*, UN Doc A/48/935 (UN, 6 May 1994) at 41, online: <[www.un.org/Docs/SG/agdev.html](http://www.un.org/Docs/SG/agdev.html)>.

economic model is on gross domestic product (GDP)/income as measured in terms of the value of total goods and services produced by an economy.

The limitations in this model of development as growth have not been lost on commentators and agencies of the United Nations (UN). It is conceivable that states can develop economically, while individuals are denied the fruits of that development. According to Sen, human development, unlike economic growth, represents an end in itself.<sup>16</sup> Thus, “the recent decades show all too clearly that there is no automatic link between growth and human development.”<sup>17</sup> It follows that equating the concept of development with economic growth “could actually miscalculate welfare: a majority of a country’s people could be living without access to the essential goods and services required for human functioning, with a small percentage of its population capturing a disproportionate amount of the overall wealth.”<sup>18</sup> Indeed, while international trade may lead to economic growth, economic growth does not *ipso facto* lead to human development in SSA.<sup>19</sup> Put in a slightly different way, the extent to which economic growth promotes human development is debatable.

Gyekye on his part has coined the label ‘economism’ to describe the phenomenon of reducing development into concepts of gross national products and theories of western epistemology and values.<sup>20</sup> He stresses that even though it is not entirely bad to construe development in terms of economic growth, such a limited worldview of development economics seldom brings to the fore the challenges to Africa’s development. Indeed, after decades of experimentation with the economic growth model, including the adoption of Structural Adjustment and Economic Recovery programs spearheaded by the Bretton

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<sup>16</sup> Sen, *Development as Freedom*, *supra* note 11 at 14.

<sup>17</sup> UNDP, *Human Development Report 1996*, *supra* note 14 at 1.

<sup>18</sup> Chon, “IP and the Development Divide”, *supra* note 5 at 2832.

<sup>19</sup> See Richard Frimpong Oppong, “Trade and Human Rights: A Perspective for Agents of Trade Policy using a Rights-based Approach to Development” (2006) 6 Afr Hum Rts LJ 123.

<sup>20</sup> Gyekye, “Taking Development Seriously”, *supra* note 13 at 46.

Woods institutions,<sup>21</sup> the situations of many SSA countries have not changed for the better. Rather, African countries continue to experience a reduction in their share of the volume of international trade and a deterioration in their economic conditions.<sup>22</sup>

Also, the SSA region still plays host to the highest number of the UN's 'low human development' countries in the world.<sup>23</sup> Recent statistics have confirmed that over 91 per cent of the UN's 'low human development' countries are in SSA.<sup>24</sup> This grim reality in SSA thus calls for renewed focus on human-centered approaches to development. As the renowned economist Sachs has noted, "if you want to understand the problems of Africa, you really need to understand malaria,"<sup>25</sup> and, more recently, the escalating HIV/AIDS and TB pandemics in SSA. But as it stands now, access to quality healthcare remains the province of the few elite in SSA. The general population cannot afford to buy patented brand name medicines owing largely to the high cost of pharmaceutical products in the marketplace.

Given that the healthcare needs of citizens in SSA are largely unmet, this chapter fills this virtual lacuna in the health delivery outcomes through the instrumentality of patent law. It argues that having access to medicines to treat the HIV/AIDS, malaria, and TB epidemics will alleviate human suffering and, as a corollary, promote human development in SSA. As such, a sustainable human development-oriented patent paradigm should foster access to essential medicines and enrich people's lives. Therefore, a human development-

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<sup>21</sup> The three Bretton Woods Institutions comprise: the World Bank, the International Monetary Fund, and the World Trade Organization.

<sup>22</sup> Oppong, "Trade and Human Rights", *supra* note 19 at 124, citing UNCTAD, *Trade and Development Report* (2004).

<sup>23</sup> See Bush, *Poverty & Neoliberalism*, *supra* note 11 at 28.

<sup>24</sup> See UNDP, *Human Development Report: Human Development Index Rankings*, 2009, available online <<http://hdr.undp.org/en/statistics/>>. The 24 'low human development' countries are: Togo, Malawi, Benin, Timor-Leste, Cote d'Ivoire, Zambia, Eritrea, Senegal, Rwanda, Gambia, Liberia, Guinea, Ethiopia, Mozambique, Guinea-Bissau, Burundi, Chad, DR Congo, Burkina Faso, Mali, Central African Republic, Sierra Leone, Afghanistan, and Niger. This classification comes against the backdrop of the vast mineral and biological resources in SSA

<sup>25</sup> Jeffrey Sachs, quoted in Julia Stewart, *Stewart's Quotable Africa* (South Africa: Penguin Books, 2004) at 117.

oriented patent paradigm, including public health, should become the new foundation, or at least play a key role, in the pursuit of sustainable development in SSA.

## **B. On Patents and Development**

In the province of patent law, the dominant approaches in policy and academic discourse have also focused chiefly on using patents as instruments for economic growth rather than for human development.<sup>26</sup> The primary focus of TRIPS has been to promote trade liberalization by supporting adequate and effective protection for patents, among other IP rights.<sup>27</sup> Under this dominant economic approach, technology transfer, including access to medicines, is supposed to occur as a by-product of foreign direct investment, encouraged by the adoption of IP minimum standards and aided by technical assistance.<sup>28</sup> Proponents of this economic thinking conclude that a country cannot opt out of the international patent system and yet still achieve economic development.<sup>29</sup> Further, Idris notes that the “absence of an IP culture results in a stagnant or receding economy and a reduction in creativity and inventiveness.”<sup>30</sup> He further writes that,

These ideas – that patents are not relevant to developing nations or that they are incompatible with the economic objectives of the developing nations – are inaccurate because they give the impression that it is possible to simply opt out of the international patent system and yet still achieve economic development. This is an error, as patents are an essential

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<sup>26</sup> See generally Robert Sheerwood, *Intellectual Property and Economic Development* (Boulder, CO: Westview Press, 1990); Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth* (Geneva: WIPO, 2003); Carsten Fink & Keith E Maskus, eds, *Intellectual Property and Development: Lessons from Recent Economic Research* (New York: Oxford University Press, 2005); Keith E Maskus, ed, *Intellectual Property, Growth and Trade* (The Netherlands: Elsevier, 2008); Keith E Maskus, “Using the International Trading System to Foster Technology Transfer for Economic Development” (2005) 2005 Mich St L Rev 219.

<sup>27</sup> Ruth L Okediji, “The Limits of Development Strategies at the Intersection of Intellectual Property and Human Rights” in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 355 at 357.

<sup>28</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 97.

<sup>29</sup> See Idris, *IP: A Power Tool for Growth*, *supra* note 26 at 133.

<sup>30</sup> Idris, *IP: A Power Tool for Growth*, *ibid* at 6.

component of economic strategy regardless of whether the country is developed or developing.<sup>31</sup>

The downside is that this dominant free-market or neoliberal orthodoxy marginalizes the individual who is the central subject of international trade and development economics. Even worse, this traditional bias towards patents-as-growth model has disabled scholars from appreciating, in a nuanced way, the negative ramifications of WTO patent rules on human development in SSA countries. Hence, the public interest and the public health considerations of TRIPS have been consigned to the periphery of international patent law-making as well as domestic policy discourse.

In particular, the preceding chapters 1 to 4 have shown that the globalized patent regime has placed the private property interests in pharmaceuticals over the public interest to deliver medicines to the masses affected by epidemics in SSA. The ideology of the globalized patent system privileges western standards over the needs of SSA countries, and has consequently failed to promote social benefits and human progress. The influence of big pharma in the debate leading to the adoption of TRIPS confirms this bias towards extracting additional rents from the less developed world. Big pharma is less than enthusiastic to find cures for tropical diseases that afflict the citizens of SSA, because the need does not match the market.<sup>32</sup> Indeed, the fact that “R&D for neglected tropical diseases receives only \$1 of every \$100,000 spent worldwide on biomedical research and product development”<sup>33</sup> gives an insight into the psychology of the pharmaceutical industry.

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<sup>31</sup> Idris, *IP: A Power Tool for Growth*, *ibid* at 133.

<sup>32</sup> Oguamanam, “Patents and Pharmaceutical R&D”, *supra* note 2 at 559 & 561, citing 2006 WHO report and 2008 Oxfam report.

<sup>33</sup> Oxfam, *Ending the R&D Crisis in Public Health: Promoting Pro-Poor Medical Innovation*, Oxfam International Briefing Paper No. 22, (Oxford, November 2008) at 1, online: <http://www.oxfam.org/policy/ending-r-and-d-crisis-public-health>.

More troubling, bilateral TRIPS-plus commitments are increasingly transforming the frontiers of the international patent system into a strongly protective mechanism for regulating pharmaceuticals in the marketplace. The result is an access gap, whereby many patients in the less developed world cannot afford to purchase patented medicines, while many in the developed world have such access.<sup>34</sup> The quest for a well balanced patent system that promotes innovation and social benefits has become elusive for poor regions such as SSA. In consequence, patent protection undermines efforts to develop regulatory policies aimed at promoting affordability of and/or access to essential life-saving medicines needed for achieving sustainable human development in SSA. This lack of adequate healthcare in SSA is, however, likely to change for the better if the design of the globalized patent system and its domestic prototypes is re-calibrated to take cognizance of human development principles.

So conceived, this chapter explores ways to achieve human development ends through the instrumentality of patent law. It makes a case to reconstruct the globalized patent framework to be responsive to the health needs of the citizens of SSA by incorporating human development concepts into the design of international patent rules. The question then is: how do we reshape the contours of the globalized patent regime to be responsive to the health needs and aspirations of the citizens of SSA? This chapter should be read keeping in mind chapters 3 to 5 which canvassed arguments as to how to address some of the regulatory dysfunctions associated with the globalized patent system. Those retooling proposals include stemming the trends of biopiracy, checking industry's rent-seeking behaviour, increasing the participation of the citizens in patent lawmaking processes, as well as tackling the democratic deficits inherent in international patent law making initiatives and their reflections in domestic jurisdictions.

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<sup>34</sup> Beirne Roose-Snyder & Megan K Doyle, "The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level" (2009) 35 Am JL & Med 281 at 282.

Moreover, the notion of the applicability of a ‘one-size-fits-all’ mantra of global IP governance needs to change in order to take account of the impact-in-fact of patent rules in SSA countries. This implies utilizing real evidence on epidemic diseases as well as access to medicine challenges in SSA to influence domestic patent law- and policy-making. In addition, chapter 6 has made a case for the right to health to trump rigid pharmaceutical patent rules in SSA via socio-economic rights enforcement. Given that not all jurisdictions in SSA have robust socio-economic rights enforcement jurisprudence, this chapter makes additional prescriptions for human development-oriented concepts to be incorporated into the design, interpretation and implementation of WTO patent rules. A human development-oriented patent paradigm is a promising avenue to address asymmetries in the international trading system. It will also limit the growing breadth of pharmaceutical patent rights in the global economy and ensure sustainable public healthcare policies in SSA.

### **C. Outline of this Chapter**

This chapter is divided into four parts including this introduction. Part II of this chapter is further divided into two sections. Section A analyzes post-TRIPS development-friendly initiatives that have sought to mitigate the hardships associated with the globalized patent system. This discussion is situated within the contexts of the development mandates of WIPO and the WTO, the two most important institutions for global knowledge governance. My conclusion is that WIPO is increasingly embracing the overall human development goals of the UN. In contrast, the WTO has paid relatively less attention to global human development goals. As a consequence, the WTO’s development-friendly measures have not succeeded in rectifying the inequities inherent in the prevailing international patent and institutional frameworks. To reverse such trends, section B proposes that extrinsic human development concepts, including social justice and equity issues, which have long been at the periphery of international patent law making initiatives, should be incorporated into the design, interpretation and implementation of WTO patent rules.

The approach to integration that I propose in this study can be undertaken in two ways: first, I propose the opening of a new round of trade negotiations with the mandate to come out with a framework treaty that integrates human development considerations into global and national patent regimes. This proposed legal framework should develop additional public health and human development exceptions/limitations to the exercise of patent rights. The proposed negotiations can be undertaken at the TRIPS Council meeting with the aim of making recommendations to the General Council of the WTO for adoption as an amendment to TRIPS. Second, but complementary to the above point, I propose interpreting/implementing patent rules in a manner that allows state agencies and the dispute settlement bodies of the WTO to recognize the salience of human health (life) over patent rights. As I elaborate further below, this suggestion for a broad-based re-conceptualization of patents would redress the WTO's approach of limiting itself to the use of the built-in 'flexibilities' under its constitutive instruments and thus promote human development.

Part III employs the objectives (i.e., Article 7) and the principles (i.e., Article 8) of TRIPS as foundational/theoretical bases to justify the need to incorporate human development and social justice-oriented concepts into the interpretation and implementation of WTO patent law. It bears emphasizing that both Articles 7 and 8 of TRIPS have a special significance in matters of interpretation of international patent/trade-related obligations under the WTO system.<sup>35</sup> In addition, this part articulates the point that general international law supports the use of human development-friendly concepts/principles to inform the interpretation and implementation of WTO patent law. For the same reason, the proposed human development-oriented patent paradigm should inform the contents of domestic implementation of international patent obligations in SSA. Part IV concludes the discussion.

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<sup>35</sup> See Paragraph 19 of the Doha Ministerial Declaration.

## **II. Human Development and Social Justice Issues Revisited**

### **A. Pro-Development Agenda-Settings in WIPO and the WTO**

The concept of development is neither new to the WIPO system nor the GATT/WTO system. The constitutive instruments of both WIPO and the WTO underscore that the concept of development is part of their mandates. Yet the two organizations' pro-development mandates have traditionally favored private right holders who seek new or increased patent standards across the globe. Also, the norm-setting activities of WIPO and the WTO have been eclipsed by western economism, an approach that undermines the public interest considerations of IP jurisprudence. Perhaps, more accurately, the two institutions have not fully integrated human development concepts into their patent norm setting activities; they have not been particularly imaginative in how they implement their development mandates to improve human lives in poor countries.

This is not to suggest that WIPO and the WTO have been wholly insensitive to the plight of poor regions such as SSA. There are growing efforts in the post-TRIPS era to mitigate the rigidities associated with the international patent regime, as epitomized by TRIPS. Today, the two institutions are increasingly abandoning their traditional views that IP is universally applicable and that it inevitably leads to economic development.<sup>36</sup> Thus, WIPO and the WTO have been challenged, if not pressured, to adopt measures that promise to promote human development and public health in less developed countries. As I explain below, whereas WIPO's response has been more far-reaching, the WTO's approach has been less than enthusiastic.

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<sup>36</sup> See E Richard Gold & Jean-Frederic Morin, "From Agenda to Implementation: Working outside the WIPO Box" in Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization's Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009) 57 at 59.

## 1. WIPO

As a specialized agency of the UN, WIPO is required to contribute to the UN's overall development mandate.<sup>37</sup> WIPO is "responsible for taking a more appropriate action in accordance with its basic instrument, treaties and agreements administered by it, *inter alia*, for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development."<sup>38</sup> This mandate has emboldened WIPO to re-assert its authority (which was lost to the WTO) on matters of IP and development. The recent adoption of the Development Agenda by WIPO as part of its norm setting-activities is an apt illustration of this point.<sup>39</sup>

This paradigm shift became possible because of pressure from the less developed world as well as civil society groups. One such force is the Group of Friends of Development that tabled a proposal for WIPO to pursue a development agenda, which takes account of a country's level of development.<sup>40</sup> The proposal by the Group of Friends of Development stressed "the need to integrate the 'development dimension' into policy making on intellectual property protection."<sup>41</sup> It thus sought to reform WIPO so that its principles and norm-setting activities are development-oriented rather than the

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<sup>37</sup> See De Beer, "Defining WIPO's Development Agenda", *supra* note 11 at 4; Hans Morten Haugen, "Access versus Incentives: Analyzing Intellectual Property Policies in Four UN Specialized Agencies by Emphasizing the Role of the World Intellectual Property Organization and Human Rights" (2010) 13 *Journal of World Intellectual Property* 697 at 698.

<sup>38</sup> Article 1, *Agreement between the UN and the WIPO*, 1974, online: <<http://www.wipo.int/treaties/en/agreement/index.html>>.

<sup>39</sup> See the WIPO Development Agenda (2007), online: <<http://www.wipo.int/export/sites/www/ip-development/en/agenda/recommendations.pdf>>.

<sup>40</sup> WIPO, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, DoCWO/GA/31/11. The initial proposal for this development agenda was made by Argentina and Brazil, and joined by Bolivia, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela. The above countries formed the Group of Friends of Development.

<sup>41</sup> See Part II, the *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, DoCWO/GA/31/11.

unidirectional approach of promoting IP whilst neglecting the public interest.<sup>42</sup> After 3 years of negotiations, this proposal by the Group of Friends of Development was unanimously adopted in September 2007 as the WIPO Development Agenda. Without attempting to be exhaustive, what follows is a brief discussion of some the recommendations under the WIPO Development Agenda.

The WIPO Development Agenda has 45 recommendations. These recommendations have been grouped into topical clusters: A (Technical Assistance and Capacity Building), B (Norm-setting, flexibilities, public policy and public domain), C (Technology transfer, Information and Communication Technologies and Access to Knowledge), D (Assessment, Evaluation and Impact Studies), E (Institutional Matters including Mandate and Governance), and F (Other Issues). It is worth noting that these groupings do not signify that some of the recommendations are of a higher priority than others. Altogether, the recommendations under the Development Agenda attempt to rectify the imbalances associated with the international IP system, as ushered into force by TRIPS.

In particular, the Cluster B recommendations mandate that WIPO's IP and development norm-setting activities shall:

- be inclusive and member driven;
- take into account different levels of development;
- take into consideration a balance between costs and benefits;
- be a participatory process, which takes into consideration the interests and priorities of all WIPO member states and the viewpoints of other stakeholders, including accredited inter-governmental organizations (IGOs) and NGOs; and
- be in line with the principle of neutrality of the WIPO Secretariat.<sup>43</sup>

The prevailing thinking, therefore, is that the Development Agenda creates a soft international law which rejects a one-size-fits-all approach to IP protection.<sup>44</sup> Soft law

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<sup>42</sup> Martin Khor & Sangeeta Shashikant, eds, *Negotiating a 'Development Agenda' for the World Intellectual Property Organization* (Penang, Malaysia: TWN, 2009) at 1.

<sup>43</sup> Recommendation 15 of the WIPO Development Agenda, 2007.

refers to certain categories of norms, technically non-binding, that states nonetheless follow in practice or to which they at least subscribe.<sup>45</sup> The Agenda thus recognizes that human development concerns cannot be addressed unless the globalized patent regime recognizes different levels of development among nations. This recognition has contributed to changing the patent and development landscape by advocating a balance between patent rights protection and access to medicines in less developed countries. The recommendations in the Development Agenda also suggest that WIPO has shifted focus from being a defender of the protection of IP rights to a global pro-development organization.

So far, developed countries have not patently exhibited any rejection of the forty-five recommendations in the Development Agenda. As soft law, the recommendations in the Agenda may have a moral effect on both developed and developing countries alike. Soft law can be a useful tool in interpreting the *TRIPS Agreement*.<sup>46</sup> In addition, soft-law approaches have proven to be a very reliable mechanism for consensus seeking among opponents and proponents of international patent norm-creating endeavors. Soft law initiatives have also become entry points for gaining access to the WTO and the WIPO in order to influence crucial patent and development initiatives. The recommendations in the Agenda may also influence the actual practices of states in formulating domestic patent/development policies to promote access to medicines.

Furthermore, some of the recommendations, especially those that seek to reorient WIPO towards development, are earmarked by the WIPO General Assembly for immediate implementation.<sup>47</sup> Presumably, those recommendations earmarked for immediate

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<sup>44</sup> De Beer, "Defining WIPO's Development Agenda", *supra* note 11 at 10-11.

<sup>45</sup> Edward Kwakwa, "Some Comments on Rulemaking at the World Intellectual Property Organization" (2002) 12 *Duke J Comp & Int'l L* 179 at 187.

<sup>46</sup> Laurence R Helfer, "Regime Shifting: the TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29 *Yale J Int'l L* 1 at 77.

<sup>47</sup> It is worth noting that 19 out of the 45 recommendations have been identified by the WIPO General Assembly for immediate implementation.

implementation do not require huge financial or human resources to move forward.<sup>48</sup> For example, recommendation 1 of the Development Agenda provides that WIPO's technical assistance shall be development-oriented, demand-driven and transparent, taking into account the priorities and the health needs of countries as well as their levels of development. In addition, recommendation 12 mandates WIPO to mainstream development considerations into its substantive and technical assistance activities. Such development considerations include promoting the development goals agreed within the UN system, including the Millennium Development Goals (MDGs) to fight health inequality in less developed countries.<sup>49</sup>

In addition, WIPO is obliged to take into account the flexibilities in international IP agreements, especially those that benefit less developed countries.<sup>50</sup> WIPO must also enhance the participation of civil society in its activities.<sup>51</sup> The participation of civil society in WIPO's technical assistance activities in SSA would enhance the public interest dimension of IP law jurisprudence, a point which I emphasize in chapter 2 of this text. The central thrust of these recommendations is to move WIPO adroitly in the direction of a human-centered approach to development in international patent law making endeavors. By adopting the Development Agenda, WIPO has embraced the prevailing international human development goals of the UN.

Outside the corridors of the UN, scholars have shown interest in the implementation of the WIPO Development Agenda. They have begun to delineate the scope and contents of the Development Agenda, an approach that should facilitate its implementation.<sup>52</sup> According to De Beer, defining the Development Agenda in negative terms – by what it

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<sup>48</sup> De Beer, "Defining WIPO's Development Agenda", *supra* note 11 at 6.

<sup>49</sup> See also recommendation 22 of the WIPO Development Agenda.

<sup>50</sup> See recommendation 17 of the WIPO Development Agenda.

<sup>51</sup> See recommendation 42 of the WIPO Development Agenda.

<sup>52</sup> For commentaries on the implementation of the WIPO Development Agenda see Jeremy de Beer, ed, *Implementing the World Intellectual Property Organization's Development Agenda* (Ottawa: Wilfrid Laurier University Press, 2009).

is not rather than by what it is – could be counterproductive.<sup>53</sup> He thus defines the Development Agenda by four features: malleability (i.e., shaping the agenda to suit different stakeholders' interests), complexity (i.e., viewing the development agenda in light of the larger framework of the IP regime complex), opportunity (i.e., presenting a platform for WIPO to recapture its lost image and to maintain its relevance to the less developed world), and gravity (i.e., implementing the development agenda in good faith will bring on board WIPO's largest constituents, the developing world).<sup>54</sup>

Also, development scholars have argued that implementing the Development Agenda presents an opportunity to incorporate a substantive equality principle and social justice concepts into global knowledge governance issues.<sup>55</sup> Although the Development Agenda does not make explicit reference to human rights and public health considerations, Haugen justifies the need for WIPO, as an agency of the UN, to mainstream human rights principles into the implementation of its IP norms and the Development Agenda.<sup>56</sup> The justification for integrating international norms on patents and human right norms is that they share similar social functions and goals. Indeed, both bodies of norms seek to pursue the attainment of the social dimensions of human personhood.

In conclusion, the need to integrate the 'development dimension', including development principles extrinsic to WIPO, into international patent law making has received increased recognition at the international level.<sup>57</sup> Incorporating human development principles, including human rights principles, into WIPO's norm-setting activities is consistent with the organization's mandate as a specialized agency of the UN. In consequence, the WIPO Development Agenda is increasingly re-establishing the social/public policy dimension

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<sup>53</sup> De Beer, "Defining WIPO's Development Agenda", *supra* note 11 at 3.

<sup>54</sup> De Beer, "Defining WIPO's Development Agenda", *ibid* at 9-16.

<sup>55</sup> De Beer, "Defining WIPO's Development Agenda", *ibid* at 17; Barbosa et al, "Slouching towards Development", *supra* note 3; Chon, "IP and the Development Divide", *supra* note 5.

<sup>56</sup> Haugen, "Access versus Incentives", *supra* note 37 at 702.

<sup>57</sup> Khor & Shashikant, eds, *Negotiating a Development Agenda*, *supra* note 42 at 14.

of patent protection, an approach that was subdued during the TRIPS negotiations. However, it will take years before such efforts bear fruits and also reverse the inequities inherent in the international patent system.

Given that WIPO lacks enforcement mechanisms against non-complaint member states, the WTO should play a key role in any attempts to mainstream development considerations into global trade-related IP matters.

## 2. WTO

The concept of development forms a core aspect of the WTO's norm setting activities. For example, the Preamble to the Marrakesh Agreement Establishing the WTO provides that trade relations should be conducted "with a view to raising standards of living...while allowing for optimal use of the world's resources in accordance with the objective of sustainable *development*." As Cho explains, the WTO charter connotes a much broader idea of integration that ensures that both trade values and social values are upheld in a coherent and synergetic manner, rather than competing fashion.<sup>58</sup> In addition, the Preamble to the *TRIPS Agreement* recognizes "the underlying public policy objectives of national systems for the protection of intellectual property, including *developmental* and technological objectives" of WTO member states as part of global trade relations. To these ends, the WTO has become a forum for continued negotiations on the liberalization of trade-related matters, including international patent law making and global development.<sup>59</sup>

More fundamentally, the post-TRIPS epoch has witnessed the conclusion of a number of human development-friendly initiatives that have sought to forge a more humane and equitable international patent regime. Notably, these post-TRIPS initiatives include the

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<sup>58</sup> Sungjoon Cho, "Linkage of Free Trade and Social Regulation: Moving beyond the Entropic Dilemma" (2005) *Chi J Int'l L* 625 at 646-647.

<sup>59</sup> See Paragraph 4 of the Doha Ministerial Declaration.

adoption of the Doha Ministerial Declaration, the Doha Declaration, and the WTO General Council's 'Augusts 30' Decision. For example, under the Doha Ministerial Declaration, the trade ministers of the WTO member-states reaffirmed their commitment to the concept of sustainable human development as stated in the Preamble to the Marrakesh Agreement.<sup>60</sup> This Ministerial Declaration also sought to redress the marginalization of least developed countries (LDCs) in international trade and to improving their effective participation in the multilateral trading system.<sup>61</sup> It also emphasized that countries should not be prevented from taking measures to protect human health, provided they are non-discriminatory.<sup>62</sup> In this vein, the implementation and interpretation of TRIPS must support public health, by promoting access to medicines.<sup>63</sup>

A more specific *Declaration on the TRIPS Agreement and Public Health* affirmed the sovereign right of governments to take measures to promote public health and ensure access to medicines for all.<sup>64</sup> This Declaration recognized that IP protection is important for the development of new medicines and also took note of the concerns about the effects of IP protection on the prices of new medicines.<sup>65</sup> The Doha Declaration explained that states have the sovereign right to determine the grounds upon which compulsory licenses are granted to tackle health related emergencies.<sup>66</sup> And also that states are not required to consult patent right holders before issuing compulsory licenses to address public health concerns.<sup>67</sup> The Doha Declaration further clarified that countries

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<sup>60</sup> See paragraph 6 of the Doha Ministerial Declaration.

<sup>61</sup> Paragraph 3 of the Doha Ministerial Declaration.

<sup>62</sup> Paragraph 6 of the Doha Ministerial Declaration.

<sup>63</sup> Paragraph 17 of the Doha Ministerial Declaration

<sup>64</sup> See Paragraph 4 of the Doha Declaration.

<sup>65</sup> Brenda Pamela Mey, "Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: A Dead-End Journey for Patients? Kenya and India Case Studies" (2010) 13 *Journal of World Intellectual Property* 403 at 412.

<sup>66</sup> See Paragraph 5(b) of the Doha Declaration.

<sup>67</sup> See Article 31(b) of the *TRIPS Agreement*.

have the prerogative to decide whether they will allow a regime of international or national exhaustion of patents to be applied in their territories.<sup>68</sup>

While some hail the Doha meeting as a post-TRIPS success, others disagree with that assertion. According to Hoen, Doha signalled a sea change in thinking about “IP as a social policy tool for the benefit of society as a whole, rather than [as] a mechanism to protect limited commercial interests.”<sup>69</sup> Similarly, other scholars contend that these post-TRIPS developments are indicative of the emergence of a new era of IP,<sup>70</sup> an era that promises to deliver human development outcomes for the less developed world. For Gold et al, this new era of IP reverses the old era which hinged on the core belief that if some IP is good, then more must be better.<sup>71</sup> On the other hand, critics of the international patent system argue that the Doha meeting failed to achieve any meaningful success.<sup>72</sup> Notably, Doha failed to allow for medicines to be exported to countries which lacked domestic manufacturing capacity; countries with manufacturing capacities were only allowed to use compulsory licenses to produce medicines ‘predominantly’ for the supply of the domestic market.<sup>73</sup> In essence, the implementation of the Doha declarations over time made it obvious that there were still some inflexibilities inherent in the international patent system.

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<sup>68</sup> See Paragraph 5(d) of the Doha Declaration.

<sup>69</sup> Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health* (The Netherlands: AMB, 2009) at xvi.

<sup>70</sup> See Richard Gold et al, “Toward a New Era of Intellectual Property: From Confrontation to Negotiation” (2008) *A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property*, at 13, online: [http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf).

<sup>71</sup> Gold et al, “Toward a New Era of IP”, *ibid* at 7.

<sup>72</sup> See e.g., Richard Elliot, “Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada’s Law on Compulsory Licensing for Export” (2007) 3 McGill JSDLP 23; Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003) at 161-162.

<sup>73</sup> See Article 31(f) of the *TRIPS Agreement*.

In a further move to inject real flexibility into the globalized patent system, the WTO General Council issued the *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* on August 30, 2003. This ‘August 30’ Decision allows for the export of medicines manufactured under compulsory licenses into countries that lack domestic production capacity. The ‘August 30’ Decision also became the key platform for the permanent amendment to Article 31 of TRIPS. Yet still, the ‘August 30’ Decision contains inflexibilities relating to the quantity of medicines to manufacture; limits on the quantity to export or import; and, then an added requirement for the payment of adequate remuneration by exporting members, among others. Srivastava & Satyanarayana have articulated these drawbacks thus:

The tedious process...includes: (i) prior negotiation necessary before compulsory license granted; (ii) anti-diversion measures to kill incentives for generic production; (iii) notification of intention to use August 30 Decision; and [sic] (iv) the decision is unrealistic; and (v) the decision is not automatic, but a succession of complex procedural steps.<sup>74</sup>

Similarly, Sampath notes that having to go through the scrutiny of the TRIPS Council before a state can proceed further limits access to generic medicines.<sup>75</sup> This notification process unnecessarily exposes less developed countries to political pressure from industrialized countries, thereby creating a disincentive to use the ‘August 30’ mechanism.<sup>76</sup> The ‘August 30’ Decision has yet to roll back the adverse effects of the globalized patent system on public health and human development in poor regions such as SSA. The fact that Rwanda is the only country which has so far notified the TRIPS Council and utilized the ‘August 30’ mechanism to import generic medicines, Apo

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<sup>74</sup> Sadhana Srivastava & K Satyanarayana, “Amendment of Article 31(f) is far from a ‘solution’” (2008) *Indian J Med Res* 84 at 86.

<sup>75</sup> Padmashree Gehl Sampath, “India’s Product Patent Protection Regime: Less or More of ‘Pills for the Poor’?” (2006) 9 *Journal of World Intellectual Property* 694 at 696.

<sup>76</sup> Hoen, *The Global Politics*, *supra* note 69 at 37.

TriAvir, from Canada speaks volumes.<sup>77</sup> Even with this Rwandan experience, the rigid nature of the application procedures under Canada's *Access to Medicines Regime*,<sup>78</sup> and the high cost of Canadian generics as compared to that of India made the whole deal unattractive.<sup>79</sup> For Chon, the protracted implementation of the 'August 30' Decision demonstrates an ongoing lack of enthusiasm within the WTO system to move towards a broader conception of development.<sup>80</sup>

As earlier mentioned, following the 'August 30' Decision, Article 31 of the *TRIPS Agreement* has been amended to facilitate access to cheaper generics via the use of compulsory licensing schemes. This amendment known as Article 31*bis* comes into force when two-thirds of all WTO members ratify the change. However, doubts still remain about these 'humanitarian' prescriptions and the actual ability of African countries to make use of those prescriptions.<sup>81</sup> In expressing skepticism about the amendment of Article 31 of the *TRIPS Agreement*, Mgbeoji posits that African countries have not fared much better in terms of developing local industrial manufacturing capacity and thus significantly addressing the dire health challenges in Africa.<sup>82</sup> Far more worrisome, these modest gains made in the post-TRIPS era are in imminent danger of being reversed, owing largely to the recent imposition of TRIPS-plus obligations via bilateral trade and investment agreements between the west and countries in Africa.

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<sup>77</sup> For a discussion of the obstacles associated with Canada's Access to Medicines regime see Paige E Goodwin, "Right Idea, Wrong Result – Canada's Access to Medicines Regime" (2008) 34 Am JL & Med 567.

<sup>78</sup> See Government of Canada, *Report of the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (2007) <[http://camr-rcam.hc-sc.gc.ca/index\\_e.html](http://camr-rcam.hc-sc.gc.ca/index_e.html)>.

<sup>79</sup> See Goodwin, "Right Idea, Wrong Result", *supra* note 77 at 580-583.

<sup>80</sup> Margaret Chon, "Substantive Equality in International Intellectual Property Norm Setting and Interpretation" in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 475 at 490 [Chon, "Substantive Equality in International IP"].

<sup>81</sup> Ikechi Mgbeoji, "TRIPS and TRIPS-Plus Impacts in Africa" in Daniel J Gervais, ed, *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era* (Oxford: Oxford University Press, 2007) 259 at 274.

<sup>82</sup> Mgbeoji, "TRIPS and TRIPS-Plus in Africa", *ibid* at 274-275.

In short, the adverse impacts of TRIPS on public health in poor regions such as SSA are emerging. Yet the WTO's re-calibration measures have not fully addressed the gargantuan inadequacies associated with the globalized patent regime. Perhaps, more accurately, the WTO's calibration process has left a sour taste in mouths of proponents of human development and public health policies in poor countries. The *ad hoc* suspension of the obligations to implement patent rules on pharmaceuticals for LDCs is evidence of the limitations or failures in the WTO's approach. Still, those transitional arrangements fail to address how differential needs would be catered for in the post transition period. Presumably, the WTO's formal suspension of TRIPS' obligations for LDCs is likely to be renewed, as the organization strives to manage the welfare costs associated with the implementation of international norms on patents.

To address these persistent failures in the international patent system, the WTO must look beyond its sphere of operations and tap in to proposals that assure human development outcomes in less developed countries. More needs to be done through the incorporation of extrinsic human development principles into the agenda setting activities of the WTO. A move towards a broader conception of development in patent law making will facilitate access to medicines and other life-saving healthcare services in poor regions such as SSA.

## **B. Promoting Human Development: Thinking Outside the WTO Box**

This section takes up the argument that human development-friendly concepts that have evolved outside the WTO system should be integrated into the interpretation and implementation of international norms on patents. Such incorporation is crucial for the realization of the object and purpose of the international patent system to promote public health and human development in SSA. Before setting out how this integration can be undertaken, it is worth pausing momentarily to discuss a number of human development and social justice-oriented proposals that have been advanced in policy and academic discourse. These human development-oriented principles should be infused into the

formulation of pharmaceutical patent regulatory policies, as they hold the key to scaling up access to medicines that could eventually ensure sustainable human development and public health in SSA. The discussion that follows should not be seen as exhaustive, however. Also, the account below is brief and is mainly intended to highlight some of the proposals in in policy and academic discourse.

### 1. In Search for Substantive Equality Principle(s)

As noted in chapters 3 and 5 of this study, even though efforts have been made to extend the transition period of TRIPS' implementation for LDCs, TRIPS' non-discriminatory principles of Most Favoured Nation (MFN) treatment and national treatment must be complied with across the globe, be it in Kiribati<sup>83</sup> or Sudan. The MFN principle proscribes trade-related discrimination among foreign nationals. On the other hand, national treatment is a principle of non-discrimination barring internal discrimination in favour of domestic actors over non-nationals.<sup>84</sup> Both MFN and national treatment principles are termed 'formal equality principles', as they impose minimum standards on all countries regardless of their level of development.<sup>85</sup> Thus, under these non-discriminatory principles, states are deemed to be equal before the law despite inequalities in actual levels of states.<sup>86</sup> Formal equality principles under TRIPS promote a 'one-size-fits-all' approach to patent law making in a manner that is hostile to nuanced differentiation among states.<sup>87</sup> Hence, both MFN and national treatment principles have the insidious effects of rendering formal suspension of TRIPS' implementation meaningless for many SSA countries.

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<sup>83</sup> Drahos reports that in Kiribati, a relatively unknown island nation, there are over 20 pharmaceutical patents registered in its patent office. See Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (New York: Cambridge University Press, 2010) at 1.

<sup>84</sup> Barbosa et al, "Slouching towards Development", *supra* note 3 at 114.

<sup>85</sup> Chon, "IP and the Development Divide", *supra* note 5 at 2823.

<sup>86</sup> Chon, "Substantive Equality in International IP", *supra* note 80 at 526.

<sup>87</sup> Barbosa et al, "Slouching towards Development", *supra* note 3 at 114-115.

Besides MFN and national treatment principles, there are other formal equality principles under TRIPS.<sup>88</sup> For example, TRIPS binds WTO members to grant patent rights without discrimination as to place of invention, the field of technology and whether the products are imported or locally produced.<sup>89</sup> Also, the WTO's dispute settlement mechanism is rooted in 'formal equality' at the level of applicable legal principles.<sup>90</sup> WTO member states are considered as complete equals before the Dispute Settlement Body; countries compete on the same normative terms and condition. This arrangement favors developed countries both *de jure* and *de facto*: less developed countries are disadvantaged when it comes to employing complex and expensive legal processes to prosecute claims of bio-piracy.<sup>91</sup> For instance, the EU is seen as a single entity within the WTO set-up. It has standing before the dispute settlement bodies. The economic power of one of the EU states is stronger than that of all SSA countries combined. Therefore, a dispute between the EU and a country in SSA is like killing a mosquito with a rifle.

In effect, TRIPS' universal minimum standards epitomize what Chon calls a 'universalist approach of deep integration', a phenomenon which ties preferential treatment for poor countries to the ever-pervasive process of global economic liberalization.<sup>92</sup> Since SSA countries are interested in participating in international trade under the aegis of the WTO, these patent-related formal equality principles are imported into domestic jurisdictions of states with few or no options. Moreover, chapters 3 and 5 have shown that technical assistance initiatives have steered SSA countries to enact TRIPS-compliant and TRIPS-plus laws in their domestic jurisdictions. In light of these developments, the transition rules and patentability exceptions under TRIPS are honored more in the breach than in

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<sup>88</sup> Chon, "Substantive Equality in International IP", *supra* note 80 at 501.

<sup>89</sup> See Article 27.1 of the *TRIPS Agreement*.

<sup>90</sup> Chon, "Substantive Equality in International IP", *supra* note 80 at 502.

<sup>91</sup> Joseph E Stiglitz & Andrew Charlton, *Fair Trade for All: How Trade Can Promote Development* (Oxford: Oxford University Press, 2005) at 82-83.

<sup>92</sup> Chon, "IP and the Development Divide", *supra* note 5 at 2841.

their observance. The net result is that the public interest and public health considerations of the globalized patent system remain imperiled.

To remedy these regulatory dysfunctions, Chon suggests that patent globalization must embody ‘substantive equality’ principles to counter the ‘myth’ (as defined in chapter 4 as a defect) in the ‘formal equality’ principles under TRIPS.<sup>93</sup> Thus, in order for IP globalization to achieve human development outcomes, substantive equality norms must be incorporated into the trade-related decision-making itself.<sup>94</sup> This substantive equality principle posits that the goal of IP law should be to promote human development, by facilitating access to basic healthcare.<sup>95</sup> It ensures that patent law is construed and applied in a way that defers to the basic healthcare needs of those who require access to medicines.

A substantive equality principle is analogous to the doctrine of strict scrutiny in the judicial context of US constitutional law.<sup>96</sup> This strict scrutiny doctrine allows policy makers to accord much less deference and exercise much more skepticism towards government regulation, such as the grant of patents in the context of the provision of basic healthcare.<sup>97</sup> The strict scrutiny doctrines empower policy-makers to review and strike down a state-granted right which conflicts with the enjoyment of basic human development needs.

By application, Chon suggests that in measuring IP’s welfare-generating outcomes, we should not only be guided by economic growth but also by its distributional effects.<sup>98</sup> Thus, as a necessary corollary to the formal equality principles, a substantive equality

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<sup>93</sup> Chon, “Substantive Equality in International IP”, *supra* note 80 at 475; Chon, “IP and the Development Divide”, *ibid*

<sup>94</sup> Chon, “IP and the Development Divide”, *ibid* at 2912.

<sup>95</sup> Chon, “Substantive Equality in International IP”, *supra* note 80 at 479.

<sup>96</sup> Chon, “IP and the Development Divide”, *supra* note 5 at 2836, 2885.

<sup>97</sup> Chon, “IP and the Development Divide”, *ibid* at 2836.

<sup>98</sup> Chon, “IP and the Development Divide”, *ibid* at 2823.

principle must give heightened attention to distributional and social justice concerns that form the core of a human development-driven concept of ‘development’.<sup>99</sup> In the peculiar context of SSA, integrating substantive equality principles into domestic patent law making will require giving priority to the right to health in SSA. Given that public health is a prerequisite for any technological progress, access to medicines must have priority over the grant of exclusionary patent rights.<sup>100</sup> By emphasis, this vein of argument requires policy makers to give priority to both the short-term access and affordability to life-saving medicines and the long-term innovation policy goals in places such as SSA. It also implies maximizing TRIPS flexibilities and making nuanced distinctions among technologies despite the mandate of Article 27.1 of TRIPS.<sup>101</sup> Finally, this substantive equality principle should inform IP norm-setting and implementation at both the domestic and international levels.

## 2. Building Human Capabilities

Scholars such as Sen and Nussbaum have theorized an approach to development that emphasizes the enhancement of human capabilities.<sup>102</sup> This capabilities approach posits that a society is not developed until certain basic needs are provided for its people.<sup>103</sup> In regard to this capabilities thesis, Sen has propounded a model of development as freedom, which emphasizes the enhancement of human capability through the provision of basic needs such as education and health.<sup>104</sup> According to Sen,

Development requires the removal of major sources of unfreedom: poverty as well as tyranny, poor economic opportunities as well as systematic

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<sup>99</sup> Chon, “IP and the Development Divide”, *ibid* at 2835.

<sup>100</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 118.

<sup>101</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 118.

<sup>102</sup> See Sen, *Development as Freedom*, *supra* note 11; Martha Nussbaum, *Women and Human Development: The Capabilities Approach* (Cambridge: Cambridge University Press, 2000); Martha C Nussbaum, “Capabilities and Human Rights” (1997) 66 Fordham L Rev 273 at 287. The capabilities here involve being able to live a life of normal length and in good health via access to healthcare services.

<sup>103</sup> See Chon, “IP and the Development Divide”, *supra* note 5 at 2832.

<sup>104</sup> See Sen, *Development as Freedom*, *supra* note 11.

social deprivation, neglect of public facilities...Despite unprecedented increases in overall opulence, the contemporary world denies elementary freedoms to vast numbers – perhaps even the majority – of people. Sometimes the lack of substantive freedoms relates directly to economic poverty, which robs people of the freedom to satisfy hunger, or to achieve sufficient nutrition, or to obtain remedies for treatable illnesses....<sup>105</sup>

In criticizing the use of GDP as the primary measure of development, Sen stresses that development should be measured based on the provision of basic services including healthcare that allow human beings to function and live fuller lives.<sup>106</sup> Thus, “development has to be more concerned with enhancing the lives we lead and the freedoms we enjoy.”<sup>107</sup>

In the context of SSA, where epidemics have truncated human lifespan and also diminished human capacity to function, having access to medicines would play a pivotal role in the citizen’s quest to live a meaningful life. Further, Sen observes that development is a polycentric and integrative concept: while social opportunities including the provision of health care services facilitate economic participation, economic facilities help generate personal abundance as well as public resources needed for social facilities.<sup>108</sup> It goes without saying that economic growth is a necessary but not sufficient condition to achieve full development in SSA. In short, the work of Sen, as an alternative to the utilitarian focus on wealth maximization, must be central to discussions about the goals of patents and development, both at the domestic and international levels.

Similarly, Nussbaum propounds an approach to human development that emphasizes the improvement of living standards and quality of life.<sup>109</sup> For her, an individual should be “able to live to the end of a human life of normal length,” and be “able to have good

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<sup>105</sup> Sen, *Development as Freedom*, *ibid* at 3-4.

<sup>106</sup> Sen, *Development as Freedom*, *ibid* at 3-4.

<sup>107</sup> Sen, *Development as Freedom*, *ibid* at 14.

<sup>108</sup> Sen, *Development as Freedom*, *ibid* at 11.

<sup>109</sup> Nussbaum, “Capabilities and Human Rights”, *supra* note 102 at 279.

health, including reproductive health.”<sup>110</sup> In addition, Nussbaum has grounded this capabilities thesis in constitutional/social justice discourse by emphasizing the idea that “all human beings are precious, deserving of respect and support, and that the worth of all human beings is equal.”<sup>111</sup> As Nussbaum has perspicaciously observed,

[This capabilities approach] does...suggest that many of the most central human capabilities, given their enormous importance to basic social justice, should be placed beyond majority whim through constitutionally protected status....The special status of fundamental entitlements need not be guaranteed through a written constitution, but that is one common way of protecting them and ensuring that they are not held hostage to the vicissitudes of politics.<sup>112</sup>

In consequence, Nussbaum argues that there is a constitutional imperative for governments to supply basic human entitlements to their citizens.<sup>113</sup> The corollary is that individuals also have the right to demand basic healthcare services, among others, from their governments. It remains to emphasize that some of the modalities for protecting/prioritizing the right to health guaranteed in national constitutions in SSA have already been analyzed in chapter 6 of this text.

The above human capabilities model espoused by Sen and Nussbaum has featured prominently in the international development norm-making activities of the UN. As Barbosa et al point out the capabilities model underlies the objectives of UN MDGs, which seeks to assure a certain basic threshold of respect for human development and dignity across the world.<sup>114</sup> The reverse is true, however, with respect to the influence of the human capabilities model on international patent law making. Thus, the capabilities model has yet to inform the design, interpretation and implementation of the globalized

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<sup>110</sup> Nussbaum, “Capabilities and Human Rights”, *ibid* at 287.

<sup>111</sup> Martha C Nussbaum, “Constitutions and Capabilities: ‘Perception against Lofty Formalism’ (2008) 121 Harv L Rev 4 at 10.

<sup>112</sup> Nussbaum, “Constitutions and Capabilities”, *ibid* at 56.

<sup>113</sup> Nussbaum, *Women and Human Development*, *supra* note 102 at 5, 12.

<sup>114</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 76.

patent system under the WTO system.<sup>115</sup> Significantly, scholars and policy advocates have given directions on how the human capabilities model can mesh with international and domestic norms on patents.<sup>116</sup> The point is that the contents of this human capabilities model should inform international and domestic patent law making *vis-à-vis* access to pharmaceuticals in SSA

In reality, the work of the UNDP has been influenced by Sen and Nussbaum's theorization of the human capabilities model.<sup>117</sup> Consequently, the UNDP has, since 1990, propounded the approach of putting human beings at the center of development at both national and international levels. The UNDP's approach is based on the use of the 'human development index', as measured in terms of life expectancy at birth, educational attainment, and the standard of living as determined by real per capita income. Specifically, the UNDP has employed its human development report to promote an equitable sharing of the benefits of globalization.<sup>118</sup> This report has identified global inequality as the bane of human development, and has thus urged that sharing in the benefits of globalization requires the need to put human concerns and human rights at the centre of international policy and action.

In the year 2000, the UNDP dedicated its report to issues of 'human rights and human development'. This report emphasized the point that the realization of human rights is indispensable to the attainment of human development.<sup>119</sup> It noted that "when human development and human rights advance together, they reinforce one another – expanding

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<sup>115</sup> See Chon, "IP and the Development Divide", *supra* note 5 at 2832.

<sup>116</sup> See generally: Barbosa et al, "Slouching towards Development", *supra* note 3; Chon, "IP and the Development Divide", *ibid*

<sup>117</sup> See Barbosa et al, "Slouching towards Development", *ibid* at 76, 119; Chon, "IP and the Development Divide", *supra* note 5 at 2877.

<sup>118</sup> See UNDP, *Human Development Report 1999: Human Development in this age of Globalization*, online: [http://hdr.undp.org/en/media/hdr\\_1999\\_ch1.pdf](http://hdr.undp.org/en/media/hdr_1999_ch1.pdf)

<sup>119</sup> UNDP, *Human Development Report 2000: Human Rights and Human Development* (New York: Oxford University Press, 2000) at 2.

people's capabilities and protecting their rights and fundamental freedoms."<sup>120</sup> It stressed further that, at all levels of development, "the three essential capabilities are for people to lead a long and healthy life, to be knowledgeable and to have access to the resources needed for a decent standard of living."<sup>121</sup> In effect, the UNDP's exhibited experience in global developmental issues has significantly impacted on patent law making initiatives in the post-TRIPS period. The UNDP has, for instance, concluded that the "relevance of TRIPS is highly questionable for large parts of the developing world."<sup>122</sup> The UNDP has, therefore, urged developing countries to adopt a flexible approach to interpreting and implementing TRIPS while negotiating to replace the Agreement.<sup>123</sup> The point is that reconstructing the globalized patent regime along human development lines will enlarge the public domain and thus facilitate access to medicines for the poor in SSA.

### 3. Taking Account of Principles of Equity and Fairness

Development economists have made suggestions for the integration of principles of equity and fairness into the global trade agenda. Such suggestions are especially relevant in addressing some of the dysfunctions associated with the workings of the globalized patent system. In particular, the preceding chapters of this text have made allusions to the inequities and inadequacies inherent in the globalized patent system. These inadequacies include the aggregation of pharmaceutical patents into price fixing cartels, non-recognition of states' (in)capacities in patent law making, the presence of democratic deficits in the global patent law making processes, the lack of sufficient disclosure of the utility of inventions for future benefits, the lack of incentives in the development of drugs that treat diseases predominantly found in poor countries, and the rigid enforcement of pharmaceutical patent rights across the globe, among others. In consequence, the social

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<sup>120</sup> UNDP, *Human Development Report 2000*, *ibid*.

<sup>121</sup> UNDP, *Human Development Report 2000*, *ibid* at 17.

<sup>122</sup> UNDP, *Making Global Trade Work for People* (2003) 221 at 222, online: <<http://www.undp.org/dpa/publications/globaltrade.pdf>>.

<sup>123</sup> UNDP, *Making Global Trade Work for People* (2003), *ibid*.

dimension of the globalized patent regime to promote public health and human development has been subdued in international patent law making.

In light of these developments, issues bordering on ‘fairness’ and ‘equity’ have attained new salience in policy and academic discourse. According to Stiglitz, fairness in international trade discourse implies that any agreement is assessed in terms of its impact on development, thereby excluding items with negative effects; that any agreement is based on a concern for social justice; that any agreement entails procedural fairness; and that trade-related agenda be limited to development-friendly issues.<sup>124</sup> Also, fairness in global trade relations entails that “the poor share in the gains of society as it grows, and that the rich share in the pains of society in times of crisis.”<sup>125</sup> Thus, applying this notion of fairness in international debates surrounding patent law can remedy some of the historically rooted disparities in the globalized patent system, as discussed in chapter 3 of this text. Also, taking these suggestions into account in international patent law making would not only address the deficit in the democratic process but also enhance its outcome.

Closely related to the notion of fairness is the principle of equity. In legal terms, the doctrine of equity evolved as part of the process of adjudication by the Court of Chancery in the United Kingdom. This doctrine evolved in response to the hardship associated with the development of the common law, which most countries in SSA have inherited as part of their colonial legal heritage. The idea is that notwithstanding the capacity of human beings to appreciate the general notion of fairness in decision making processes, this formal equity doctrine ensured that “the equities of a particular case and the consequences of choosing one outcome were part of the process of adjudication.”<sup>126</sup> Equity has played a significant role in the development of customary law in many SSA

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<sup>124</sup> Stiglitz & Charlton, *Fair Trade for All*, *supra* note 91 at 68.

<sup>125</sup> Joseph E Stiglitz, *Globalization & Its Discontents* (New York: W.W. Norton & Company, 2002) at 78.

<sup>126</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 108.

countries; the notion of equity served as a litmus test in determining the legitimacy of customary law in many parts of Africa. For instance, countries such as Ghana, Zimbabwe, Nigeria, Kenya, Angola, Uganda, Tanzania, and Swaziland, all ascertained the legitimacy of customary law by ensuring that ‘human interactional expectancies’ is not repugnant to natural justice, equity and good conscience.<sup>127</sup>

Furthermore, Chon argues that using equity, which is itself a public good, would enrich the processes and outcomes of international patent law making. Thus, giving a chance to equity principles in international patent law making would help resolve policy impasses within the international trading arena.<sup>128</sup> She succinctly explains that:

Equity functions in an instrumental way to promote cooperative behavior in the shared production of public goods, thus enabling a greater volume of public goods to be produced than would be produced in its absence. Related but not identical to this observation, ‘norms of fairness and justice provide focal points around which social conflicts can be mitigated and efficiency-enhancing social bargains made,’ and thus equity ‘lubricates’ the process to cooperation.<sup>129</sup>

Similarly, the equitable doctrine of unconscionability has been deployed in the law of contract to invalidate bargains that are considered an affront to equity and good conscience. Consequently, arguments about principles of equity that have held sway in domestic debates should be welcomed into the international patent law making arena.<sup>130</sup>

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<sup>127</sup> In the context of Ghana, see section 87 of the *Supreme Court Ordinance* of 1876. This Ordinance has however been repealed since 1960 by the various Courts Acts. Under the current *Courts Act*, 1993 (Act 459), section 55 makes the ascertainment of the content and validity of customary law a question law for the courts. For a discussion of the workings of customary law see Lon L Fuller, “Human Interaction and the Law”, *supra* note 1.

<sup>128</sup> Chon, “IP and the Development Divide”, *supra* note 5 at 2890-2891.

<sup>129</sup> Chon, “IP and the Development Divide”, *ibid* at 2890, citing J Mohan Rao, “Equity in a Global Public Goods Framework” in Inge Kaul et al, eds, *Global Public Goods: International Cooperation in the 21st Century* (New York: Oxford University Press, 1999) at 68.

<sup>130</sup> Stiglitz & Charlton, *Fair Trade for All*, *supra* note 91 at 56.

To the extent that the international community has applied equitable principles to natural resource allocation, the international patent system deserves the same treatment.<sup>131</sup>

Already, evidence of this suggestion for the integration of principles of equity and fairness into the WTO's norm making initiatives is increasingly gaining root in the post-TRIPS era. For example, paragraph 2 of the Doha Ministerial Declaration recognizes "the need for all our peoples to benefit from the increased opportunities and welfare gains that the multilateral trading system generates." This Declaration also stresses the need to implement and interpret the TRIPS Agreement in a way that supports public health – by promoting both access to existing medicines and the creation of new medicines.<sup>132</sup> The WHO has also established that equity in healthcare implies that persons in need of such services receive them, regardless of their social position or other socially determined circumstances.<sup>133</sup>

Furthermore, Carrier urges a need to re-invigorate equity-based defences such as "the doctrines of inequitable conduct, prosecution laches, patent misuse, exhaustion, implied license, repair, and estoppel limits on the doctrine of equivalents" in patent law jurisprudence.<sup>134</sup> In this vein, the failure to disclose material information, such as the source of biological resources contained in an invention, for purposes of an application should be considered as an inequitable conduct to warrant the revocation of the patent in question.<sup>135</sup> Also, patent misuse, as an equitable doctrine, should place limits on the exploitation of pharmaceutical patent rights in domestic jurisdictions in order to check patent abuses. The point is that the integration of principles of equity and fairness into

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<sup>131</sup> Donald P Harris, "Carrying a Joke Too Far: TRIPS and Treaties of Adhesion" (2006) 27 U Pa J Int'l Econ L 681 at 738.

<sup>132</sup> See Paragraph 17 of the Doha Ministerial Declaration.

<sup>133</sup> WHO, *Equity Social Determinants and Public Health Programme* (Geneva: WHO, 2010) at 7, online: <[http://whqlibdoCwho.int/publications/2010/9789241563970\\_eng.pdf](http://whqlibdoCwho.int/publications/2010/9789241563970_eng.pdf)>.

<sup>134</sup> Michael A Carrier, "Cabining Intellectual Property through a Property Paradigm" (2004) 54 Duke LJ 1 at 106.

<sup>135</sup> See Carrier, "Cabining IP through a Property Paradigm", *ibid* at 110.

international patent law making would provide avenues to maximize the existing flexibilities as well as generate new ones on access to medicines. It will also mitigate the persistent disagreements on international patent negotiations that have partly stalled the progress of the Doha Development Round, and thus foster international cooperation.

In short, the argument to integrate human development considerations into global patent lawmaking endeavours takes inspiration from the proposal that “when human development and human rights [are] advance[d] together, they reinforce one another – expanding people’s capabilities and protecting their rights and fundamental freedoms.”<sup>136</sup> In the same vein, patents should exist as “rights of inclusion, participation and access that reasonably complement, rather than undermine, the realization of other human rights.”<sup>137</sup> Likewise, pharmaceutical patents should only be granted on the basis of their social usefulness. That is to say the adoption of a regulatory framework for meshing patent law making with human development-friendly principles will enhance the public-interest considerations of the globalized patent regime and its domestic reflections in SSA. This proposed patent and development regulatory paradigm will, in a way, plug the development, distributive and public-regarding gaps in the extant globalized patent regime symbolized by TRIPS.<sup>138</sup> The next task, then, is to demonstrate how human development considerations could be integrated into the design and implementation of WTO patent rules. An integrative-approach here implies creating additional limitations/exceptions in a legal framework that allows for equity/human development oriented principles to serve as limits on the exercise of pharmaceutical patent rights.

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<sup>136</sup> UNDP, *Human Development Report 2000: Human Development and Human Rights* (New York: Oxford University Press, 2000) at 64.

<sup>137</sup> Bita Amani, *State Agency and the Patenting of Life in International Law: Merchants and Missionaries in a Global Society* (England: Ashgate, 2009) at 14.

<sup>138</sup> Oguamanam, “Patents and Pharmaceutical R&D”, *supra* note 2 at 572.

### **C. Toward an Integrated Patent and Development Framework**

The preceding analysis outlines and discusses a number of human development oriented principles both in policy and academic discourse that should inform global and national patent regimes in SSA countries. The proposals evince that the underlying rationale of patents and, for that matter, the global trade system is to promote social benefits. The concept of patents and progressive development principles can conjoin to promote public health and serve human development needs. In a similar vein, the patent system must be conceived of as a social institution, namely, as that which society expresses its commitment to promote human welfare. The globalized pharmaceutical patent regulatory framework should reflect the shared values in promoting access to medicines in poor countries in SSA. This notion that the regime of patents serves a social function has wide acceptance in international law, as expressly indicated by Articles 7 and 8 of TRIPS and by Article 15 of the ICESCR. Similarly, the pursuit of equitable development and fair trade can foster social progress consistent with the objectives of patent law and human rights law. Thus, interpreting and implementing WTO patent rules through a pro-development lens will provide avenues to scale up access to medicines in parts of Africa devastated by epidemics. This growing relationship between patents, access to medicines, and development is thus enhanced by social and distributive justice issues.

As further proof that patents and development concepts are not antithetical to each other, the 2001 Doha Declaration and the Doha Ministerial Declaration have endorsed the pursuit of integration between the concept of patent law and the concept of development in global trade relations.<sup>139</sup> The complete justifications for this integrative-approach will be discussed in the following part III below. For now, it must suffice to indicate that the regime of patents as a social and political institution can be reconfigured to take account of public health and human development considerations. As the analyses in chapter 3 of this study have shown, the regime of patents is not cast in stone; it has evolved to serve

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<sup>139</sup> See paragraph 2 of the Doha Declaration; paragraph 6 of the Doha Ministerial Declaration.

the instrumentalist goals of national governments for centuries. For Oguamanam, patent rules, like other IP laws, “are instruments of socioeconomic policy and have been known to shift over time to accommodate changing demands and times.”<sup>140</sup> Therefore, the realization that society pays a price for the grant of patents is a credible basis for ensuring that the public benefit goals of such institutional arrangements are realized. There is the need to reform/recalibrate global patent rules in order to make global trade system more equitable and human development-oriented.

Significantly, the prescription for integrating human development considerations into the design of patent law and policy can be undertaken in two ways. First, I propose the opening of a new round of trade negotiations with the mandate to come out with a framework treaty (or amendment to TRIPS) that integrates human development considerations into global and national patent regimes. This proposed legal framework should aim at developing additional public health and human development exceptions/limitations to the exercise of patent rights. Perhaps, negotiating a new round that investigates and suggests additional exceptions and limitations to the exercise of patent rights could serve a useful purpose in promoting the social benefit goals of patent law. Also, generating additional exceptions and/or limitations to the exercise of patent rights could provide a formidable entry point for integrating patent and human development concepts in SSA countries. Admittedly, the presence of exceptions and/or limitations in IP legal frameworks is not new; the contribution here is the argument to integrate human development concepts into patent law, via the introduction of additional exceptions/limitations, in ways that have not been undertaken.

This prescription draws support from scholarship, policy studies and international documents. As Levin has observed, limitations and exceptions provide the necessary

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<sup>140</sup> Chidi Oguamanam, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (Toronto: University of Toronto Press, 2006) at 172.

regulatory framework to realize the welfare goals of the global trade system.<sup>141</sup> Exceptions and/or limitations curtail the right holder's exclusive power to prevent exploitation by others via authorizing certain (limited) use of the protected subject matter for specific purposes.<sup>142</sup> That is to say, developing additional limitations and exceptions to patents will enhance domestic 'policy space' for ensuring increased access to pharmaceuticals in SSA countries. It will also allow WTO members to adopt diverse measures within their right to achieve particular policy outcomes and the necessary institutional balance in granting pharmaceutical patents.<sup>143</sup> As it is, there is insufficient policy space and discretion under the prevailing international patent regime to integrate public interest demands for access to patented medicines.<sup>144</sup>

The proposed negotiations – dubbed 'patenting for life and development round' – can be undertaken at the TRIPS Council meetings with the aim to making recommendations to the General Council of the WTO for adoption as a framework treaty or as amendments to TRIPS. Generally, the WTO TRIPS Council has the mandate under Article 68 of TRIPS to monitor the operations of the *TRIPS Agreement*. The TRIPS Council is thus conceived of as a competent body to review national compliance with TRIPS standards and as a forum for the resolution of interpretational disputes.<sup>145</sup> The Council consists of representatives of WTO member states, and thus partly enhances participation by less developed countries in the decision-making processes. It follows that the TRIPS Council

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<sup>141</sup> Marianne Levin, "The Pendulum Keeps Swinging – Present Discussions on and Around the TRIPS Agreement" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 3 at 47.

<sup>142</sup> Henning Grosse Ruse-Khan, "Assessing the Need for a General Public Interest Exception in the TRIPS Agreement" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 167 at 199 [Ruse-Khan, "General Public Interest Exception in TRIPS"].

<sup>143</sup> Amani, *State Agency and the Patenting of Life*, *supra* note 137 at 319.

<sup>144</sup> See Ruse-Khan, "General Public Interest Exception in TRIPS", *supra* note 142 at 174, 199.

<sup>145</sup> Antonina Bakardjieva Engelbrekt, "The WTO Dispute Settlement System and the Evolution of International IP Law: An Institutional Perspective" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 106 at 156.

should act in the interest of its members, who are overwhelmingly less developed.<sup>146</sup> Any movement to recalibrate global patent rules to be sensitive to the access needs of African countries should not be discriminatory. Indeed, the objective of creating non-discriminatory international legal arrangements remains the cornerstone of the global trade system. Yet there could be express or formal distinctions among local and foreign nationals and patentable subject matters, provided the effects are non-discriminatory.<sup>147</sup>

More concretely here, the mandate of the TRIPS Council should be to come out with balanced global rules on patents that ensure that countries that are worst affected by epidemics are allowed to create exceptions in accordance with global human development goals.<sup>148</sup> The discussion to set public interest priorities in patent reform should be influenced by the above-noted human development-friendly concepts that have evolved outside the WTO system; it should recognize the differences in the level of development among states in order to allow SSA countries to optimize strategies that can promote access to life-saving medicines. This transition to a reconfigured patent regime should be embodied in a framework treaty that empowers national governments to develop broad-based public health/development exceptions to patent rights. Admittedly, this proposed approach to creating additional human development exceptions/limitations to patent rights in a framework treaty is without doubt in need of details, as I do not craft the rules here themselves. Rather, my aim is to give directions as to how the negotiations at the TRIPS Council can be facilitated in order to create additional public health exceptions consistent with global human development goals. This is because providing

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<sup>146</sup> The suggestion is based on public choice theorization that international institutions act in response to the demands of their constituents. See Richard Frimpong Oppong, *Legal Aspects of Economic Integration in Africa* (Cambridge: Cambridge University Press, 2011) at 75.

<sup>147</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge: Cambridge University Press, 2005) at 74.

<sup>148</sup> See Andrea Wechsler, "Spotlight on China: Piracy, Enforcement, and the Balance Dilemma in Intellectual Property Law" in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 61 at 65-67 [Wechsler, "Spotlight on China: Piracy Enforcement"].

directions on how to reconfigure global patent rules to be sensitive to human development concerns is as important as the outcome itself.

In particular, the TRIPS Council's exhibited experience in discussing patent reforms in the last decade has positioned the Council as a competent body to spearhead such a fused patent/development paradigm; thus, between 2001 and 2003, the TRIPS Council's forum was employed to initiate discussions that led to the passage of the 'August 30' Decision, which has now become a permanent amendment to TRIPS. The 'August 30' Decision allows countries lacking manufacturing capacity in pharmaceuticals to use compulsory licensing flexibilities to import medicines from abroad. In consequence, lessons from how developing countries, especially the African Group, dealt with western powers between 2001 and 2003 at the TRIPS Council negotiations and thus succeeded in giving the 'August 30' Decision its final shape should inform this new agenda.<sup>149</sup> The role of the African Group as a crucial political bloc in the post-TRIPS era is itself a complex discourse outside the scope of this study. The salient point is that the participation of SSA countries that are worst affected by public health crises is decisive in facilitating such change and regime flexibility. It is through such increased participation that SSA countries can learn, be heard and make international norms on patents take account of their special needs and interests.

Moreover, existing international instruments such as TRIPS' Articles 13, 17, 26.3 and 30 (dealing with the prescribed tests for creating exceptions and/or limitations) could serve as a useful basis for any revisions to allow progressive human development principles to operate as limits on patents. In addition, the general exception rules in GATT (dealing with trade in goods) and in GATS (dealing in trade in services), which allow the adoption and maintenance of legislation and measures to protect important societal interests, could

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<sup>149</sup> For a discussion of developing countries negotiating strategies, see Frederick M Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public" (2005) 99 Am J Int'l L 317.

be used as a template in developing additional exceptions/limitations to patents.<sup>150</sup> In discussing the contents of those additional limitations and exceptions to TRIPS, WTO jurisprudence suggests an approach of protecting private interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.<sup>151</sup> In the context of SSA, such relevant (pressing) public policies or social issues implicate human life and access to medicine challenges in the world’s poorest region. Thus, the necessity to protect human life or health should be made to override private pharmaceutical patent rights, provided such measures further the legitimate public interest/health objectives of the state concern.

Admittedly, the approach of the WTO Panel seems to militate against adopting a general GATT/GATS-style exception under TRIPS because of the nature of IP rights as negative rights. Thus in the *European Communities – Geographical Indications* case, the WTO Panel stated:

These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.<sup>152</sup>

It is worth stressing that the above description of IP rights as mainly negative rights by the WTO Panel is too simplistic. First, the said description fails to appreciate the reality that there is a thin line between the grant of negative rights and the exercise of positive

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<sup>150</sup> See Article XX of GATT and Article XIV of GATS. For a detailed analysis of the general exceptions in GATT and GATS see Ruse-Khan, “General Public Interest Exception in TRIPS”, *supra* note 142.

<sup>151</sup> *Canada – Patent Protection of Pharmaceutical Products*, WD/DS114, Report of the Panel (17 March 2000), paras 7.20 – 7.24; see also Annette Kur, Limitations and Exceptions under the three-step test – How Much room to walk the Middle Ground?” in Annette Kur & Marianne Levin, eds, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Cheltenham: Edward Elgar, 2011) 208.

<sup>152</sup> Panel Report (WT/DS/174R), 15 March 2005, para 7.210.

monopolies by right holders. Indeed, some aspects of IP confer positive entitlements, such as the right to be granted a patent upon fulfilling the requisite conditions.<sup>153</sup> Second, the right to prevent others from manufacturing patented medicines may equally limit the ability of the right holder to trade in such products. Indeed, the patent statutes of many SSA countries allow the right holder to stockpile the patented product, thereby enhancing the patentee's market exclusivity.<sup>154</sup> It follows that patents may obstruct a right in making such protected subject matter available to the public.<sup>155</sup> Third, the so-called negative rights conferred on the right holder can be employed as a sword (i.e., asserted positively) to sustain a monopoly position. The point is that patentees positively assert their rights over inventions through patent litigation. In consequence, the rights over patents cannot be said to be solely negative. In this vein, the regulations of pharmaceuticals should thus be opened to general exceptions and/or limitations that advance the public interest.

Furthermore, as noted in various parts of this study, the 'practice of history' that allowed countries such as the US, the Netherlands, the UK, and China to employ pharmaceutical patents as instruments for national development provides a convincing argument for global patent reforms. Further, the work of WIPO and its Committee on Development and IP, which insists on a broad-based consensus building approach to implementing the 'development dimension' of IP in global trade governance, should provide important insights for such an enterprise. Though the implementation of the WIPO Development Agenda has been slow, the Agenda symbolizes the idea that change in global IP governance is possible.<sup>156</sup> Also, since the proposed negotiations implicate public health issues, the work of the WHO may provide some invaluable lessons to the TRIPS Council; the WHO has already discussed and approved a draft resolution for a medical research

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<sup>153</sup> WR Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights*, 4<sup>th</sup> ed (London: Sweet & Maxwell, 1999) at 6.

<sup>154</sup> See e.g. section 11(2)(a)(i) of Ghana's *Patents Act*, 2003 (Act 657).

<sup>155</sup> Ruse-Khan, "General Public Interest Exception in TRIPS", *supra* note 142 at 198.

<sup>156</sup> See Chidi Oguamanam, "IP in Global Governance: A Venture in Critical Reflection" (2011) 2 WIPO Journal 196 at 207.

and development (R&D) treaty to address global health inequality.<sup>157</sup> This proposed medical R&D treaty could serve as guide in developing a framework for integrating development-friendly principles into patent lawmaking initiatives.

Legal scholars also provide insights into how such reform agendas should be approached. For Abbott, in preparing for such negotiations, trade negotiators from developing countries such as the African Group should identify their shared subject matter interests, develop common policy positions, coordinate their negotiating strategy, and establish coalitions committed to their common cause.<sup>158</sup> This approach, according to him, proved effective in negotiating the ‘August 30’ Decision to enable countries lacking manufacturing capacity in pharmaceuticals to make effective use of compulsory licensing. Oguamanam on his part urges new and emerging economic power-blocs, especially in the global south, to form alliances to spearhead a move to mainstream equity and development imperatives into global governance of IP.<sup>159</sup> It is envisaged that such a collaborative approach will ensure that there is optimization of negotiation or bargaining leverage. It will also ensure cost efficiency in regard to optimizing access to the wiggle room, or for exploiting the flexibilities of the current global IP order and other relevant multilateral trade negotiation arrangements.<sup>160</sup> To get there, the pursuit of such coalition agendas should have public health and human development considerations as their main focus in the ‘patenting for life and development round’.

Finally, the TRIPS Council has the benefit of other works that have made proposals to improve the international patent regime. For instance, a project by the Intellectual

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<sup>157</sup> This resolution is titled “Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action”, online: <[http://apps.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_R24-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf)>. See Oguamanam, “Patents and Pharmaceutical R&D”, *supra* note 2 at 569.

<sup>158</sup> Abbott, “The WTO Medicines Decision”, *supra* note 149 at 343-344.

<sup>159</sup> See Oguamanam, “IP in Global Governance”, *supra* note 156.

<sup>160</sup> Oguamanam, “IP in Global Governance”, *ibid* note at 209.

Property in Transition (IPT)<sup>161</sup> provides indications on how the Objectives of TRIPS could be amended to take account of ‘overriding public interests’ in order to promote a desirable balance in patent law making.<sup>162</sup> The IPT project also proposes an amendment to the overarching Principles of TRIPS in order to ensure “a fair balance between private economic interests and the larger public interests as well as the interests of third parties” in legislative processes.<sup>163</sup> It implies giving serious consideration to the proposal to have an elaborate public interest exception under TRIPS in order to offer a considerable degree of legislative flexibility to WTO member states.<sup>164</sup> Also, the aim here is to develop foundations for the design of a more balanced patent regime which contributes to social benefits and human development. History and research tell us that defining and enlarging the policy space and flexibilities that allow countries to tailor IP laws to their national needs is more likely to ensure technological development.<sup>165</sup> In all that, the issues of fairness, equity, and the pursuit of human needs as the ultimate aim of trade should be at the core of the new patent order. The conclusion of the proposed negotiations should then pave the way for a transition to a reconfigured global patent order. Next is to analyze how the reconfigured global patent framework could be implemented in domestic jurisdictions in SSA countries in order to solve practical human development problems.

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<sup>161</sup> This project is being spearheaded by the Max Planck Institute for Intellectual Property and Competition Law in Germany and other institutions in Europe.

<sup>162</sup> Wechsler, “Spotlight on China: Piracy Enforcement”, *supra* note 148 at 91.

<sup>163</sup> Wechsler, “Spotlight on China: Piracy Enforcement”, *ibid* at 92.

<sup>164</sup> See Article 2(2) of the *Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay*, Applicability of the Basic Principles of GATT and of Relevant International Intellectual Property Conventions (MTN.GNG/NG11/W/71) 14 May 1990. [In formulating or amending their national laws and regulations on IPRs, Parties have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition or to promote public interest in sectors of vital importance to their socio-economic and technological development].

<sup>165</sup> Wechsler, “Spotlight on China: Piracy Enforcement”, *supra* note 148 at 93.

***Implementation in National Jurisdictions***

The second leg of the suggestion to mainstream equity and human development considerations into patent lawmaking is through the implementation of the reconfigured international patent framework in both domestic law and policy. The transition to a reconfigured framework should be time-bound, and must thus regulate how SSA countries implement their international patent obligations. This approach has happened with respect to the implementation of TRIPS benchmarks on patents in the last decade and a half. Equally, the proposed framework treaty should oblige countries to enact national patent rules that take into account domestic access to medicine needs in order to combat epidemics in poor countries. In the context of SSA, countries need to conduct local assessment needs and employ empirical data to influence such domestic patent law making endeavours. In employing evidenced-based approaches to implementation, the citizens and civil society groups should be involved in enacting such crucial pieces of health-related statutes. Insights on the need to enact patent laws that reflect social realities have been provided in chapter 5 of this study. To succeed, there is a need for law- and policy-makers to develop the right *political* will and imprimatur by ensuring that pharmaceutical patent regulations fit social conditions, rather than making social conditions fit rules. In essence, domestic state agencies need to recognize the salience of human health (life) over patent rights, an issue which I have addressed in chapter 6 of this study.

In addition to the urgency to reform domestic patent laws in SSA countries, domestic guides on how to integrate public-health and development considerations into patent policy making is sorely needed. Thus, the task of recalibrating patent rules to respond to public health concerns in SSA countries should be complemented with domestic policy guides. Such guides should give priority to human development needs, by setting out clear avenues for access to essential medicines. As parties to the newly reconfigured patent and development framework, SSA countries should employ such access guides to

promote public health and access to pharmaceuticals; the guides should be employed to flesh out and strengthen the exceptions and limitations that are needed to promote the social benefit goal of patents and thus take into account the peculiar circumstances of countries endemic for the HIV/AIDS, malaria and TB epidemics in parts of Africa. The important point to emphasize is that the implementation of the new international patent standards should not be discriminatory.

Moreover, SSA countries should work within regional economic blocs to bolster their capability to utilize the new flexibilities that will come out of the reconfigured global patent order. The advances of south-south collaborative initiatives would enable countries in SSA to harness economies of scale for the purposes of building local innovative capacity. To be considered ‘effective’, such south-south initiatives should be able to realize the objectives that have been outlined in such cooperative agendas. It will also require building the industrial and human capacities to facilitate the manufacture of medicines at cheaper rates in SSA countries. In summary, the recommendations made in various parts of this thesis lie at the heart of mainstreaming public health considerations and human development imperatives in global patent law- and policy-making. As I elaborate below, not only is this proposed approach to integration consistent with general international law, it also consistent with the international norms on patents.

### **III. Justifying a Human Development-Oriented Patent Paradigm**

This part provides justifications for the argument that integrating human development-friendly concepts into the interpretation and application of international patent law is consistent with WTO law and general international law. In so arguing, I divide this part into two sections. Section A employs the *TRIPS Agreement* and international norms on patents as justification for integrating human development and social justice oriented concepts into patent law making endeavors. Section B then portends that general international law supports the need to incorporate human development principles into international and domestic patent law making initiatives. General international law

comprises rules on the law of treaties, state responsibility, the interplay of norms, and the settlement of disputes.<sup>166</sup> General international law supplements and enriches WTO law, and vice versa.<sup>167</sup>

#### **A. Justification from within the International Patent System**

As noted earlier, the constitutive instruments of the WTO and WIPO require the two organizations to promote development as part of the globalization of international patent standards. Also, paragraph 6 of the Doha Ministerial Declaration envisions the pursuit of integration between the concept of patent law and the concept of development in global trade relations. Thus, there is widespread consensus within the international trading system that development, as a polycentric and integrative concept, meshes well with the concept of patent law. The concept of development and the concept of patent seek to promote human needs as the ultimate source of rights.<sup>168</sup> Consequently, a construction that incorporates human development-friendly concepts into international patent law making can effectuate the broad objectives and principles of TRIPS to promote public health and to foster technology transfer for human development.

More fundamentally, the *TRIPS Agreement* provides avenues for human development-friendly proposals (such as those discussed above) to be integrated into its interpretation and implementation, save that its pursuit has been unimpressive. Article 7 of TRIPS provides in relevant part that the protection and enforcement of IP rights should be conducive to social and economic welfare. Moreover, Article 8 of TRIPS directs WTO members to adopt measures necessary: to protect public health, to promote public interest, and to prevent the abuse of IP rights. These public health and public interest considerations under TRIPS represent the bedrock of the foundational balance in IP law

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<sup>166</sup> Joost Pauwelyn, “The Role of Public International Law in the WTO: How Far Can We Go?” (2001) 95 *Am J Int’l L* 535 at 536.

<sup>167</sup> Pauwelyn, “Role of International Law in WTO”, *ibid* at 552.

<sup>168</sup> On the issue of human need as the ultimate source of rights, see Jeanne M Woods, “Justiciable Social Rights as a Critique of the Liberal Paradigm” (2003) 38 *Tex Int’l L J* 763 at 764.

discourse.<sup>169</sup> Thus, the objectives and principles of TRIPS demonstrate that the issue of accessibility of medicine is significant to the international patent law balance. Again, the objectives and principles set forth in Articles 7 and 8 were conceived to attenuate the social costs involved in complying with TRIPS' standards, especially in poor countries.<sup>170</sup> Hence, their interpretations must be consistent with the principle of *in dubio mitius*, an approach to interpretation that is less restrictive of the sovereignty of the state or the state's obligations on patents.<sup>171</sup>

Furthermore, the negotiating history of both Articles 7 and 8 of TRIPS attests to the fact that the Group of 14 developing countries<sup>172</sup> that introduced the two provisions insisted that both the objectives and the principles be included in the text of TRIPS in order to serve the purpose of 'development' and promote 'public health'. Thus, the public health and development safeguards were intended to serve as a check on the globalization of IP standards.<sup>173</sup> Yet another idea in the original draft presented by developing countries was to have a public interest exception under TRIPS in order to offer a considerable degree of legislative flexibility to WTO member states.<sup>174</sup> Subsequently, these public health, interests and development safeguards have been used by the Group of Friends of Development to make a case that IP enforcement should be undertaken in the context of

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<sup>169</sup> Chon, "Substantive Equality in International IP", *supra* note 80 at 486.

<sup>170</sup> Moncayo von Hase, "The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights" in Carlos M Correa & Abdulqawi A Yusuf, eds, *Intellectual Property and International Trade: The TRIPS Agreement* (London: Kluwer Law International, 1998) 137.

<sup>171</sup> See Amani, *State Agency and the Patenting of Life*, *supra* note 137 at 323.

<sup>172</sup> These countries comprise: Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay, and Zimbabwe. Instructively, the bulk of these countries also form part of the Group of Friends of Development which initiated and spearheaded the adoption of the WIPO Development Agenda

<sup>173</sup> Chon, "IP and the Development Divide", *supra* note 5 at 2887.

<sup>174</sup> See Article 2(2) of the *Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay*, Applicability of the Basic Principles of GATT and of Relevant International Intellectual Property Conventions (MTN.GNG/NG11/W/71) 14 May 1990. [In formulating or amending their national laws and regulations on IPRs, Parties have the right to adopt appropriate measures to protect public morality, national security, public health and nutrition, or to promote public interest in sectors of vital importance to their socio-economic and technological development].

broader societal interests and development-oriented concerns, in accordance with the object of TRIPS.<sup>175</sup> The point is that explicitly incorporating these safeguards into international and domestic patent law making can provide avenues for enhancing access to essential medicines.

Additionally, in *Canada – Patent Protection of Pharmaceutical Products*,<sup>176</sup> the WTO dispute settlement panel referred favorably to the public interest safeguards contained in Articles 7 and 8 of the *TRIPS Agreement*.<sup>177</sup> The WTO dispute settlement panel indicated in connection with Article 30 of TRIPS (dealing with exceptions to patent rights) that “both the goals and the limitations stated in Articles 7 and 8” and “other provisions of the TRIPS Agreement which indicate its object and purpose...must obviously be borne in mind” when examining patent limitations.<sup>178</sup> This interpretation is consistent with paragraph 19 the Doha Ministerial Declaration, which provides that both the objectives and principles of the *TRIPS Agreement* occupy a special place in the interpretation of the public health and human development objectives of TRIPS.

Furthermore, the Doha Declaration provides that the *TRIPS Agreement* “shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”<sup>179</sup> The TRIPS Council “shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the *development* dimension”<sup>180</sup> of the IP system. These mandatory precepts provide the bulwark for incorporating human development and social justice-oriented thinking into the design of WTO patent rules. The objectives and principles of TRIPS

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<sup>175</sup> See recommendation 45 of the WIPO Development Agenda

<sup>176</sup> WT/DS114/R (17 March 2000).

<sup>177</sup> See Peter K Yu, “Access to Medicines, BRICS Alliances, and Collective Action” (2008) 34 Am JL & Med 345 at 380.

<sup>178</sup> Panel Report, *Canada – Patent Protection of pharmaceutical Products* WT/DS114/R (17 March 2000) parA 7.26.

<sup>179</sup> Paragraph 5(a) of the Doha Declaration.

<sup>180</sup> Paragraph 19 of the Doha Ministerial Declaration.

permit the linking of patent law with global development and social/distributive justice concerns in order to facilitate access to medicines in poor countries. Hence, the failure to mesh human development and social justice concepts with the implementation of TRIPS undermines the public interest rationale embodied in the objectives and principles of TRIPS. Such a failure does not only violate the precepts of WTO law, it also violates the obligations of general international law.

## **B. Justification from outside the International Patent System**

Non-WTO law also supports the need to integrate human development- and social justice-oriented concepts into international patent law making. First, the international patent system is not an isolated system. WTO law forms part of the wider *corpus* of public international law.<sup>181</sup> According to Pauwelyn, “the WTO is not a secluded island but part of the territorial domain of international law.”<sup>182</sup> Indeed, TRIPS is subject to Article 3.1 of the DSU, which requires the use of dispute settlement as a means to promote a balanced IP system among WTO members.<sup>183</sup> The DSU also requires WTO rules to be interpreted in accordance with rules of public international law.<sup>184</sup> In line with this submission, the WTO dispute settlement panels have looked outside the WTO system to other sources of law for the meaning of ‘sustainable development’ in the preamble to the WTO Agreement.<sup>185</sup> In the words of the Appellate Body, the WTO treaties’ objective of sustainable development implies “integrating economic and social

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<sup>181</sup> Pauwelyn, “Role of International Law in WTO”, *supra* note 166 at 538.

<sup>182</sup> Pauwelyn, “Role of International Law in WTO”, *ibid* at 552.

<sup>183</sup> See Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement, 1869 UNTS 401, 33 ILM 1226 (1994).

<sup>184</sup> See Pauwelyn, “Role of International Law in WTO”, *supra* note 166 at 542.

<sup>185</sup> See Barbosa et al, “Slouching towards Development”, *supra* note 3 at 83.

development” concerns.<sup>186</sup> The Appellate Body has also stated authoritatively that WTO agreements should not be read in clinical isolation from public international law.<sup>187</sup>

Second, the globalized patent regime implicates non-trade issues such as the fundamental human right to health. The analysis in chapter 6 of this text clearly evinces that international human rights law impinges upon international patent law and vice versa. The argument is that human rights law and patent law share a common goal of promoting social benefits. As a consequence, human rights and social justice issues can legitimately inform the interpretation and implementation of global norms on patents. As Hestermeyer explains “the right to access to medicine as an interpretative aid lends specificity to the vague terminology of public health [under TRIPS] and focuses the attention on the individual, namely the availability and accessibility of medication to the individual.”<sup>188</sup> Therefore, not only should interpretation to promote access to medicine be justified on grounds of public health, but also in terms of the object and purpose of TRIPS. Conversely, avoiding cross-fertilization between patents and human development-oriented concepts would impoverish the public health and the public interest objectives of the *TRIPS Agreement*.

Finally, integrating human development-driven norms into the design, interpretation and implementation of WTO law is consistent with the *Vienna Convention*, which codifies customary international law on treaty law. Article 31(3)(c) of the *Vienna Convention* directs that in interpreting treaties (in this case WTO rules) account should be taken of rules of international law. Such rules of public international law include non-WTO rules such as universal human rights norms and human development concepts accepted by the international community. Additionally, Article 31(1) of the *Vienna Convention* supports

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<sup>186</sup> *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Appellate Body Report (WT/DS58/AB/R) 12 October 1998, para 129.

<sup>187</sup> *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R 16-17 (1996).

<sup>188</sup> Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 223.

interpreting the *TRIPS Agreement* in accordance with its object and purpose. Further, the *Vienna Convention* allows subsequent treaties and obligations of WTO member states to be taken into account in interpreting the *TRIPS Agreement*. These subsequent rules applicable to WTO members include the Doha Ministerial Declaration, the Doha Declaration, and the ‘August 30’ Decision, as explained in part II of this chapter. These post-TRIPS initiatives reinforce the primacy of integrating human development and public health flexibilities into WTO norm-setting and implementation.<sup>189</sup> The Doha declarations also establish normative frameworks for access to medicine issues to have primacy in patent law jurisprudence. They underscore further the importance of access to medicine for persons afflicted with epidemics and thus ensure sustainable human development. However, the implementation of WTO patent rules over time have brought to the fore some of the lingering inadequacies in the international patent system.

In short, incorporating human development-friendly concepts traditionally considered to be exogenous to the WTO will not be easy.<sup>190</sup> But nothing in the world comes easy; regime change takes time and efforts to mature. In the post-TRIPS epoch, the adoption of the Doha Ministerial Declaration, the Doha Declaration, the ‘August 30’ Decision, and the WIPO Development Agenda came about as a result of perseverance from governments in the less developed world. Now, such initiatives have re-directed the focus of international patent discourse from *pure* trade to public health and development. Perhaps, with the benefit of hindsight and experience, the African Group is better prepared to play a crucial regime-changing role. Thus, embracing global issues of equity, fairness, human rights, and distributive justice will bolster the credibility of the international patent system. The important point is that a fused patent and development paradigm will contribute to improve the effectiveness of the globalized patent regulatory

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<sup>189</sup> Barbosa et al, “Slouching towards Development”, *supra* note 3 at 106.

<sup>190</sup> See Daniel J Gervais, “(Re)implementing the Agreement on Trade-Related Aspects of Intellectual Property Rights to Foster Innovation” (2009) 12 *Journal of World Intellectual Property* 348 at 351.

and institutional frameworks and also facilitate the attainment of the social benefit goal of patent law.

#### **IV. Conclusion**

This chapter has stressed that the globalized patent regime and its domestic prototypes have become a drawback to human development in SSA. It has argued for the integration of human development- and social justice-oriented principles into the design, interpretation and implementation of international norms on patents. The approach to integration that I propose should be undertaken at the TRIPS Council forum with the mandate to come out with a framework treaty on patents that ensures that countries that are worst affected by epidemics are allowed to create additional public-exceptions/limitations in accordance with global human development goals. Such approach to integration finds support from both WTO law and non-WTO law; a development-driven patent framework will break the insular character of the WTO's norm-making and interpretation processes. The fact that it is difficult to justify exceptions that have not explicitly been stated in TRIPS makes it more imperative to embrace the transition to a reconfigured patent framework that expressly takes account of human development considerations. Such reconfiguration will ensure that the globalized patent system remains relevant in serving the social benefit goal of promoting access to medicines at affordable prices in SSA. This approach of providing avenues for the citizens of SSA to have access to medicines will in turn promote sustainable human development and public health.

## Chapter 8

### General Conclusions

This final chapter is intended to provide an overview of the arguments advanced in support of the need to reconstruct the globalized pharmaceutical and institutional frameworks to scale up access to medicines at affordable prices in SSA. This study lends support to integrating equitable and human rights/development concepts into patent law making endeavors. The arguments in this text have been presented in the contexts of laws, institutions, practices, and politics, which were identified as the key elements driving the agenda of domestic and international patent law. The use of such a broad and interdisciplinary approach as the fulcrum of analysis, also brings to the fore the urgent need for patent reforms in SSA countries.

Chapter 1 on *General Introduction and Overview* sets out the framework for making the globalized patent regime more equitable and human development-oriented in order to scale up access to medicines to treat pandemics in poor regions such as SSA. The fundamental premise was that patents occupy a central place in the innovation system, which delivers medicines to the masses. Like many of life's essentials, the importance of medicine is most evident when it is not available / affordable. Therefore, in critiquing the rigid propertization of various interests over pharmaceuticals, I suggest a move towards enhancing the scope of public access to essential medicines in SSA countries. I also urge the need to build industrial and scientific capacity in order to facilitate increased drug manufacturing in SSA and bolster research and development (R&D) into tropical and neglected diseases. Moreover, technical assistance in implementing international patent standards in SSA should take cognizance of human rights and human development concepts. However, to fully grasp the urgency of pharmaceutical patent reforms, chapter 2 outlines the need to understand the literature and policy discourse on patents through the prism of laws, institutions, practices, and politics. The claim is that the workings of

the legal, institutional, political, and practical developments in the pharmaceutical industry, both at the national and international levels, help shape the direction of any meaningful discourse on patents. Equally, the use of multiple concepts of laws, institutions, practices, and politics as a methodological guide in this study provides avenues for making nuanced prescriptions for pharmaceutical patent reforms in SSA.

Since “those who cannot remember the past are condemned to repeat it,”<sup>1</sup> Chapter 3 recounts the story of the negotiations that led to the establishment of the prevailing international patent regime. The story of *Patents Evolution and the Politics of Exclusion* depicts the lack of meaningful participation by SSA countries in the patent negotiations that institutionalized the globalized pharmaceutical legal order. As the drafting history of TRIPS confirms, SSA countries were not significant players in the design of patent rules for protecting pharmaceuticals at the international level. Through applying a theory of democratic bargaining, I demonstrate that the ‘participation’ of SSA countries in TRIPS negotiations defied the basic tenets of democratic bargaining. Indeed, it was not until 1989 after the ‘world’ had decided to link IP rights with trade that SSA countries such as Tanzania and Nigeria joined other developing countries to save a sinking ship. Notwithstanding the lack of meaningful participation by SSA countries in the Uruguay Round of multilateral negotiations, the reality is that countries have enacted TRIPS-compliant legislation to implement international patent standards. In essence, the claim that the globalized patent regime may not command respect in poor regions such as SSA merely caricatures the realities on the ground. The reality is that western ‘experts’ and institutions have provided ‘technical assistance’ to SSA countries by replicating the laws and institutions that they are familiar with in domestic jurisdictions in Africa. In addition, post-TRIPS recalibration efforts are being hampered by renewed coercion by the US and

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<sup>1</sup> George Santayana’s maxim is quoted in Charles R Stith, *For Such a Time as This: African Leadership Challenges* (Boston, MA: APARC Press, 2008) at 13.

the EU for SSA countries to adopt TRIPS-plus patent standards via bilateral arrangements.

To reverse these negative trends, suggestions have been made in this study for African countries to become much more influential in international negotiations bordering on patents, access to medicines, and development in the post-TRIPS era. It is also imperative to have enhanced participation by the citizens of SSA countries in the enactment of patent laws and policies that affect access to medicines. It is only through public participation that the needs and interests of individuals who are affected by epidemics can be heard and addressed. Moreover, significant attention must be accorded to the contributions of some pro-access/development-oriented institutions such as the WHO, UNDP, UNCTAD, and WIPO; the works of these intergovernmental organizations in the post-TRIPS era have challenged the neoliberal rhetoric about securing pharmaceuticals in the global market-place. Their works also give hope to the central argument of this study to integrate public-regarding considerations into the design and implementation of global patent rules.

Chapter 4 on *The ‘Myth’ of Patent Justifications* then examines the foundations of the theories/assumptions proffered by scholars to justify the grant of patent protection in both developed and less developed countries alike. In particular, the natural rights theory in tandem with the incentive theory have steered the international patent legal order – as epitomized by TRIPS – towards granting robust patent standards for pharmaceuticals, among others, in SSA countries. The replication of international patent standards in SSA has brought in its wake enormous challenges to access to medicine goals. As it turned out, the promises entailed in these theoretical justifications for patent protection to promote social benefits have become illusory for the poor in SSA. Many people die from diseases such as HIV/AIDS, malaria, and TB largely because they are unable to afford life-saving medicines in SSA. By emphasis, the regime of patents, and its effects on

medicine pricing, remains an important factor for the lack of sufficient access to medicines in SSA.

For example, Novartis' patented-medicine such as Coartem, which has proven effective for treating the malaria parasites in SSA, costs almost US\$10 per every treatment cycle. The price of another anti-malarial medicine – Duocotecxin – is almost US\$12 in many countries in SSA. Since a person can contract malaria in a month or two in SSA, the patient would need to go through the treatment cycle to get rid of the plasmodium parasites on each occasion. Given that more than half of the population in SSA lives on less than US\$1 a day, sufficient access to anti-malarial medications such as Coartem and Duocotecxin is a distant aspiration for the masses. This anecdote is not an isolated one, however; several persons who are infected with the agents that give AIDS and TB in Angola through South Africa to Zimbabwe do not have sufficient access to essential medicines. The conceptual foundations of western-engineered justifications for securing private rights over pharmaceuticals are a poor fit for socio-human conditions in SSA.

Rather than leave this discussion hanging with a critique of the conceptual foundation of the globalized patent regime, I explore diverse regulatory mechanisms to scale up access to medicines in SSA. I suggest the need to reposition WTO law to reflect the impact-in-fact of patent rules on societies in SSA. Taking account of the impact-in-fact of patent rules on the access to medicine needs of the citizens of SSA countries implies a drug patent model that insists on full disclosure of the use of bio-resources, a model that avoids TRIPS-plus demands, a model that permits nuanced differentiation between essential and non-essential facilities, a model that provides more latitude for compulsory licensing and/or parallel imports, and a model that gives priority to public health issues. On top of that, I have argued that the protection of the fundamental right to health in national constitutions should be employed as a corrective measure against excessive exploitation of pharmaceutical patent rights in SSA. Prioritizing the right to health can serve as a justification for SSA states threatened with epidemics to limit pharmaceutical

patent rights in order to cater for the needs of their citizens. Admittedly, most of the pro-access-to-medicine mechanisms detailed in chapters 4 and 6 can provide short-term relief for some of the access to medicine challenges in SSA countries. However, on a more sustainable basis, there is a need to address the prevailing access to medicine challenges in SSA through international and national efforts.

### **I. Appraising the Discussion and Moving Forward**

This study has underscored the reservations about the ability of the globalized patent regime to promote access to life-saving medicines at affordable prices in poor regions such as SSA. The analyses have shown that the prevailing globalized patent regime fails to take cognizance of the differences in individual states' (in)capacities; it establishes a monopoly that allows the West to reap the bulk of the benefits while people suffer in the South; it is based on an economic ideology of self-interest that obliterates human values and the practices of indigenous communities; it fails to acknowledge the communal nature of ownership interests in resources in less developed countries; and, it also fails to differentiate between essential life-saving medicines and non-essential commodities. Furthermore, the regime of patents does not encourage big pharma to develop new medicines to treat diseases prevalent in poor countries. Patent protection also undermines efforts to explore alternative regulatory policies that can scale up access to medicines at affordable prices in poor regions such as SSA.

Notwithstanding the above noted shortcomings, this study acknowledges the point that the regime of patents – emblemized by TRIPS – has become inseparable from global trade governance. For decades, SSA countries have established domestic patent regulatory and institutional frameworks to protect pharmaceuticals in compliance international standards. In consequence, any suggestion to abolish the regime of patents in SSA countries is not likely to succeed within the world trade system; it will only create distortions in global trade relations. Given the established nature of the regime of patents across nations, I make two important prescriptions that can address the problems inherent

in the globalized patent system and its institutional frameworks on a more sustainable basis. First, I propose the adoption of a framework treaty (or as amendments to TRIPS) that integrates human development considerations into the design of global patent rules. This transition to a reconfigured patent framework implies reforming the international patent system to take account of public health and human development concerns in poor regions such as SSA. Second, and based on this reconfigured global patent framework, I urge SSA countries to undertake domestic patent regulatory and institutional reforms in light of their public health and human development needs. That way, SSA countries that are worst affected by epidemics will be encouraged to create pharmaceutical patent exceptions in accordance with global human development goals.

## **II. International Action: Towards a Reconfigured Patent Framework**

As noted in the preceding chapter, the imperative to integrate human development-oriented concepts into global trade governance is recognized within and outside the world trade system. The issue, however, remains whether international patent lawmaking endeavours have articulated this approach to integration in any significant measure. At the international level, the post-TRIPS calibration efforts have moved valiantly to consider a number of public health and development-related issues in redefining and repositioning international norms on patents. Without being exhaustive, the adoption of the Doha declarations, the WTO ‘August 30’ Decision and the resultant amendment to TRIPS show global commitments to overhaul the international patent regime in order to facilitate access to life-saving medicines in places such as SSA. More importantly, the successful push by less developed countries for the adoption of a Development Agenda at WIPO in 2007 symbolizes the idea that human development issues are increasingly gaining traction in global trade governance. Though laudable, these post-TRIPS calibration (or call it ‘integration’) efforts have not succeeded in addressing the dire public health challenges in Africa that compelled such ‘humanitarian’ initiatives.

To succeed, there is the need to reform the prevailing international norms on patents within the context of the WTO. The goal of the reform agenda should be to integrate universally accepted human development norms into the planning and redesign of international patent rules. The approach to integration that I advocate here requires the creation of additional exceptions/limitations to the exercise of pharmaceutical patent rights in a way that will enhance access to life-saving medicines and thus promote human development. In providing directions on the need to infuse human development principles into pharmaceutical patent lawmaking, I suggest that the forum to commence negotiations that can bring about such patent regulatory and institutional changes is the Council for TRIPS. As in the negotiations that led to the passage of the 'August 30' Decision, the TRIPS Council's forum will provide an avenue for increased participation in the reform agenda by regional coalitions such as the African Group. Thus far, the experiences gained by the African Group in the post-TRIPS epoch provide new vistas for SSA countries to influence global patent law making. Once the terms and scope of the reconfigured patent framework have been agreed upon, timelines should be set to ensure the implementation of the new rules across states. Next is to analyze how the reconfigured global patent framework could be implemented in domestic jurisdictions in SSA countries in order to solve practical human development problems.

### **III. Domestic Implementation: Towards an Evidenced-based Approach**

Despite recent claims of progress in the fight against epidemics, SSA is still teetering on the brink of a human calamity. HIV/AIDS, malaria, and TB epidemics threaten the moral, economic and political fabric of societies in SSA, first, by killing the labour force at its prime; second, by increasing the costs associated with health care provision, prevention efforts, and the sustainability of health care institutions; third, by diverting crucial resources from other equally important initiatives like education and rural development. What makes diseases such as HIV/AIDS, malaria, and TB more lethal in SSA countries is that access to treatment and prevention is reportedly inadequate. The situation is further exacerbated by high prices of brand name medicines due to the prevailing international

patent regime. And, attempts to promote the manufacture and import of generic versions of drugs are sometimes met with stiff resistance from pharmaceutical companies who own the patents. It goes without saying that a poorly configured patent system can perpetuate high prices for medicines and hinder access to essential life-saving medicines in SSA.

So far, the reactions to the suitability of the globalized patent regime as it relates to SSA countries have been mixed. On the one hand, proponents of the patent system point to a number of flexibilities under TRIPS that can facilitate access to medicines in poor countries. The claim is that the globalized patent regime allows governments to invoke patent exceptions/limitations including the use of compulsory licensing mechanisms, parallel imports as well as the use of transition rules to scale up the supply of essential medicines for their citizens. The argument further goes that in several African countries essential medicines are either not patented or, even if such medicines are patented, some pharmaceutical companies do not enforce patents on their essential medicines in SSA.

Whatever the truth of this tale, TRIPS flexibilities and transition rules for LDCs in SSA are of little relevance with respect to pharmaceuticals for four reasons: first, much of the patent laws of many SSA countries are TRIPS-compliant. It is therefore merely academic for one to insist that LDCs in SSA need not provide protection for pharmaceutical products until 2016. Second, some of the patent rules in SSA countries, owing to the lack of fine-tuning, provide robust protections (via TRIPS-plus arrangements) to pharmaceuticals and have thus become hindrances to access to essential medicines. Third, the vast majority of SSA countries lack the manufacturing capability to utilize compulsory licensing mechanisms to manufacture generic medicines locally. Worse still, big pharma has shielded itself from competition by obtaining patents in all countries in

which factories capable of manufacturing medicines are located.<sup>2</sup> It is therefore pointless even if big pharma does not obtain patents in technologically-deficient countries in SSA. And fourth, the reality is that patent rules have been enacted as part of the legal systems of SSA countries without serious consideration of their inhibiting effects on the ability of individuals to have access to medicines in parts of Africa. Thus far, patent regulatory and institutional frameworks in SSA have failed to meet domestic access to medicine needs because the rules have not been the product of preliminary study of the conditions to which they were to apply.<sup>3</sup>

Moving forward, it is worth stressing that the implementation of international patent standards in SSA countries should be preceded by detailed national studies in regard to the impacts of WTO rules on access to medicine issues in parts of Africa. In regard to that, chapter 5 has highlighted the need to adopt an evidence-based methodology to implementing international norms on patents. An evidence-based approach rests on the proposition that, before enacting or revising patent legislation in SSA countries, law- and policy-makers should consider real evidence and the actual environment in which the law will operate. This evidence-based approach would include mechanisms like local needs assessments and the use of empirical data to shape domestic patent law making endeavors. The approach also implies considering the opinions of individuals and pro-public institutions in enacting crucial pieces of health-related statutes in SSA countries. The approach I propose in this thesis is sensitive to the public health needs of the citizens affected by epidemics, and to the imperative of building local manufacturing capabilities in pharmaceutical research and development in SSA. In regard to that, the law reform commission system – that uses empirically generated evidence from the public – will play a vital role in ensuring the quality of patent legislation in many SSA countries. This

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<sup>2</sup> Holger Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007) at 72.

<sup>3</sup> On this point see Roscoe Pound, “Mechanical Jurisprudence” in Ray D Henson, ed, *Landmarks of Law* (Boston: Beacon Press, 1960) 101 at 107.

evidence-based approach to implementing WTO patent rules should bring about legislative changes that advance human development-related exceptions/limitations adopted as part of the newly reconfigured international patent framework.

Besides statutory reforms, the implementation of global patent standards in SSA countries should be embodied in a domestic policy guide on access to medicines. This guide must set out clear avenues to explore to promote access to medicines for impoverished populations. Elsewhere, there are guidelines for ensuring public-health sensitive approaches to examining pharmaceutical patent applications.<sup>4</sup> India has also amended its patent legislation to insist on ‘enhanced efficacy’ of pharmaceutical inventions and this has ensured that pharmaceutical patents are not issued for ‘me too drugs’.<sup>5</sup> The goal of the proposed guide should be to flesh out and strengthen the exceptions and limitations that are needed to promote the social benefit goal of patents and thus take into account the peculiar circumstances of countries endemic for the HIV/AIDS, malaria and TB epidemics in parts of Africa. It should pay attention to the dichotomy between essential life-saving medicines and non-essential commodities in matters of pharmaceutical patent regulation, subject of course to the principle of non-discrimination that underpins the global trade system. To do that the guide must of necessity be informed by the evidence-based methodology discussed earlier under this study. Thus, there must be broad-based consultations among agents in the pharmaceutical patent industry and an imperative for citizens to participate in such crucial policy debates. Related to this is the participation of civil society groups in raising public awareness of the benefits for transitioning to a reconfigured patent legal order. Though, the participation of the citizens and public interest organizations in domestic patent law- and

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<sup>4</sup> See Carlos Correa *Guidelines for the examination of pharmaceutical patents: developing a public health perspective* (Geneva, ICTSD, UNCTAD, WHO, UNDP, 2007), online: <[http://www.emro.who.int/emp/media/pdf/patentability\\_guidelines.pdf](http://www.emro.who.int/emp/media/pdf/patentability_guidelines.pdf)>.

<sup>5</sup> See *Novartis AG & Another v Union of India & Others* (2007) 4 MLJ 1153, online: <[http://www.gnaipr.com/GNACaseLaws/Judgement\\_GliveCpdf](http://www.gnaipr.com/GNACaseLaws/Judgement_GliveCpdf)>; Chennai Patent Office order in the application for patent no. 1602/MAS/98 filed on 17 July 1998, online: <<http://www.gnaipr.com/Articles/Glivec%20Order.pdf>>.

policy making may not guarantee instant economic justice, but it may open the door for individuals to make the connections with other like-minded groups that are necessary to achieve the social benefit goals of patent law. This will, however, require strong political will and determination from governments in SSA to counter powerful interest groups that may want to frustrate such initiatives. It will also require the building of industrial and human capacities to facilitate the manufacture of medicines at cheaper rates in SSA.

In sum, this concluding chapter has reiterated the key analytical strands for reconstructing the globalized pharmaceutical patent and institutional frameworks to be responsive to the needs and aspirations of the citizens of SSA. The proposal to blend the concept of patent law with human development-oriented concepts should be backed by an international legal framework in order to make its implementation in SSA countries more effective. The overall arguments for reconstructing the globalized patent regime are both moral and legal. They range from a trenchant critique of the globalized patent regime, to prescribing how the fundamental right to health can override pharmaceutical patents, to a discourse on how the citizens of SSA can benefit from a human development-oriented patent paradigm, as part of global trade relations. The pursuit of a human development-oriented patent regulatory framework can play that seminal role in scaling up access to medicines to treat pandemics in SSA. Indeed, providing avenues for people infected with the HIV/AIDS, malaria, and TB pandemics to have access to essential medicines at affordable prices is the key to rebuilding a fractured SSA region.

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