JUSTICE IN GENETICS: INTELLECTUAL PROPERTY AND HUMAN RIGHTS FROM A COSMOPOLITAN LIBERAL PERSPECTIVE

By
Louise Bernier

Faculty of Law
McGill University
Montréal, Québec, Canada

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Abstract

Genetics is one sector in which there has been tremendous evolution and progress over the last few decades. While it is believed that genetics could offer tremendous opportunities for global health improvement, there is also a fear that existing global health inequalities will be amplified by the evolution of genetics.

It thus appears necessary to analyse the way current assumptions define what is just and acceptable with regard to global access and distribution of resources in this field. Indeed, given the importance of genetics to human health globally, this thesis will evaluate two principal legal regimes – intellectual property and international human rights – to determine to which extent they further the goal of distributing the benefits of these technologies equitably and globally. This evaluation is vital to ensure that legal regimes assist in ensuring that this promising field develops in a way that improves global health without leaving the most vulnerable outside of the process. This dissertation will undertake this complex task by employing and building upon cosmopolitan liberal theories developed over the few last decades as an extension of the work of Rawls and Daniels.

A theoretical framework to justify engaging in a global and more equitable redistribution of benefits produced by genetics is required. Ultimately, our analysis will produce strong normative benchmarks based on justice considerations for engaging in a global and more equitable redistribution of the benefits likely to emerge from genetic science. Universal consideration of all human beings, importance of health needs, normal functioning and equality of opportunities are some of the notions that will be analysed to construct this framework. We will then attempt to determine how and if this theory of distribution translates into positive law and to identify and analyse the main obstacles to legal compliance with global distributive justice. We will assess two main international normative systems: intellectual property law and human rights law to determine if their underlying philosophy,

structure, and functioning take account of the principles highlighted in our theoretical framework and how underlying politics and economics matter.

This will set out a basis for further discussion on how we could work around some of the major obstacles identified throughout our analysis. It will also help us move from the vague and often symbolic ideal of benefit sharing actually prevailing toward the establishment of a real, enforceable concept of global benefit sharing in health that would position genetics at the rank of essential tool for achieving global health.

Sommaire

La génétique est une science fort prometteuse en général et qui pourrait vraisemblablement être très utile pour répondre aux besoins des pays en développement dans le futur si elle leur était accessible. Cependant, plusieurs craignent que les inégalités globales existant déjà en santé pourraient être amplifiées par l'évolution de la génétique.

C'est pourquoi il est essentiel d'analyser ce qui apparaît juste et acceptable en termes d'accès et de distribution dans ce domaine. Cette thèse se veut une contribution au débat sur la division génétique (*genetic divide*). En effet, face à l'importance que pourrait prendre la génétique au niveau global, nous évaluons deux importants régimes légaux – le droit de la propriété intellectuelle et le droit international de la personne- afin de déterminer s'ils encouragent une distribution équitable des bénéfices émergeant de la génétique. En effet, face à l'influence énorme du marché sur les problématiques d'accès et de distribution et confrontée aux lacunes normatives du populaire concept de partage des bénéfices, il est crucial d'analyser ces problématiques différemment, dans une perspective qui vise à remédier aux injustices globales dans le domaine de la santé généralement et de la génétique plus particulièrement. Cette thèse entreprend cette tâche complexe en s'appuyant sur une théorie de justice distributive *cosmopolitaine* en santé, développée, en partie, par Rawls et Daniels.

Pour ce faire, l'élaboration d'un cadre théorique qui justifie la redistribution globale et plus équitable des ressources produites par la génétique est essentielle. La considération universelle des êtres humains, l'importance spécifique de la santé et de la génétique comme éléments essentiels au fonctionnement normal des individus, l'égalité des opportunités sont quelques unes des notions que nous analyserons pour l'élaboration de ce cadre théorique. Nous évaluerons ensuite comment ces principes de justice distributive globale en santé sont transposés en droit positif, s'ils le sont, et quels sont les principaux obstacles à l'application globale des ces principes. Pour ce

faire, nous évaluerons leur compatibilité avec deux importants systèmes normatifs internationaux: le droit de la propriété intellectuelle et les droits de la personne afin de déterminer si leur philosophie inhérente, leur structure et leur fonctionnement tiennent compte des principes fondamentaux de notre cadre théorique. Nous analyserons aussi le rôle des facteurs politiques et économiques dans ce contexte.

Cette étude nous permettra d'établir les bases solides nécessaires pour entreprendre d'autres études, dans l'avenir, sur les stratégies politiques possibles pour contourner les obstacles identifiés à l'occasion de notre analyse. Nous serons aussi à même de rejeter la traditionnelle notion vague et symbolique de partage des bénéfices en santé pour la remplacer par un concept solide et complet qui élèvera la génétique au rang d'outil essentiel pour l'amélioration de la santé globale.

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Introduction

Of all forms of inequality, injustice in health care is the most shocking and inhumane.

Martin Luther King, Jr.[1]

The Global Health Challenge

Today's world is characterised by a disturbing reality: on one hand, there is remarkable and ongoing technological progress in various spheres of activity while, on the other, the substantial gap existing between the world's rich and its poor constantly deepens. Indeed, despite our impressive state of knowledge, innovation, and development, at least one billion individuals continue to fight for their daily survival and more than two billion others live in acute poverty, on less than $2 a day.[2] Such extreme poverty engenders terrible consequences, such as widespread infant mortality and adult premature deaths, severe malnutrition, and lack of access to basic necessities such as drinkable water, basic sanitation, shelter, and health care.[3] All UN Member States acknowledged the seriousness of

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[1] Quoted in L. Sheremeta & B.M. Knoppers, "Beyond the Rhetoric: Population Genetics and Benefit-Sharing" (Annual 2003) 11 *Health Law Journal* 89.

[2] S.R.Benatar, "A Perspective from Africa on Human Rights and Genetic Engineering" in R. Dawkins, *The Genetic Revolution and Human Rights* (Oxford: Oxford University Press, 1999) 159; L. London, "Human Rights and Public Health: Dichotomies or Synergies in Developing Countries? Examining the Case of HIV in South Africa" (Winter 2002) 30:4 *The Journal of Law, Medicine & Ethics* 677; A.J. McMichael & R. Beaglehole, "The Changing Global Context of Public Health" (2000) 356 *Lancet* 495; K. Heggenhoughen, "Are the Marginalised the Slag-Heap of Economic Growth and Globalization? Disparity, Health and Human Rights" (1999) 4 *Health and Human Rights* 205.

[3] Pogge reports that, every day, 50 000 people die from poverty-related causes such as starvation, tuberculosis, malaria, and diarrhoea, and that even if those conditions affect 20% of the world population, they receive only 0.3% of all research funds: T. W. Pogge, "Human Rights and Global Health: A Research Program" (2005) 36:1/2 *Metaphilosophy* 182, at 197; T.W. Pogge, "Recognized and Violated by International Law: The Human Rights of the Global Poor" (2005) 18:4 *Leiden Journal of International Law* 717; see also UN Development Programme, *Human Development Report 2004* (New York: Oxford University Press, 2004), at 129-130; S. Chen & M. Ravallion, "How Have the World's Poorest Fared since the Early 1980s?" (2004) *World Bank Research Observer* 153; UNICEF, *The State of the World's Children 2005* (New York: UNICEF, 2005).

the situation in September 2000 when they adopted the *United Nations Millennium Declaration* that included commitments to encourage development, decrease poverty, and improve people's living conditions and health by 2015.[4]

One of the greatest enduring problems in the world is the major disease burden affecting a large portion of the world population. The most important and serious health variations between individuals are not, for the most part, associated with biological and genetic determinants but with patterns of resources distribution.[5] Indeed, poverty is one of the main determinants of health deficits, and wealth and power often have a direct positive impact on health.[6] Health is directly influenced by many factors including health research investment and availability of financial, material, and human resources, which differ greatly across socio-economic groups and countries.[7] In other words, access to essential medicines and medical knowledge, services, and technology is essential to human health but unfortunately remains out of reach for a majority of people, a situation that creates significant disparities in health.[8]

The impact of economic inequality on people's health can be observed both within and between countries and depends on various factors including governmental resources and priorities and the availability and affordability of universal or private health insurance coverage. Even if we acknowledge the importance and seriousness of health inequities arising at the national level, our dissertation will focus on the growing global health divide between populations of the nations of the North and

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[4] UN General Assembly Resolution, *United Nations Millennium Declaration*, September 2000, A/RES/55/2, online on the UN website, <http://www.un.org/millennium/declaration/ares552e.pdf> (accessed May 20th, 2006).

[5] A. K. Acharya, "Toward Establishing a Universal Basic Health Norm" (2004) 18:3 *Ethics and International Affairs* 65; B. G. Link et al., "Social Epidemiology and the Fundamental Cause Concept: on the Structuring of Effective Cancer Screens by Socioeconomic Status" (1998) 76 *Milbank Quarterly* 375.

[6] D. Willison & S. M. Macleod, "Patenting of Genetic Material: are the Benefits to Society Being Realised?" (2006) 167:3 *Canadian Medical Association Journal* 259.

[7] Indeed, this reality has been called the 10/90 gap, where 90% of all health research gets dedicated to the most affluent 10% of the world. For more on this, refer to E. Dowdeswell, A.S. Daar & P.A. Singer, "Bridging the Genomics Divide" (2003) 9 *Global Governance* 1.

[8] World Health Organization, *World Health Report 1999: Making a Difference in People's Lives: Achievements and Challenges*, Geneva, 1999; T. Evans et al., *Challenging Inequities in Health: From Ethics to Action* (New York: Oxford University Press, 2000).

South[9] and on the possibility that this divide will be aggravated by the introduction of genetic technologies aimed at health improvement.

Genetics is one sector in which there has been tremendous evolution and progress over the last few decades. While it is believed that genetics could offer tremendous opportunities for global health improvement and play an important role in meeting the UN *Millennium Development Goals* (MDGs) as we will discuss below, there is also a fear that existing global health inequalities will be amplified by the evolution of genetics. Such a divide already exists in numerous vital health-related spheres such as nutrition, water, labour, and the environment. Genetics is only one among many spheres in which we are likely to continue being confronted with gross inequalities in health. Indeed, this dissertation follows the multi-causal conception of health under which health is influenced by biological, social, economic, psychological, environmental, and genetic factors. Therefore, biology and genetics are only a few among many determinants of health. In this sense, this dissertation does not provide a complete picture of global health problems and inequalities but instead focuses on one important sphere of activity and on how it can be harnessed and developed to improve global health: genetics in health care.

Given the importance of genetics to human health globally (as discussed below), this thesis will evaluate two principal legal regimes – intellectual property and international human rights – to determine to which extent they further the goal of distributing the benefits of these technologies equitably and globally. This evaluation is vital to ensure that legal regimes assist in ensuring that this promising field

[9] We acknowledge that different developing countries are at varying stages of development and that some of the issues they face might be different depending on the country. The *Economic and Social Council of the United Nations* has identified some countries with the label "least developed countries" based on different criteria such as low income, human resources weakness, and economic vulnerability. Other countries not part of this latter category are nevertheless characterised as developing countries given their level of development and a plethora of different socio-economic, demographic, and political factors. For the purposes of this dissertation, we adopt an inclusive notion of developing countries, taking different degrees of poverty, lack of resources, and health access problems as our general benchmark. All through our dissertation, the expression "developing nations" or "developing world" should therefore be read to include a range of countries, mostly southern, in need of more health resources, including the least developed ones as well as those who are at a medium level of development.

develops in a way that improves global health without leaving the most vulnerable outside of the process. Such an investigation has not, so far, been developed at length with respect to the field of health and genetics. This dissertation will undertake this complex task by employing and building upon cosmopolitan liberal theories of distributive justice developed over the few last decades as an extension of the work of Rawls and Daniels. Our study will lead to the conclusion that, as presently implemented, neither intellectual property nor international human rights offer assurance that the benefits of health-related genetics research will be distributed equitably.

To set the grounds for this analysis, we first need to say more on the science of genetics and to indicate how we intend to use and circumscribe this concept for the purpose of this dissertation. We will then say a few words on the potential of genetics for solving global health issues, discuss the widely used concept of benefit-sharing as applied to this area and present a brief structure of the dissertation.

Specificity of Genetic Research and Information

> *Few developments in science have had the impact on society, institutions, laws, and health care that genetics is having and, undoubtedly, will continue to have.*[10]

In less than fifteen years, our understanding of genetics has evolved considerably in various areas such as agriculture, biodiversity, traditional knowledge, biomedical research, and medical applications.[11] In the field of human genetics, we went from

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[10] J. P. Hinojosa, "The Human Genome, Property of All: Opportunities Under the ALRC Inquiry into Gene Patenting and Human Health" (2004) 26 *Syndey Law Review* 447, at 448.

[11] Indeed, some genetic resources are already used for agriculture, medicine, and industrial development both in developed and developing countries. However, since this dissertation focusses on the global medical promises of human genetics and the distribution arising from the development of genetics at this level of activity, it is beyond its scope to address, in detail, the fields of agriculture, plant genetics, and traditional knowledge. We are, however, aware that many issues addressed here also find application in other genetics-related sectors of crucial importance for human health.

knowing very little of the particulars of biological genetics to a situation where a tremendous amount of information about the structure of individual genes is discovered daily.[12] Three years ago, *Nature* and *Science* published two series of articles highlighting the great potential of genetics and the need to do much more in terms of discovery and analysis of gene and protein functions, interactions, and their role in diseases, conditions, and reactions.[13] If successful, these initiatives will provide the basis and the tools necessary for developing promising new therapeutic approaches and techniques with the potential to prevent, screen, and cure very serious diseases. Scientists thus face numerous and exciting challenges in this area.[14]

Genetic factors play some role in almost all human diseases. These factors either confer susceptibility, resistance or influence individuals' interactions with their environment. For many years, genetics has been critical in revealing the cause of certain monogenic diseases.[15] However, things become more difficult when we try to establish connections between individual genotypes and complex diseases involving many genes and environmental factors like, for example, hypertension, cancer, or

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[12]The *Human Genome Project* (HGP) was launched in the early 1990s to "determine the complete sequence of the three billion DNA (molecules encoding genetic information) subunits (bases), identify all human genes, and make them accessible for further biological study". It marked the beginning of a new age in science. In June 2000, Francis Collins from the HGP and Craig Venter from *Celera Genomics* simultaneously announced the completion of a first working draft of the human genome sequence, and in February 2001, both groups published their initial draft map independently. This sequencing disclosed much information on the number of human genes (about 30 000 instead of the first estimated 80 000-100 000) and their composition, and helped to identify many other interesting biological mutations, including more than two million genetic variations (*single nucleotide polymorphisms : SNPs*). For a few references on the development of genetics see: L. Peltonen & V. A. Mckusick, "Dissecting Human Disease in the Postgenomic Era" (16 Feb. 2001) 291:5507 *Science* 1224; Human Genome Project Information, *Frequently Asked Questions*, on line on the HGP website <http://www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml> (accessed March 3rd, 2006); The White House, *President Clinton Announces the Completion of the First Survey of the Entire Human Genome*, 25 June 2000; J.C.Venter et al., "The Sequence of the Human Genome" (Feb. 16, 2001) 291:5507 *Science* 1304; International Human Genome Sequencing Consortium, "Initial Sequencing and Analysis of the Human Genome" (Feb. 15, 2001) 409 *Nature* 860.

[13] F.S. Collins, M. Morgan & A. Patrinos "The Human Genome Project: Lessons from Large-Scale Biology" (April 11, 2003) 300: 5617 *Science* 286; M. E. Frazier et al., "Realizing the Potential of the Genome Revolution: The Genomes to Life Program" (Apr 11, 2003) 300: 5617 *Science* 290; F. S. Collins et al., "A Vision for the Future of Genomics Research" (April 24, 2003) 422 *Nature* 835; S. B. Carroll, "Genetics and the Making of *Homo sapiens*" (April 24, 2003) 422 *Nature* 849; J. Arnold & N. Hilton "Genome Sequencing: Revelations from a Bread Mould" (April 24, 2003) 422 *Nature* 821.

[14] B. Albert & A. Klug, "The Human Genome Itself Must be Freely Available to all Humankind" (March 23, 2000) 404 *Nature* 325.

[15] B. E. Bihai et al., "Génomique, Promesses et Réalités" (16 janvier 2000) 16:1 *Médecine/Sciences* 17; A. D. Roses, «Pharmacogenetics and the Practice of Medicine», (15 June 2000) 405 *Nature* 857.

schizophrenia.[16] This is where genomics, the "study of genes and their function,"[17] becomes extremely useful and important. It allows broad analysis of numerous genes simultaneously to obtain a better idea of how they interact with one another and become expressed in specific cell types.[18] Attention is increasingly focussed on using a combination of genetics, genomics and cutting edge software tools to develop "sophisticated microarray technologies" that could be used in the future to screen for complex diseases and achieve better cellular and molecular understanding of those conditions.[19] In this dissertation, we understand the science of genetics in a broad sense, as an entire field of activity that includes the interaction between functional genomics, new computational analytical methods, proteomics, traditional genetic testing and screening techniques, and the understanding and conversion of the data emerging from this research into practical and useful applications to improve global health.

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[16] N.A. Holtzman & T.M. Marteau, "Will Genetics Revolutionize Medicine" (July 13, 2000) 343:2 *The New England Journal of Medicine* 141.

[17] Human Genome Project Information, *Genome Glossary*, on line on the HGP website, <http://www.ornl.gov/sci/techresources/Human_Genome/glossary/glossary_g.shtml> (accessed March 3rd, 2006)

[18] M.J. Khouri, "Genetics and Genomics in Practice: The Continuum From Genetic Disease to Genetic Information in Health and Disease" (July-August 2003) 5:4 *Genetic Medicine* 261; R. Service, "Genetics and Medicine: Recruiting Genes, Proteins for a Revolution in Diagnostics" (April 11, 2003) 300:5617 *Science* 236; A.E. Guttmacher & F.S.Collins "Genomic Medicine—a Primer" (November 7th 2002) 347:19 *New England Journal of Medicine* 1512; M. Mowzoon, "Access Versus Incentive: Balancing Policies in Genetic Patents" (2003) 35 *Ariz. St. L.J.* 1077.

[19] Up to now, numerous polymorphisms influencing how one responds to and metabolises certain drugs have been identified with novel sequencing and bioinformatics methods. Also, new vaccines arising from pathogen DNA are being developed and progress has been made in understanding cancer mechanisms with research in genetics. Indeed, the most important mutations have been identified in a family of "cellular oncogenes," and the next step is now to find the specific genes associated with the more common cancers with wide genomics investigations. WHO, *Genetics, Genomics and the Patenting of DNA : Review of Potential Implications for Health in Developing Countries*, Geneva, 2005, online on the WHO website, <http://www.who.int/genomics/FullReport.pdf> (accessed February 23rd, 2006); B. R Bloom & D. D. Trach, "Genetics and Developing Countries" (April 28, 2001) 322:7293 *British Medical Journal* 1006; J.A. Roberston, "The $1000 Genome: Ethical and Legal Issues in Whole Genome Sequencing of Individuals" (2003) 3:3 The American Journal of Bioethics W 35; W.E. Evans & J. A. Johnson, Pharmacogenomics: The Inherited basis for Interindividual Differences in Drug Response (2001) 2 *Annu. Rev. Genomics Hum. Genet.* 9; D.M. Livingston & R. Shivdasani, "Towards Mechanism-Based Cancer Care" (2001) 285 *Journal of the American Medical Association* 588.

A very simple definition of human genetics is the "study of inheritance patterns of specific traits."[20] It can be used for different purposes, broadly classified into two categories: enhancement, on the one hand, and prevention and treatment, on the other. In this dissertation, we focus on the application of genetics for the second aim. Indeed, for the purposes of this dissertation, we will concentrate on those aspects of health that are common to all individuals. This universal perspective is therefore not adjustable to personal circumstances and does not vary with each individual's perception and preferences. We will focus on universal and objective human health needs, leaving questions pertaining to the enhancement of otherwise normal traits to others.[21] This definition of health thus relates to *normal functioning* as opposed to a perfectionist conception of healthy human beings, where normal functioning is the objective capacity of individuals to take advantage of a reasonable range of opportunities. For the purposes of this dissertation, genetics therefore represents one tool among many to satisfy essential medical needs and to help bring individuals to a universal minimal health level under which they can expect a "decent" life.

The development of human genetics touches on many dimensions of human life, giving rise to a variety of normative concerns and provoking a number of reactions from decision-making authorities. In this thesis, we concentrate on the global human health and medical dimensions of genetic research.[22] Because genetics is a relatively

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[20] Human Genome Project Information, *Genome Glossary*, on line on the HGP website, <http://www.ornl.gov/sci/techresources/Human_Genome/glossary/glossary_g.shtml> (accessed March 3rd, 2006)

[21] For more on the role of genetics in enhancement, we refer the reader to: J. Hudson, "What Kinds of People Should we Create?" (2000) 17:2 *J Appl Philos* 131; A. Newson & R. Williamson, "Should we Undertake Genetic Research on Intelligence?" (1999) 13:3/4 *Bioethics* 327; D. Shickle, "Are "Genetic Enhancements" Really Enhancements?" (2000) 9:3 *Camb Q Healthc Ethics* 342; L. B. Andrews, *Future Perfect* (New York: Columbia University Press, 2001); A. Buchanan et al,, *From Chance to Choice: Genetics and Justice* (Cambridge: Cambridge University Press, 2000); D.S. David, *Genetic Dilemmas* (New York: Routledge, 2001); J. G. Palmer & W. LeRoy, *The Ethics of Human Gene Therapy* (New York: Oxford University Press, 1997); T. Peters, *Playing God: Genetic Determinism and Human Freedom* (New York: Routledge, 1997); P. Braude et al., "Preimplantation Genetic Diagnosis" (Dec. 2002) 3:12 *Nature Review Genetics* 941; J. Tsien et al., "Genetic Enhancement of Learning and Memory in Mice" (September 2, 1999) 401 *Nature* 63.

[22] Other widely discussed characteristics of research and clinical applications of genetics relate to its potential for revealing important personal and familial health information. This raises important issues, including confidentiality of data, consent of patients and research subjects, access and disclosure of medical information to family members and third parties, and potential for discrimination. Although very interesting, those issues will not be addressed in our dissertation. For more on the personal

new and evolving field, it is important to examine its social implications globally and to lay the basis for developing preventive and corrective measures that address inequalities among countries, encourage efforts to reduce those inequalities, and build safeguards for investment and research. Moreover, the strong presence of the private sector in this area and its growing focus on profit-making call for special attention to the issues of health priorities, benefit-sharing, and the distribution of resources.[23]

Influence of Genetics on Global Health

Even if genetic innovation has mainly occurred in the developed world because the development of genetics requires high capital investment, cutting edge technology, and well-equipped infrastructure, this does not mean that genetics does not have the potential to help the less affluent. In 2001, the former director general of the World Health Organisation, Gro Harlem Brundtland, stated: "[w]e have started to examine the implications of advances in genomics and other critical areas of biotechnology. They clearly have huge potential for improving human health."[24] Recent studies also reveal that human genetics offers a number of targetted possibilities for improving health in the developing world such as through the use of

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dimension of genetics refer to T. Lemke, "Beyond Genetic Discrimination. Problems and Perspectives of a Contested Notion" (2005) 1:3 *Genomics, Society and Policy* 22; J. Sorenson & J. Botkin, eds., "Genetic Testing and the Family" (2003) 119C *American Journal of Medical Genetics Pan G Seminars in Medical Genetics* 1; American Society of Human Genetics, "Professional Disclosure of Familial Genetic Information" (Feb. 1998) 62:2 *American Journal of Human Genetics* 474; E. Boetzkes, "Genetic Knowledge and Third-Party Interests" (Summer 1999) 8:4 *Camb Q Healthc Ethics* 386; C. G. Thomas, *Vulnerable Subjects: Ethics and Life Writing* (Ithaca: Cornell University Press, 2004); R. Rhodes, "Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge" (Feb. 1998) 23:1 *Journal of Medicine and Philosophy* 10.

[23] T. Caulfield, "Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research" (2003) 66 *Sask. L. Rev.* 629; D. Nelkin & L. Andrews, "Homo Economicus: Commercialization of Body Tissue in the Age of Biotechnology" (1998) 28:5 *Hastings Center Report* 30; A. Persidis, "The Business of Pharmacogenomics" (February 1998) 16:2 *Nature Biotechnology* 209.

[24] Address by Dr Gro Harlem Brundtland, Director-General to the Fifty-fourth World Health Assembly, *Bridging the Health Divide: The Way Forward*, May 14, 2001, online on the WHO website, <www.who.int/director-general/speeches/2001/english/20010514_wha54.html> (accessed February 26th, 2006).

molecular diagnosis for better management and screening of infectious, non-infectious and parasitic diseases, and through new drug and vaccine development.[25]

For example, genomics can be used in research to understand the variability in patient reactions to infectious diseases[26] and to develop new approaches to treatment and vaccine development.[27] A DNA-based AIDS vaccine designed specifically for Africa has already been developed and is being tested in clinical trials, while a candidate vaccine for the main malaria type found in India was recently identified through a collaborative research effort.[28] There is also new evidence to suggest that the study, manipulation, and analysis of pathogen vectors and genomes can lead to crucial information for the establishment of preventive and therapeutic initiatives aimed at controlling significant diseases such as malaria, tuberculosis, and HIV/AIDS.[29] For example, in October 2002, the sequence of the two parasites and the mosquito carrier

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[25] University of Toronto Joint Centre for Bioethics, *Top 10 Biotechnologies for Improving Health in Developing Countries*, Toronto, 2002; WHO, The Advisory Committee on Health Research of the World Health Organization, *Genomics and World Health*, Geneva, 2002, online on the WHO website, <http://www3.who.int/whosis/genomics/pdf/genomics_report.pdf> (accessed March 4th, 2006), on concrete possibilities for the development of new vaccines, diagnostics, and therapeutic tools, refer especially to section 2 and 3; A.S. Daar et al., "Top Ten Biotechnologies For Improving Health In Developing Countries" (October 2002) 32 *Nature Genetics* 269 this study identifies the ten most promising biotechnologies for improving health in developing countries in the next decade. Out of ten, six are directly or indirectly related to genetics; see also T. Ogundiran, "Africa Must Come on Board the Genomics Bandwagon" (2005) 1:3 *Genomics, Society and Policy* 66; P. A. Singer & A. S. Daar, "Harnessing Genomics and Biotechnology to Improve Global Health Equity", (October 5, 2001) 294 *Science* 87; A. Buchanan, *Justice, Legitimacy and Self-Determination, Moral Foundations for International Law* (Oxford: Oxford University Press, 2004) Chap 4, 191; I. Wickelgren, "Heart Disease: Gene Suggests Asthma Drugs may Ease Cardiovascular Inflammation" (February 13, 2004) 303:5660 *Science* 941; V. Brower, "Tackling the most Difficult Diseases: Genetics and Genomics Open New Strategies to Fight Vector-Borne Diseases" (October 2001) 2:10 *EMBO Reports* 875.

[26] For an example on the variability of patients' responses to HIV drugs in West Africa, see H. Jomaa, et al., "Inhibitors of the Nonmevalonate Pathway of Isoprenoid Biosynthesis as Antimalarial Drugs" (1999) 285 *Science* 1573.

[27] I.M. Orme, D.N. McMurray & J.T. Belisle, "Tuberculosis Vaccine Development: Recent Progress" (2001) 9 *Trends in Microbiology* 115; K.A. Bojang et al., "Efficacy of RTS,S/ASO2 Malaria Vaccine Against *Plasmodium Falciparum* Infection in Semi-Immune Adult Men in The Gambia: a Randomised Trial" (2001) 358 *Lancet* 1927; WHO, *supra* note 25, at 51.

[28] For more details on those initiatives, refer to P. A.Singer and A. S. Daar, *supra* note 25

[29] L. Stein, "Genome Annotation: from Sequence to Biology" (2001) 2 *Nature Reviews Genetics* 493; S. P. Verma, "Malaria Genome Project and its Impact on Disease" (March-June 2003) 40:1/2 *Journal of Vector Borne Diseases* 9; WHO, *supra* note 25; M. Enserink, "Two New Steps Towards a "Better Mosquito" (2000) 293 *Science* 2370; E. Dowdeswell, A.S. Daar and P.A. Singer, *supra* note 7.

responsible for most cases of malaria was published as a first step toward developing a new class of anti-malarial drugs and vaccines.[30]

Moreover, in the clinical setting, genetic testing can be used to address the specific health needs of the developing world's populations. Genetic testing is performed by analysing information contained in an individual's DNA once that DNA has been isolated or copied. In general, genetic testing involves analysing individuals' DNA for various purposes such as screening for genetic abnormalities before birth, confirming a disease diagnosis, and identifying individuals more susceptible to diseases because of the genetic variations they carry.[31] Numerous existing genetic services could be beneficial in the developing world where non-communicable diseases "are now the leading cause of death [...] and their prevalence is expected to rise significantly in the next several decades."[32] Indeed, a number of severe and life-threatening non-communicable diseases with a strong genetic component could likely be prevented, recognised, diagnosed, and treated in the future if safe and efficient genetic-predisposition testing were made available.[33] Such preventive strategies could

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[30] H.Thorsteinsdottir et als. "Genomics—a Global Public Good?" (March 15, 2003) 361:9361 *The Lancet* 891; M.J. Gardner et al., "Genome Sequence of the Human Malaria Parasite Plasmodium Falciparm" (2002) 419 *Nature* 498; J.M. Carlton et al., "Genome Sequence and Comparative Analysis of the Model Rodent Malaria Parasite Plasmodium Yoelii Yoelii" (2002) 419 *Nature* 512; R.A. Holt et al. "The Genome Sequence of the Malaria Mosquito Anopheles Gambiae" (2002) 298 *Science* 129; H. Jomaa, *et al.*, Inhibitors of the Nonmevalonate Pathway of Isoprenoid Biosynthesis as Antimalarial Drugs (1999) 285 *Science* 1573.

[31] A. Alwan & B. Modell, "Opinion: Recommendations for Introducing Genetics Services in Developing Countries" (Jan. 2003) 4:1 *Nat Rev Genet.* 61.

[32] University of Toronto Joint Centre for Bioethics, *supra* note 25, at 59-60; D.G. Richards, *Intellectual Property Rights and Global Capitalism, The Political Economy of the TRIPS Agreement* (London: M.E. Sharpe, 2004) c. 6, 141.

[33] For example, the application of diagnostic measures that use DNA analysis to identify genetic carriers or diseases could be very helpful to screen for red blood cell disorders like thalassaemia and sickle cell disorders (very common in developing countries) and inform carriers of the risk to their health and their offspring's health. Another example is prenatal diagnosis, which has been found to be useful in the identification of sickle cell anaemia, a very serious condition associated with a high level of mortality and morbidity. Access to this measure would be of particular interest to allow preventive action in West Africa where almost 25% of the population are sickle cell carriers. Early molecular diagnosis and neonatal screening for Cystic Fibrosis (CF) is a third example of preventive genetic medicine that could be of great value for the developing world. In Brazil, where there is a high incidence of CF, it is not rare that persons afflicted with the disease die undiagnosed. Therefore, basic genetic testing could be extremely useful in Brazil and other countries with similar rates of CF, especially for lower-income families. However, for now, those existing diagnostic tools do not reach the bulk of the world's population who need it the most, particularly those living in remote rural areas of developing countries. A. Alwan & B. Modell, *Community Control of Genetic and*

be especially beneficial in addressing situations where neither individuals nor governments are able to pay for costly and lengthy treatments.[34]

Nevertheless, the science of genetics has some limits. As stated above, most diseases, even some Mendelian "single gene disorders" are caused by a variety of factors and by complex interactions between genes and the environment.[35] In response to the growing enthusiasm for the genetic revolution, some observers suggest that the excitement surrounding genetics is, at times, over-stated and that excess of optimism should be moderated.[36] There are still many technological and statistical obstacles to overcome in linking phenotypes to genetic markers, and some believe that progress will take significantly more time. [37] Further, clinical applications of genetic knowledge sometimes remain limited, even when much information is available.[38]

Congenital Disorders, EMRO Technical Publications, Series 24, World Health Organization, Regional Office for the Eastern Mediterranean, Cairo, 1997; I.C. Verma et al., "Genetic Counselling and Prenatal Diagnosis in India - Experience at Sir Ganga Ram Hospital" (April 2003) 70:4 *Indian J Pediatr* 293.; WHO, Guidelines for Control of Haemoglobin Disorders. Geneva, 1994, WHO/HDP/HB/GL/94.1; WHO, *supra* note 25, at 81-84; T.A. Adewole et al. "Application of Polymerase Chain Reaction to the Prenatal Diagnosis of Sickle Cell Anaemia in Nigeria" (July-Sep 1999) 18:3 *West Afr J Med.* 160; C. Streit et al., "CFTR gene: Molecular Analysis in Patients from South-Brazil' (2003) 78 *Molecular Genetics and Metabolism* 259; M. Petrou & B. Modell, "Prenatal Screening for Haemoglobin Disorders" (1995) 15 *Prenat. Diagn* 1275; B. R. Bloom & D. D. Trach, *supra* note 19, at 1008.

[33] C. Streit et al., "CFTR gene: Molecular Analysis in Patients from South-Brazil' (2003) 78 *Molecular Genetics and Metabolism* 259.

[34] A. Alwan & B. Modell, *supra* note 31, at 62.

[35] J. Alper, "Genetic Complexity in Human Disease and Behavior" in J. Alper et al., eds., *The Double-Edged Helix: Social Implications of Genetics in a Diverse World* (Baltimore: Johns Hopkins University Press, 2002) 17; E. T Juengst "FACE Facts: Why Human Genetics Will Always Provoke Bioethics" (Summer 2004) 32:2 The Journal of Law, Medicine & Ethics 26.

[36] T.M. Bubela & T. Caulfield, "Media Representations of Genetic Research" in E.F. Einsiedel & F. Timmermans, eds, *Crossing Over. Genomics in the Public Arena.* (Calgary: University of Calgary Press, 2005); T.M. Bubela & T. Caulfield, "Does the Print Media Hype Genetic Research?: A Comparison of Newspaper Stories and Peer Reviewed Research Papers" (2004) 170:9 *Canadian Medical Association Journal* 1399; S. Jones, *Genetics in Medicine: Real Promises, Unreal Expectations: One Scientist's Advice to Policymakers in the United Kengdom and the United States* (London: Milbank Memorial Fund, 2000); L. B. Andrews, "Past as Prologue: Sobering Thoughts on Genetic Enthusiasm" (1997) 27 *Seton Hall L. Rev.* 893

[37] J. Altmuller et al., "Genomewide Scans of Complex Human Diseases: True Linkage is Hard to Find" (2001) 69 *American Journal of Human Genetics* 936; D.S. Roos, "Bioinformatics – Trying to Swim in a Sea of Data" (2001) 291 *Science* 1260.

[38] B. R. Bloom & D. D. Trach, *supra* note 19, at 1008; N. Holtzman, "Will Genetics Revolutionize Medicine?" (2000) 343 *New England Journal of Medicine* 141.

One must therefore come to this subject by realising that people working in genetics are still in the early phase of understanding the complexity of gene interactions. Nevertheless, significant progress has been made in a very short time. There are many signs that valuable technological development will continue to take place and that genetics will have an important preventive and therapeutic role to play in future health care and medical practice.[39] Therefore, for the purposes of this dissertation, we will focus on the positive impact that genetics is likely to have on global health in the future. In other words, although we realise that it might take many more years and significant investment to get to a point where genetics can fully deliver on its promises, we will focuss on the progress already made, starting from the premise that it is only a matter of time before technical challenges are overcome and genetic research can create greater benefits for the delivery of health care.[40]

Consequently, given the fact that genetics is a very promising field for helping to improve global health—and considering that it has not, up to now, been developed with this focus but in the context of commercial and profit motivations—we consider it essential to discuss how the field's emerging benefits (knowledge, expertise, research tools, products and services, and profits) should be distributed on the global scene in the future.[41] There are a plethora of normative, socio-economic and political obstacles to more equitable distribution of health related benefits and we will address some of these in the course of this dissertation. However, before we go any further, it is important to say a few words on the concept of *benefit sharing* used more and more as a response to the widening global health divide, especially in the field of genetics.

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[39] F.S. Collins et al., *supra* note 13 ; J.A. Robertson, *supra* note 19 ; A.E. Guttmacher & F.S. Collins, *supra* note 18; H. Varmus, "Getting Ready for Gene-Based Medicine" (2002) 247 *N Eng J Med* 1526.
[40] WHO, The Advisory Committee on Health Research of the World Health Organization, *Genomics and World Health*, Geneva, 2002, online on the WHO website, <http://www3.who.int/whosis/genomics/pdf/genomics_report.pdf> (accessed March 4th, 2006)
[41] B. R Bloom & D. Duc Trach, "Genetics and Developing Countries" (April 28, 2001) 322 *BMJ* 1006.

Benefit sharing

The expression *benefit sharing* is used broadly in relation to biodiversity, traditional knowledge, and human genetic research to indicate that some of the benefits (economic or social) arising from these fields should be shared with those from whom the goods or knowledge originated.[42] For example, the *Human Genome Organisation* (HUGO) issued a statement in 2000 calling for the sharing of certain benefits arising from the commercialisation of genetic inventions with the populations or communities from which samples originated.[43] Generally, benefit-sharing obligations arise from two different situations: as a consequence of specific transactions with research participants and contributors, or as a result of a norm that the good in question ought to be used for the general benefit of all humanity.[44]

The first and most popular application of this obligation involves sharing the benefits of research with the contributors of genetic resources based on a concern for justice. Increasingly, laws, regulations, and guidelines promote ethical standards requiring researchers to share benefits with research participants and resource contributors when using the latter's traditional knowledge, biodiversity resources, and human

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[42]For example, one of the main objectives of the *Convention on Biological Diversity* (CBD) is the fair and equitable sharing of benefits arising from the knowledge deriving from biological diversity. The *Bonn Guidelines* on access to genetic resources and fair and equitable sharing adopted in April 2002 provide a strategy for the access and benefit sharing process and the Food and Agriculture Organization (FAO) Conference approved the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA), which entered into force in June 2004 and by which contracting parties will provide easier access to identified genetic resources through a unique *Multilateral Material Transfer Agreement*. For reference to those legal documents, see: *Convention on Biological Diversity*, Rio de Janeiro, June 5, 1992, online: <http://www.biodiv.org/doc/legal/cbd-en.pdf,> (accessed June 4th, 2006); Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Decision VI/24, *Access and Benefit-Sharing as related to genetic resources*, April 2002, the Hague, online: <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24> (accessed June 4th, 2006); Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Decision VI/24, *Access and Benefit-Sharing as related to genetic resources*, April 2002, the Hague, online: <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24> (accessed June 4th, 2006); FAO, *International Treaty on Plant Genetic Resources for Food and Agriculture*, November 2001, online: <ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf>; For an interesting discussion on the concept of benefit sharing as applied to human genetics, see: K. Simm, "Benefit-Sharing Regarding the Meaning and Limits of the Concept in Human Genetic Research" (2005) 1:2 *Genomics, Society and Policy* 29.

[43] HUGO, *Statement on Benefit Sharing*, Vancouver, 2000, online: <http://www.gene.ucl.ac.uk/hugo/benefit.html> (accessed June 4th, 2006).

[44] This dual aspect is clearly highlighted and explained in this UNESCO report: UNESCO International Committee on Bioethics, *Report of the IBC on Ethics, Intellectual Property and Genomics*, 10 January 2002, SHS-503/01/CIB-8/2 Rev

biological tissues.[45] There is an assumption that these people are entitled to share in the benefits.[46] The actual justification put forward for this obligation varies depending on whether one is discussing human biological samples, biodiversity and plants, or traditional knowledge. We will not address each of these in detail as it is beyond the scope of our work. However, to get a better understanding of the compensatory argument, it is useful to say a few words on the rationale for sharing benefits arising from the use of biological tissues when they are provided by individuals and populations for human genetic research.[47]

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[45] For example, HUGO, *Statement on Benefit Sharing*, *supra* note 43, E. Justice, 1) Compensatory justice: meaning that the individual, group, or community, should receive recompense in return for contribution...; Convention on Biological Diversity, *supra* note 42, art. 15

[46] Participant in the 2001 Conference on Ethical Aspects of Research in Developing Countries, "Fair Benefits for Research in Developing Countries" (13 December 2002) 298 *Science* 2133; UN Commission on human rights, High Commissioner, "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights", Geneva, June 27, 2001;

[47] For more on the justification for providing compensation (or not) when using biodiversity and plants genetic resources and traditional knowledge, we refer the reader to: L. Mansur, "Gene Discovery, Ownership and Access for Developing Countries in the Era of Molecular Genetics" (2002) 5:1. *Electronic Journal of Biotechnology* online: <http://www.ejbiotechnology.info/content/vol5/issue1/issues/05/> (accessed May 16th, 2006); UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, September 2002, at 84; Indian Government, WTO, *Protection of Biodiversity and traditional knowledge. The Indian Experience*, July 14, 2000, WT/CTE/W/156, *International Convention of the Protection of New Varieties of Plants* (UPOV), Paris, 1961 and revised in Geneva in 1972, 1978 and 1991, online on the UPOV website, <http://www.upov.int/en/publications/conventions/index.html> (accessed March 8th, 2006); World Intellectual Property Organization (WIPO), Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Operational Terms and Definitions*, Geneva, May 20, 2002, WIPO/GRTKF/IC/3/9; WIPO, *The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles*, Geneva, Jan. 2006, WIPO/GRTKF/IC/9/4, online on the WIPO website: <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_9/wipo_grtkf_ic_9_4.pdf> (accessed March 8th, 2006); WIPO *"Intellectual Property Needs and Expectations of traditional knowledge Holders"*, Geneva, 1999, 768E, online on the WIPO website: <http://www.wipo.int/globalissues/tk/report/final/index.html> (accessed March 8th, 2006); D. Leskien & M. Flitner, "Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System", (June 1997) 6 Issues in Genetic Resources at 42 & 46; C. Correa, *Traditional Knowledge and Intellectual Property*, The Quaker United Nations Office (QUNO), Geneva, November 2001, online on the website of netamericas: <http://www.netamericas.net/Researchpapers/Documents/Ccorrea/Ccorrea2.pdf> (accessed March 8th, 2006); WHO, *Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine*, Bangkok, 6-8 December 2000 (WHO/EDM/TRM/2001.1); E.R. Gold & D. Castle, *Traditional Knowledge and Benefit Sharing: From Compensation to Transation*, paper presented at ICABR 8th International Conference on Agricultural Biotecc: International Trade and Domestic Production, Ravello, Italy, July 2004; C. Juma & K. Fang, "Bridging the Genetic Divide," in M. Ruse & D. Castle, eds., *Genetically Modified Foods: Debating Biotechnology* (Amherst: Prometheus Press, 2002); UN Commission on Human Rights, High Commissioner, "The Impact of the

The provision of biological material is regulated by the broad principle of non-commercialisation of the human body and its components [48] illustrated by the prevalence of a "consent model" (under which individuals are entitled to give away or abandon bodily materials), in contrast to a "property model" (under which individuals are entitled to sell their tissues).[49] There is also a debate as to whether the current system should be revisited to allow property claims in some human body material.[50] However, this thesis proceeds on the basis that, as argued by Gold, it is inappropriate to apply property discourse to human bodily materials since this discourse cannot appropriately deal with goods that are valuable chiefly for *non-economic* reasons. There are numerous different values that relate to health and human biological material (dignity, community, spirituality, etc.), many of which cannot and should not be evaluated by the market.[51] This leads us to argue that we should not consider

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Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights", Geneva, June 27, 2001, at par 41.

[48] For example, see UNESCO Universal Declaration on the Human Genome and Human Rights, Paris, 1997, art.4; Department of Biotechnology - Government of India, *Ethical Policies on the Human Genome, Genetic Research and Services,* New Delhi, June 2001, online on the website of the Government of India, <http://dbtindia.nic.in/policy/polimain.html> (accessed March 8th, 2006).

[49] For example, see the case *Moore* v. *Regents of the University of California* 794 P 2d 479 Cal SC 1990, where a physician obtained a commercially valuable patent over a patient's cell and in which the California Supreme Court found that the patient did not have property interest in his cells even if they contained his DNA. The Court instead awarded compensation for breach of fiduciary duty and lack of informed consent; for more on the "consent" model vs. the "property" model, refer to European Group on Ethics in Science and New Technologies (EGE), Opinion No. 16, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Brussels, May 7, 2002, sect.1.20, at 12, online on the website of the European Parliament, <http://europa.eu.int/comm/european_group_ethics/avis3_en.htm> (accessed April 25, 2006); Medical Research Council, *Human Tissue and Biological Samples for Use in Research- Operational and Ethical Guidelines*, London: MRC Ethics Series, April 2001, s. 2.2, online on the MRC website, <http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf> (accessed March 9, 2006).

[50] E.R. Gold, *Body Parts: From Property Rights to Human Biological Materials* (Washington D.C.: Georgetown University Press, 1996); *Moore* v. *Regents of the University of California* 794 P 2d 479 Cal SC 1990; J. Bovenberg, "Whose Tissues is it Anyways?" (2005) 23:8 *Nature Biotechnology* 929; A McCall Smith, Property, dignity and the human body" (1994) 2 (3) *Hume Papers on Public Policy* 29; G. Laurie, *Response to* report *Whose Hands on Your Genes Consultation of the Human Genetic Commission.* London, January 2002, c. 8; K. Maşon & G. Laurie, "Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey" (September 2001) 64:5 *The Modern Law Review* 725; Davies J. L. "Property Interests in Human Reproductive Material" (Sept.-Oct. 2001) *Genetic Law Monitor* 6; W. Boulier, "Sperm, Spleens and Other Valuables: The Need to Recognize Property Rights in Human Body Parts" (1995) 23 *Hofstra L. Rev* 705.

[51] Refer to Gold's book for a detailed analyse of those issues: E.R. Gold, *supra* note 50, c. 7, 8 and 9; see also Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield

participants' biological tissues as commercial property, appropriately valuable, for which compensation should be awarded.[52] Therefore, even if sharing benefits with human genetic-resource contributors may seem intuitively right and equitable for many, it appears to lack a real normative basis with regards to compensatory justice and property law.

On a more practical level, a compensatory system unequally rewards contributions to individuals and communities. Some populations and individuals, because of their geographical situations, special environment, employment, or genetic makeup will be more "interesting" than others for the purpose of specific research on genetic diseases, variations, and polymorphisms. In these circumstances, compensatory benefit-sharing systems can be viewed as a kind of lottery where the luckiest individuals and populations participate and win a portion of the benefits and others, also in great need but without similar resources, are left out of the process completely.

There are ongoing discussions about proposals to impose obligations of benefit sharing on scientists toward specific resource contributors based on compensatory justice. This topic is fascinating, but given that the purpose of this dissertation is not to provide a deep analysis and critique of compensatory benefit sharing mechanisms, we leave it aside. We note that the HUGO's ethics committee "[i]n view of the ethical and logistical difficulties of defining community, [...] recommended that benefits be distributed broadly, perhaps to the health infrastructures of entire nations."[53] This dissertation will thus focus, instead, on another, more global, aspect of benefit sharing: as a tool to realise distributive justice in health.

Council on Bioethics, April 1995), s. 9.14 and 13.25, online on the Nuffield Council website, <http://www.nuffieldbioethics.org/fileLibrary/pdf/human_tissue.pdf> (accessed March 9, 2006).

[52] E.R. Gold & T.A. Caulfield, *Human Genetic Inventions, Patenting and Human Rights*, 2003, Canadian Ministry of Justice, at 47; K. Berg, "The Ethics of Benefit Sharing" (2001) 59 *Clinical Genetics* 240 at 242

[53] HUGO Ethics Committee, "HUGO Urges Genetics Benefit-Sharing" (2000) 3 *Community Genet* 88, at 90.

Indeed, as this dissertation will suggest, benefit sharing can be better justified under a theory of global distributive justice. This understanding of benefit sharing involves sharing outcomes with individuals and groups more generally, without having to refer to compensatory principles. As we will see in more detail in the course of this dissertation, this obligation is based on the idea that justice requires us to protect the neediest and the most vulnerable and that mechanisms for ensuring transfer and assistance are required to further this goal on a global scale.[54] The duties imposed by global justice demand that individuals become involved in developing just global institutions and in supporting just domestic policies that affect individuals within and outside a nation's borders.[55] Therefore, the benefits arising from genetics should be distributed in a way that contributes to everyone's equality of opportunity and benefits the least well-off.[56]

We will also argue that the particularities of genetics also necessitate a global rather than individual perspective on benefit sharing in this area of research. For example, the fact that the human genome has symbolically been qualified as the *common heritage of humanity*[57] highlights its universal value for the human race and serves as a reminder that knowledge about the human genome should benefit humanity as a whole (including future generations) instead of serving narrow economic interests.[58] Moreover, the concept of common heritage associated with the human genome

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[54] C.Beitz, "Social and Cosmopolitanism Liberalism" (1999) 75:3 *International Affairs* 515 at 518.
[55] C.R. Beitz, "International Liberalism and Distributive Justice: A Survey of Recent Thought" (1999) 51:2 *World Politics* 269, at 278 and 280;
[56] J. Rawls, *A Theory of Justice* (Cambridge, Harvard University Press, 1971) at 7-8 (difference principle); J. Rawls, *A Theory of Justice*, 2nd ed., (Oxford: Oxford University Press, 1999) at 63, 72-73; C. Beitz, "Rawls's Law of Peoples" (July 2000) *Ethics* 7; A. Buchanan, "Rawls's Law of Peoples: Rules for a Vanished Westphalian World"(July 2000) *Ethics* 697.
[57] UNESCO *Universal Declaration on Human Rights and the Human Genome,* Paris, 1997, article 1
[58] C. Joyner, "Legal Implications of the Concept of the Common Heritage of Mankind" (January 1986) 35:1 *International and Comparative Law Quarterly* 190; see also UNESCO, *International Consultation on the outline of the Universal Declaration on the Human Genome, Summary of the Response to the Questionnaire*, 1997; S. Paquerot, Les Exigence de l'État de Droit dans le Concept de Patrimoine Commun de l'Humanité: Réflexions Autour de la Mise en Représentation de la Légitimité au Plan International, Acte de la journée d'études de l'équipe CEDIM/FCAR Mondialisation, Gouvernance et État de droit, Montréal, Juin 2000; HUGO, *Statement on Benefit Sharing, supra* note 43, *Common Heritage*: "While not respected by all nations, the concept of common heritage also resonates under international law (e.g. the sea, the air, space, ...). Applied to human genetics, it maintains that beyond the individual, the family, or the population, there is a common shared interest in the genetic heritage of mankind."

involves a notion of solidarity based on the fact that we share our genetic makeup (99.9%) with all other human beings, that it is "part of every individual and integral to the evolution of the human species."[59] However, the reality is that genetic applications remain inaccessible to many individuals all over the world because they do not have access to sufficient financial, infrastructure, and human resources to make use of this precious knowledge. As Thorsteindottir et al. clearly state, "[g]enomics is only a public good to those countries that have the capacity to exploit genomics knowledge and to conduct genomics research. Because of the need for these "access goods", genomics becomes a "club good", accessible mainly to industrialised countries."[60]

This is enough to be deeply concerned about the way current assumptions define what is just and acceptable with regard to global access and distribution of resources in this field. It also highlights the need for a precise and enforceable concept of global benefit sharing in health that would position genetics as an essential tool for achieving global health rather than as a luxury beyond the reach of the most vulnerable people. To this end, we need to establish a normative basis for undertaking benefit sharing with developing countries in the global health sphere. Global benefit-sharing obligations can be built on theoretical and legal grounds but have not, up to now, been elaborated at length in the field of health and genetics. This will be the core of our thesis. We will flesh out the widely-used concept of benefit sharing to determine how we could ensure that it is used to further global health without leaving the most vulnerable out of the process.

The Structure of the Dissertation

The first purpose of this dissertation is thus to set out a grounding theory or theoretical framework to justify engaging in a global and more equitable redistribution of benefits produced by genetics. Ultimately, our analysis will produce

[59] C. Joyner, *ibid.*, at 194.
[60] H.Thorsteinsdottir et al., *supra* note 30, at 892.

strong normative benchmarks based on justice considerations that take needs into account rather than market-based power when evaluating major social, political, and legal implications resulting from the commercialisation of genetics.

The first chapter will set the contextual basis of our framework by providing justifications for a global application of distributive justice principles. To assess institutions and practices, we will propose a cosmopolitan methodology based on a global scheme of cooperation emerging from the idea of the universal importance of every human being as a unit of moral concern. This exercise will give us a sense of how institutions involved in the distribution of genetic benefits should function and within which specific parameters they should handle distribution.

The second chapter of this first theoretical part will elaborate an ideal conception of distributive justice in health to justify global access to genetics. We will establish normative grounds as the basis for our scheme of global health/health care justice, focussing on the special characteristics of health and on its crucial role in normal human functioning. After arguing that health is a crucial element of normal functioning, we will analyse the impact of normal functioning on the lives of individuals, using the criterion of the range of normal opportunities available to people. This will help us establish clear links between health problems, lack of access to the resources emerging from genetic research, and a diminution of the range of opportunities for which individuals of equal skill can build life plans. This discussion will highlight the specificity and universal importance of health. It will also flesh out our argument in favour of compensation for deviations from normal functioning and for the eradication of health inequities over which we can have some form of control through distributive justice mechanisms.

After this first part, we will have established a global distributive justice framework as the basis of our argument for more equitable and global access to health and genetics. The second part of the dissertation will attempt to determine how and if our theory of distribution translates into positive law and to identify and analyse the main

obstacles to legal compliance with global distributive justice. Although the development of genetics can affect many areas of law including privacy, employment, insurance, and criminal law, we will focus on two of the major international legal systems most concerned with distribution issues: intellectual property (IP) law (especially patent law) and human rights law. The first two chapters of the second part will be dedicated to the presentation and analysis of those international normative systems in order to determine if their underlying philosophy, structure, and functioning take account of the principles highlighted in our theoretical framework.

Our analysis will conclude that these two legal frameworks regulating the distribution of benefits and resources arising from genetics are deficient, each in their own way, in the reach, operation, and substantive content of the standards they promote. Indeed, we will realise that, despite our argument for the universal special importance of health, this does not always receive the special and universal treatment it deserves in practice. The discussion will bring to light major power imbalances and a lack of focus on distributive justice issues mainly attributable to the political and economic contexts of application of the two systems and not to an irremediable incompatibility of the principles with diffusion and equitable access to knowledge. We will indeed realise that both systems, although very different in their nature and purposes, are driven mainly by market considerations either in their philosophy, principles, and/or application and that they do not give enough attention and importance to justice and solidarity issues. Our analysis will bring us to acknowledge that the international order under which IP and human rights evolve inspires power struggles that shift our attention away from justice principles standing at the source of a shared morality and a cosmopolitan perception of humanity. Our work will aim to highlight, analyse, and explain this reality.

Following our discussion on the conceptual link existing both between IP law and access and human right law and access, our last chapter will focus on introducing practical examples to illustrate the intersection of IP and human rights law. Referring

to a few examples, this last chapter will seek to highlight the practical impact that those two systems have had on scientific data-sharing and on availability and affordability of genetics research tools, products, and services in developing countries. Following the presentation of those examples, we will conclude this last chapter with a brief analysis of the intersection between IP rights and human rights in health. This will allow us to address the effects of strong and broad IP rights on the realisation and implementation of human rights and the tension existing between the two systems, both in terms of philosophy and application.

This will conclude the second and last part of our dissertation dedicated to the assessment of the two major systems—first, with justice benchmarks established in the first theoretical part and second, with practical examples. Coming back to the evidence presented at the beginning of our work on the real potential of genetic research to improve global health, and on our support for a notion of global distributive justice in health, we will be forced to realise that, as they currently function, the intellectual property and the human rights systems are not adequate to realise global benefit sharing in the field of genetics. Without arguing for the abolition of these systems or establishing detailed solutions and practical policy options, we will conclude our dissertation with some suggestions of avenues that could be explored further to remedy this situation in order to further global distributive justice. This will set out a basis for further discussion on how we could work around some of the major obstacles identified throughout our analysis. It will also help us move from the vague and often symbolic ideal of benefit sharing actually prevailing toward the establishment of a real, enforceable concept of global benefit sharing in health that would position genetics at the rank of essential tool for achieving global health.

PART I: A THEORETICAL FRAMEWORK FOR DISTRIBUTION IN HEALTH

Building on the context established in the introduction, the thesis now moves to the theoretical basis for examining the global distribution of the benefits of genetic research and resulting products and services. The first part of our dissertation will therefore represent the grounding of our argument for engaging in a global and more equitable redistribution of the benefits likely to emerge from genetic science.

The analysis performed in this first part will produce strong normative benchmarks useful for adopting justice considerations based on health needs in order to evaluate major social, political, and legal implications resulting from the commercialisation of genetics. This framework will represent an ideal conception of global justice in health, a standard for appraising institutions and for guiding the overall direction of social change by providing a long-term goal of political endeavour and giving meaning to what we can do today in actual, existing conditions.[61] This analysis is very important because even if ideal principles of justice cannot always apply automatically and immediately to the practical reality, it is crucial to understand exactly what we are compromising by accepting non-ideal conditions, and to receive guidance as to what we should be aiming for with respect to future social and institutional reforms. As clearly put by Schrecker: "responsible ethical analysis must not regard crucial background elements of the social and economic context [...] as too big to change".[62]

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[61] J.Rawls, *A Theory of Justice*, rev. ed. (Cambridge: Harvard University Press, 1999), at 128; C. Brown, *Sovereignty, Rights and Justice, International Political Theory Today* (Cambridge: Polity Press, 2002), at 180.

[62] T. Schrecker, "Benefit-Sharing in the New Genomic Marketplace: Expanding the Ethical Frame of Reference" in B.M.Knoppers, ed., *Populations and Genetics: Legal and Socio-Ethical Perspectives* (Leiden: Martinus Nijhoff, 2003).

Thus, we believe that it is necessary to launch discussions and stir up debates on a common vision of the good and related universal basic needs, rights, and duties in order to establish appropriate principles of distributive justice in health. A distinction must be made between something that is unfeasible and something that has been demonstrated to be impossible, since ideal principles are both relevant and useful when their implementation remains a possibility.[63] To this end, a sense of moral responsibility for the actual state of the world must be developed and cultivated in order for reforms and changes to gradually take place when they are indeed possible. This first part will contribute to establish the analytical basis required to lay the foundation for this important process.

We have split this first part into two main chapters. In the first one, we will present an argument for a global application of justice principles to justify global access to genetics, referring to a cosmopolitan approach that considers each human being with their basic health needs as a unit of consideration deserving equal attention. This global focus will give us the perspective we need to determine how institutions should work towards distribution of genetic-research benefits and who should be entitled to profit from this distribution.

The second chapter will establish an ideal scheme of global health/health care justice. To this end, we will need to reflect on the special importance of health for every individual, on the role it has to play in ensuring normal functioning and in the pursuit of an ideal of equality of opportunity for all. In this moral scheme, every individual's health interests receive equal consideration and the benefits arising from genetics are distributed so as to prevent health standards' differences caused by socio-economic factors. Our analysis will highlight the importance of compensating for the divergence from normal functioning and health inequalities over which we have some power through distributive justice schemes.

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[63] T.W. Pogge, "The Moral Demands of Global Justice" (Fall 2003) *Dissent* 37.

Chapter I: Global Application of Distributive Justice: A Cosmopolitan Approach

> *When choices are to be made regarding the ends and means of political action, or the structures and rules of institutions and practices, it is natural to ask by what principles such choices should be guided.*[64]

Introduction

As discussed in the introduction, though there will probably be a considerable delay between the identification of genetic dysfunctions and mutations and the positive interventions that can successfully alter, treat, or cure them, there is evidence that genetic research could, in the long run, have significant positive effects on the health and lives of people it may reach.[65] However, for the moment, we can expect that most future genetic technologies will likely reach and benefit a very limited number of people worldwide, the majority in developed countries. In fact, expensive innovations will probably be developed to address the needs of the affluent where there is a market for them and, in any case, will likely be accessible only to those people who have insurance coverage (public or private) or who can afford to purchase such technology with private funds.[66] Genetic discoveries could thus contribute to widen the health gap between rich and poor, both within and between

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[64] C.R. Beitz, *Political Theory and International Relations* (Princeton: Princeton University Press, 1999) at 5.

[65] Collins et al, A vision for the future of genomics research, (2003) 422 Nature 835; J. Bell, "The Double Helix in Clinical Practice" (2003) 421 *Nature* 414; R. Khoury et al. "Population Screening in the Age of Genomic Medicine"(2003) 348 *England Journal of Medicine* 50; Program in Applied Ethics and Biotechnology and Canadian Program on Genomics and Global Health (University of Toronto Joint Center for Bioethics) *Top 10 Biotechnologies for Improving Health in Developing Countries* Toronto, 2003; WHO, *Genomics and World Health*, Geneva, 2002.

[66] M.J. Mehlman & J.R. Botkin, *Access to the Genome the Challenge to Equality* (Washington D.C: Georgetown University Press, 1998).

countries, adding to the substantial inequalities that already characterise some health care systems and the global health agenda.[67]

Building upon our initial remarks on benefit sharing in the Introduction and in light of the concept's growing rhetorical importance in the field of genetics, it is now time to investigate its normative basis. In this chapter, we shall see that there exists a positive obligation to ensure equitable access to genetic advancements, that research priorities should be established accordingly, and that the benefits of genetic (knowledge, expertise, research tools, products and services, and profits) should be distributed more equitably, based on actual needs rather than simply on market forces. As already mentioned, while there are already differences with respect to access to genetics applications within countries, and this situation will most likely persist, our main focus will instead be on the limited access to the benefits of this science globally. It is in this context that we will develop the theoretical framework.

This first chapter will therefore establish the theoretical basis for a global application of our equitable distributive normative framework. For the purpose of this theoretical analysis, we will contextualise our argument in order to explain why principles of distributive justice should be applied globally. To this end, we will marshal arguments for and against global distributive justice. Subsequently, we will investigate a form of cosmopolitanism as the basis to determining how to best justify institutions and practices and to ascertain the most appropriate scale for distributive issues.

[67] M. Leonard, "Just Genetics: A problem Agenda" in T.F. Murphy & M.A. Lappé, eds. *Justice and the Human Genome Project* (California: University of California Press, 1994) 133.

1.1 Distributive Justice

What are the characteristics of a normative obligation of benefit sharing?

This chapter establishes an ideal conception of justice to help us criticise, orient, and assess possibilities for global access to genetics as already mentioned. Even if an ideal theory can seem far removed from the imperfect reality of developing countries, such a theory is essential to establishing the basis for concrete changes though a global normative framework for engaging in the international redistribution of resources produced by genetic and genomic research. [68] Indeed, theorists have developed different theories of justice to justify how goods, welfare, and services should be divided in a society.[69]

Some scholars and economists who believe in libertarianism favour the allocation of goods and services on the basis that a person's willingness to pay represents an effective measure of his or her desire to obtain a specific good or service. Following this approach, the person who values a good the most or who is inclined to pay the most for it would obtain it. Supporters of the free market have argued that a society's wealth will be increased most effectively if assets are privately owned and owners can trade them freely, so long as no one has the right to appropriate the property of others without their consent. Consequently, large differences in wealth among individuals have no moral significance and egalitarian redistribution of wealth is rejected.[70] From the perspective of advocates of a libertarian conception of justice, such as Nozick and Engelhardt, the use of government's coercive authority to

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[68] A. Kupler, "Debate: Global Poverty Relied, More than Charity: Cosmopolitan Alternative to the *Singer Solution*" (2002) 16:1 *Ethics and International Affairs* 107.
[69] For a good overview of the main theories of justice refer to: W. Kymlicka, *Contemporary Political Philosophy: An Introduction*, 2d ed. (Oxford: Oxford University Press, 2002).
[70] T.H. Engelhardt Jr, *The Foundations of Bioethics* (New York: Oxford University Press, 1986) at 342-343.

extract more resources is unfair and violates people's rights, liberties and self-determination.[71]

Utilitarianism is another way of envisioning justice. It requires the maximisation of overall welfare. Utilitarianism focuses on global welfare, which can sometimes be the result of equitable distribution but can also, in other circumstances, justify ignoring some members of a community for the benefit of the majority. In the process of bringing a society to its maximum health potential, utilitarians argue that we should not care if the health of the affluent is better and is afforded better treatment than the health of the poor, so long as the improvements have a positive impact on the overall population's health.[72] Another particularity of this view is that it is based on the idea that that income incentives (resulting in income inequalities) are needed to encourage innovation.[73]

Liberalism is another theory widely applied to justice issues in political philosophy. One of the many components of liberals' ideal structure of society is justice in goods and services through distribution to create more equitable circumstances. This is

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[71] *Ibid.* at c. 8; R. Nozick, *Anarchy, State and Utopia* (New York: Basic Books, 1974). One problem with the application of this argument to health is the determination of the extent to which health care systems and resources can be considered private property, since they have often been developed with a great deal of public funding. Even if private institutions play an important role in the development and delivery of some health resources, public funds have been, and are often still, the building blocks of hospital systems, fundamental research endeavours, dissemination of results, transfer of technologies, and most medical training.Another problem with applying libertarianism to health is that there are tremendous inequities with respect to both wealth and the availability of health insurance among individuals and nations. Most importantly, those who have the greatest medical needs are not always the individuals who have the ability to pay for the corresponding treatments and medical technologies. In this sense, the point of libertarianism is not compatible with the principle of equality in health. For more on the critic of the application of libertarianism to health, see: L.M. Fleck, "Just Health Care (I): Is Beneficence Enough?" (1989) 10 *Theoretical Medicine* 167; R.A. Epstein, "Why is Health Care Special?" (1993) 40 *U. Kan. L. Rev* 307.

[72] F. Peter & T. Evans, "Ethical Dimensions of Health Equity" in T. Evans et al., eds., *Challenging Inequities in Health, from Ethics to Action* (Oxford: Oxford University Press, 2001) 25 at 28.

[73] This incentive aspect does not seem to work for health, as health inequities do not encourage people to improve their health status at all. Since utilitarianism appears insensitive to issues of equality in health, we will not be using it to ground our argument. For more on utilitarianism and equality, see: S. Anand, *The Concern for Equity in Health,* Harvard Center for Population and Development Studies (Feb. 2002) Working Paper Series, vol.12, no.1, online on the website of HCPDS <http://www.hsph.harvard.edu/hcpds/wpweb/Anand%20wp1201.pdf> (date accessed: May 30th, 2006); B. Williams, "A Critique of Utilitarianism" in J.J.C. Smart. ed., *Utilitarianism: For and Against* (Cambridge: Cambridge University Press, 1973) 75.

called distributive justice. Distributive justice is another perspective from which to consider justice in health matters and will be our focus in the establishment of our theoretical framework for global health distribution. Distributive justice aims at determining the equitable allocation and access to benefits (resources, services, goods) and burdens produced by social cooperation.[74] The most popular theory of distributive justice in the last 50 years was established by John Rawls in his book *A Theory of Justice.*[75] Unlike utilitarianism, distributive justice maintains that individuals have rights that cannot be sacrificed simply to create more benefits for others. In this view, social primary goods like liberty, opportunity, income, and wealth are to be distributed equally unless an unequal distribution will advantage the least well-off. Rawls' principles are meant to apply only to the basic structure of isolated, well-ordered societies.[76] We will come back to Rawls' liberal theory of justice at several occasions in the course of the first part of the dissertation.

Similarly to libertarian and utilitarian standards, principles of distributive justice are designed to allocate goods, resources and services when needs are greater than availability. They are however very different because they require equity and consideration of the most vulnerable in distribution, which make their application to health resources and technologies very relevant. The principles of distributive justice can differ according to the subject of the distribution (income, wealth, opportunities to the good life, etc.), the beneficiaries of it (individuals, groups of persons, compatriots, foreigners etc.), the providers of the goods and services to be distributed (individuals, fellow citizens, governments, international organisations etc.), and the basis for the distribution (according to equality, to individual characteristics, to need, etc.).[77] Within a theory of distributive justice, the role of luck, chance, and choice are also relevant when deciding distribution issues.[78]

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[74] C.R. Beitz, *Political Theory and International Relations, supra* note 64
[75] J. Rawls, *supra* note 61.
[76] *Ibid.,* at.7, 8 and 303.
[77] J. Lamont, "Distributive Justice" (Fall 2003 Edition)*The Stanford Encyclopedia of Philosophy*, E.N. Zalta (ed.), <http://plato.stanford.edu/archives/fall2003/entries/justice-distributive> (date accessed: May 30th, 2006).
[78] C. Jones, *Global Justice, Defending Cosmopolitanism* (Oxford: Oxford University Press, 1999).

In this dissertation, we chose to focus on distributive justice considerations as applied to health needs. In fact, in contrast to libertarianism and utilitarianism, liberalism recognises the principle of equality in health and consequently allows us to consider health needs as a priority. Those elements are going to prove crucial for the examination of issues of global distribution of the benefits of genetic research. Before getting into the elements of our specific theory of distributive justice for global health— that is, the rationale for the distribution of specific benefits arising from genetic applications and the normative basis for such rationale—we need to present the context of distribution by providing a clear justification of the subject and scope of distribution.

Global Distributive Justice

Most theories of justice apply to domestic situations without dealing with the requirements of international distributive justice.[79] Nevertheless, if the benefits and burdens arising from social cooperation are the basis of distributive justice, economic interdependence at the international level and direction needed to make choices that can influence the well-being of individuals located in other societies might justify standards of global distributive justice analogous to the principles applicable within domestic societies.[80]

The first part of our theoretical analysis will contextualise our framework explaining why we argue that our principles of distributive justice should be applied on a global scale. This will lead us to adopt a form of cosmopolitanism as a basis for determining how institutions and practices should be justified and on what scale distributive issues should be handled.

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[79] For example J. Rawls, *The Law of Peoples* (Cambridge: Harvard University Press, 1999) at. 106, 114-119; J. Rawls, *supra* note 61; M. Walzer, *Spheres of Justice* (Oxford: Blackwell, 1983). However, more recently, philosophers like Charles Beitz and Thomas Pogge have provided interesting arguments in favor of international distributive justice.

[80] C.R. Beitz, "International Liberalism and Distributive Justice: A Survey of Recent Thought" (1999) 51:2 *World Politics* 269.

1.2 Cosmopolitanism: a Way of Envisioning Global Justice

Current scientific developments that can help improve health and cure disease are universally essential and therefore should be accessible to all human beings who can physiologically benefit from them, by simple virtue of their humanity and needs. Cosmopolitanism provides a good starting point for the theoretical basis for such a premise.

There are two kinds of cosmopolitanism: institutional and moral. Institutional cosmopolitanism focuses on how political institutions should be established. It holds that states and other political institutions should be restructured and placed under the control of an organisation akin to a "world government" or other supranational political arrangement, so that we could see the world as a single entity in which individuals would be *citizens of the world.*[81] By contrast, this thesis shall take the perspective of moral cosmopolitanism, which focuses on the basis for the justification of institutions, practices, and interpersonal relations. Since it is widely argued that a realistic and plausible form of cosmopolitanism should take institutions rather than interpersonal transactions as its primary focal points, this thesis focuses on moral institutional cosmopolitanism, which asserts that the responsibility of ensuring that practices and rules are enacted in compliance with a cosmopolitan ideal falls on institutions.

Moral cosmopolitanism is not associated with any specific political program or philosophical theory, but is instead characterised by its perception of the moral basis upon which justice issues should be evaluated and of the proper scope of moral principles.[82] It establishes conditions that any acceptable approach to justice ought to

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[81] D. Laertius, *Diogenes, in Lives of Eminent Philosophers,* trans. R.D. Hicks, Loeb Classical Library (London: William Heinemann, 1925) vol.2, vol. 6:63

[82] O. O'Neill, *Towards Justice and Virtue* (Cambridge: Cambridge University Press, 1996) at 172; O. O'Neill, *Bounds of Justice* (Cambridge: Cambridge University Press, 2000) c.10.

meet. Cosmopolitanism does not demand specific measures. Instead, measures would flow from a specific theory of justice like global distributive justice.[83] Once a cosmopolitan direction is established, specific justice measures focus on different aspects of importance to each individual, including subjective elements like happiness, well-being, desire, and preference, as well as objective factors like needs, abilities, and opportunities.[84] We will return to those specific measures in the second part of this chapter.

A moral cosmopolitan viewpoint is impartial, universal, individualist, and egalitarian in nature.[85] For cosmopolites, individuals are the fundamental entities of moral concern, as expressed by Thomas Pogge: "every human being has a global stature as the ultimate unit of moral concern."[86] Cosmopolites envision the social world as composed of persons rather than collectives.[87] They insist that each and every human being affected by institutional arrangements—like, for example, policy choices about production and distribution of burdens and benefits, or choices regarding the establishment of a specific institution—should be respected and given equal and impartial consideration by everyone, wherever they may be.[88] This perspective is based on the premise that individuals are entitled to certain treatment and consideration due to their humanity as opposed to other particularities including culture, politics, religion, and citizenship.

This individualistic vision of the self is the object of much criticism, especially from proponents of a communitarian approach to justice. Indeed, communitarians critique a universal vision of justice and needs, instead arguing for variable principles of

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[83] C.R. Beitz, "Social and Cosmopolitanism liberalism" (1999) 75:3 *International Affairs* 515 at.515; C.R. Beitz, *supra* note 55; A Kupler, "Rawlsian Global Justice, Beyond the Law of Peoples to a Cosmopolitan law of Persons" (October 2000) 28:5 *Political Theory* 640.
[84] T.W. Pogge, "Cosmopolitanism and Sovereignty" in C. Brown, ed., *Political Restructuring in Europe, Ethical Perspectives* (NewYork: Routledge, 1994) 89.
[85] C. Jones, *supra* note 78.
[86] T. W. Pogge, "Cosmopolitanism and Sovereignty" (October 1992) 103 *Ethics* 49.
[87] C.R. Beitz, "Rawls's Law of Peoples", *supra* note 56.
[88] O. O'Neill, "Hunger, Needs and Rights" in S. Luper-Foy ed., *Problems of International Justice* (London: Westview, 1988); A Kupler, *supra* note 83.

justice originating from societies' historical, institutional, and cultural particularities. They argue that distributive justice will only find logical application within restrained social groups who share subjective needs.[89] In the field of health, efforts to apply a single common morality and to adopt a universal approach when dealing with issues arising with the production and applications of science and medicine are criticised. Indeed, such attitude is seen as an effort from the western world to export its conception of what is ethical into an area where moral meanings of the most basic concepts like disease and health can differ between countries and religions.[90] The communitarian perspective of justice deserves great consideration and can be of considerable help in approaching and resolving important justice debate in health-related matters.[91]

Although we acknowledge and appreciate that different individuals and cultures can have different views of the definition and importance of health, in this dissertation we adopt a universal perspective on health. As we will see in the course of this chapter, even if different perceptions on some aspects of health coexist, we consider that health is something universally desirable, that it is a state of normal functioning

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[89] One of the arguments often put forward to support this view is that human needs are *socially relative* and that arguing for universal standard of needs could give rise to attempts by the more powerful to impose their vision of needs and that this could result in *cultural imperialism*. For discussions on communitarianism and critique of the universal perspective of liberalism, see: M. Sandel, *Liberalism and the Limits of Justice*, 2d ed., (Cambridge: Cambridge University Press, 1998); C.Taylor, *Philosophy and the Human Sciences: Philosophical Papers 2* (Cambridge: Cambridge University Press, 1985) ch. 1; M. Walzer, *supra* note 79; M. Walzer, *Thick and Thin* (Notre-Dame: University of Notre Dame Press, 1994); W. Kimlicka, *Contemporary Philosophy: An Introduction* (Oxford: Oxford University Press, 2002), c. 6; P. Marshall and B. Koenig, "Accounting for Culture in a Globalised Bioethics" (2004) 32 *Journal of Law, Medicine and Ethics* 252; A. Heller, *The Theory of Human Need in Marx* (London : Allison & Busby, 1976) at 96-97; G. Rist, "Basic Questions about Basic Human Needs" in K Lederer, ed., *Human Needs* (Cambridge: Oelgeschlager, Gunn and Hain, 1980) 233; C. Taylor, "The Politics of Recognition" in C. Taylor & A. Gutman, eds., *Multiculturalism* (Princeton: Princeton University Press, 1994); S. Scheffler, "Conceptions of Cosmopolitanism" (1999) 11 *Utilitas* 255, at 256.

[90] P. Marshall and B. Koenig, *supra* note 89 at 252 and 256; D. DeGrazia, "Common Morality, Coherence, and the Principles of Biomedical Ethics" (2003) 13:3 *Kennedy Institute Journal of Ethics* 219; L. Turner, "Bioethics in a Multicultural World: Medicine and Morality in Pluralistic Settings" (2003) 11:2 *Health Care Analysis* 99.

[91] However, we have to be careful with any view that uses cultural differences to justify inequities and tolerate suffering. For a very good analysis and critique of such approach refer to P. Farmer, "On Suffering and Social Violence: A View from Below" in A. Kleinman, V. Das & M. Lock, eds. *Social Suffering* (Berkeley: University of California Press, 1997) 278; for an illustration of this opinion, see also J. Mukherjee, "HIV-1 Care in Resource-Poor Settings: A View from Haiti" (2003) 362 *Lancet* 994.

influenced by numerous biological, genetic, socio-economic, psychological and environmental factors and which allows people to accomplish and further important life goals. In other words, we consider that health is an objective basic human need and consequently that access to health and genetics (as previously defined) should be an issue of universal importance for every human being no matter who they are, where they come from, or where they live.[92] We, of course, acknowledge that some identified groups might have specific vulnerabilities to disease and additional health needs, and that they should be able to be treated accordingly when they are identified. However, this does not mean that the basic health needs of individuals from those groups should be considered any differently from those of any other individual.[93] With this perspective in mind, we now leave the communitarian perspective aside and adopt a moral cosmopolitan viewpoint to address the issues at stake. This being said, we appreciate that a culture-specific strategy and sensitivity could be essential, in the long run, to understand and address local and cultural specificities in the delivery of genetic products and services, and for an ethical provision of genetic counselling services, for example. However, this goes beyond the scope of this dissertation.

The universalistic/individualistic focus of moral cosmopolitanism can be justified by the common characteristics shared by all individuals. Ideed, human beings share a similar genetic makeup and are physiologically alike.[94] Our common genetic heritage thus transcends geopolitical borders. One might presume, therefore, that individuals, wherever they are, would be physically affected in similar ways by similar symptoms and diseases. However, this is not always the case. Not all people respond similarly to medical conditions, medication and illness. Indeed, human health often has a genetic component. A typical forms of a single gene or set of genes transmitted from one

[92] For more on the universal importance of certain needs, refer to the enlightening parallel established between the universality of basic needs and of suffering emerging from imperialism by Doyal, where he argues that, in both cases, victims' cultural background should not be used to assume that their suffering is qualitatively different. L. Doyal and I. Gough, *A Theory of Human Need* (NewYork: The Guildford Press, 1991), at 29-30.
[93] Idem, at. 57.
[94] Human Genome Project Information, *supra* note 12.

generation to another can cause inherited genetic diseases,[95] and many genes coupled with environmental interactions can have an incidence on more common diseases like hypertension, diabetes, and various forms of cancer and infections. Also, every individual carries numerous mutations in his or her genetic background, which are small changes in DNA that can contribute to human variation—some with, and others without, known incidence on health. Consequently, a number of genetic research projects that aim to identify significant genes and variations, and to determine who such variants affect, have been undertaken world-wide. Such studies generate important information for the screening of individuals, families, and populations more genetically at risk or susceptible to certain diseases and conditions.[96]

Even if different individuals may end up being personally affected by genetic discoveries in very different ways, at present it is difficult to predict who may benefit the most. Due to the similar characteristics we all share as human beings, it is safe to say that genetic developments carry a potential to benefit many individuals, world wide, both from a global community perspective and from a personal and familial perspective, regardless of the direct practical outcomes that might emerge from it, whether in the short or long term.

Other health and genetic differences have less to do with individual genetic makeup, but are instead clearly associated with external socio-economic, environmental, or nutritional factors. For example, some medical conditions, like malaria and other tropical diseases, are only present in some parts of the world as they are associated with environmental factors and the underdevelopment of specific medical and genetic technology. Furthermore, even when people in different parts of the world can seem to be physiologically affected the same way by diseases, socio-economic factors create huge gaps between them in how they end up burdened by the same afflictions

[95] Alzheimer's, some familial breast cancers, and cystic fibrosis are example of illnesses caused by a single gene.
[96] A.J. F. Griffiths et al., *An Introduction to Genetic Analysis* (New York: W H Freeman & Co, 1999).

in reality. This brings us to another important characteristic of cosmopolitanism: universalism.

Moral cosmopolitanism is not convinced that boundaries between territorial and political structures should have much moral importance. Principles of justice should apply to the *global community of world citizens*,[97] those who live in different countries and with whom we can seem to share little in terms of culture, language, and customs, for example.[98] The cosmopolitan perspective requires scepticism about strong nationalism and patriotism when they have the effect of prioritising only social and political affiliation in the provision and distribution of aid. It calls instead for a sense of community among human beings in a universal comity of nations where borders are less significant.[99] However, this does not mean that cosmopolitanism is indifferent to local poverty and deprivation, as some suggest. [100] Instead, cosmopolitanism holds that the state level should not be given absolute priority when considering justice. As such, we should care about the focus of our distributive justice obligations, such as deprivation and pain, wherever they exist. In fact, even if nations are an important part of the existing political picture (and cosmopolitans are not necessarily arguing for their abolition, as discussed below), the moral significance of boundaries should be justified in terms of the values and ethical principles that are chosen and the priorities such a choice represents for every individual affected.[101] In other words, nationality-based special treatments and group loyalty are appropriate but are necessarily complemented by concurrent moral obligations to individuals beyond our border. The priority given to our fellow citizens for distributive justice is not absolute; other human beings who may not be citizens can also have legitimate

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[97] W. Hinsch, "Global Distributive Justice" (January 2001) 32 (1/2) *Methaphilosophy* 58.
[98] W. Scheuerman, "Globalization" *The Stanford Encyclopedia of Philosophy (Fall 2002 Edition)*, E.N. Zalta (ed.), <http://plato.stanford.edu/archives/fall2002/entries/globalization> (accessed May 30th, 2006).
[99] I. Kant, *The Metaphysical Elements of Justice (*1797), trans. J. Ladd, 2nd ed. (Indianapolis: Hackett Publishing Co., 1999).
[100] G. Fletcher, *Loyalty: An Essay on the Morality of Relationships* (Oxford: Oxford University Press, 1993) at 21.
[101] C.R. Beitz, "Cosmopolitan Liberalism and the States System" in C. Brown, ed., *Political Restructuring in Europe, Ethical Perspectives* (NewYork: Routledge, 1994) c. 6, 123, at 124.

interests in distribution. The latter should be given important consideration in cases where the interests at stake are significant, as are, for example, claims for the protection of basic rights or vital interests.[102]

Human beings share a common sense of morality and common human interests in certain crucial spheres of universal importance. We agree with Buchanan when he says that: "we should expect some congruence of moral values across societies, given the roles that morality plays in human life [...]"[103]. Those principles and values are the ones that play a role in preventing people from being exposed to serious harm and allowing them to pursue decent human lives through access to an appropriate range of opportunities.[104] As discussed in more detail in the second part of this chapter, access to health and genetic resources is an example where the interests at stake could be so universally crucial that extending the range of rights and obligations beyond the level of citizenship is justified. Genetics has an important collective aspect. In fact, we often refer to susceptible populations or at-risk groups; in some cases, reference has been made to the concept of *genetic nationalism.*[105] This group reference can have many different applications in genetics. Sometimes, the population aspect is not necessarily associated with specific diseases, conditions, or susceptibilities but is instead associated with existing boundaries as a practical, scientifically relevant, and sometimes economically advantageous way to create a fixed heterogeneous genetic pool for research.[106]

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[102] C. Jones, *supra* note78; P. Kleingeld, E. Brown, "Cosmopolitanism" *The Stanford Encyclopedia of Philosophy (Fall 2003 Edition)*, E.N. Zalta (ed.), <http://plato.stanford.edu/archives/fall2002/entries/cosmopolitanism> (accessed June 4th, 2006); A. Buchanan,, *supra* note 25; S. Scheffler, *supra* note 89.

[103] A Buchanan, *Ibid.* at.79.

[104] S. Hampshire, *Innocence and Experience* (Harvard University Press: Cambridge, 1989) at 90.

[105] This attitude towards populations' genetic heritage has been observed namely in Iceland where the population has been presented with the idea that Icelanders are genetically special, that they might have some special genes and genetic conditions that can't be observed elsewhere. H. Rose, *The Commodification of Bioinformation: The Icelandic Health Sector Database* (London: The Welcome Trust, 2001) at 12, ftn 29.

[106] Some of those genetic pools represent whole countries, for example, in Iceland where the government granted a 12-year license to the company deCode to construct and operate a national health services database to link anonymous genotypes with medical records of consenting members of

In other cases, the group aspect of genetics is not at all clearly associated with existing political and geographical boundaries. In fact, susceptible populations will also be found in specific regions of the world, not necessarily clearly delimited, but more associated with ethnicity or types of communities such as indigenous and tribal groups.[107] By contrast, other genetically at-risk populations are dispersed all around the world.[108]

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the population. Another national project is the UK Biobank project, a joint initiative from Welcome Trust and Medical Research Council. This project aims to recruit up to 500,000 men and women aged 45-69 from the general population across England, Scotland and Wales and use their blood samples, lifestyle details, and medical histories to create a national database to study the role of genetics and environmental factors in health and disease. Other initiatives are aimed at studying smaller populations, sometimes more homogenous and isolated, like Sardinia and Israel. J. Kaiser, "Biobank: Population Databases Boom, from Iceland to the U.S." (Nov. 2002) 298:5596 *Science* 1158; A.F. Wright, A.D. Carothers & H. Campbell, "Gene-Environment Interactions: the BioBank UK Study" (2002) 2:2 *Pharmacogenomics J.* 75; UK Biobank official website: http://www.ukbiobank.ac.uk; J.F. Merz, G.E. McGee and P. Sankar, "Iceland Inc.?: On the Ethics of Commercial Population Genomics" (March 2004) 58:6 *Soc Sci Med.* 1201; A. Abott, "DNA Study Deepens Rift Over Iceland's Genetic Heritage" (Feb. 2003) 421: 6924 *Nature* 678; E. Amason, "Genetic Heterogeneity of Icelanders" (Janvier 2003) 67:1 *Annals Human Genetics* 5; S. Shifman & A. Darvasi, "The Value of Isolated Populations" (2001) 28 *Nature Medicine* 309; C. Bourgain et al., "Search for Multifactorial Disease Suceptibility Genes in Founder Populations" (2000) 64 *Annals Human Genetics* 255; M.G. Marrosu et al., "Genetic Factors and the Founder Effect Explain Familial MS in Sardinia" (Jan.2002) 58:2 *Neurology* 283; R. Lampis et al., "The Distribution of HLA Class II Haplotypes Reveals that the Sardinian Population is Genetically Differentiated from the Other Caucasian Populations" (2000) 56 *Tissue Antigens* 515; H. Lahat et al., "A Missense Mutation in a Highly Conserved Region of *CASQ2* is Associated with Autosomal Recessive Catecholamine-Induced Polymorphic Ventricular Tachycardia in Bedouin Families from Israel" (2001) 69 *American J Human Genetics* 1378.

[107]This was in fact the purpose of the Human Genome Diversity Project established in 1993 to describe and understand the 1% difference and diversity in human genomes illustrated by many of individual and population level differences. It aimed to collect biological samples from different population groups throughout the world, with the intention of building a representative database of human genetic diversity. It caused violent reactions from many of the indigenous groups targeted by the study, which gave rise to a project review by the US National Research Council in 1997. Since April, 2002 a collection of more than 1,000 DNA samples from 51 populations representing most of the world's genome variation has been available to non-profit research laboratories through collaboration between the HGDP and the Fondation Jean Dausset-CEPH in Paris. The HapMap project is a similar initiative. It seeks to understand the basis of genomic variation among unaffected individuals of similar ancestry to affected individuals by the identification of the genetic components of complex diseases and of variation in response to environmental exposures and to drugs. The long-term goal of the International HapMap Project, a collaborative endeavor among scientists in Japan, the U.K., Canada, China, Nigeria, and the U.S, is to develop a haplotype map of the human genome that could shed light on the common patterns of human DNA sequence variation. B.R.Winkelmann, "Pharmacogenomics, Genetic Testing and Ethnic Variability: Tackling the Ethical Questions" (Sep. 2003) 4:5 *Pharmacogenomics* 531; L. Andrews & D. Nelkin, *Body Bazaar; the Market for Human Tissue in the Biotechnology Age* (Crown Publishers, New York, 2001); L.L.Dog, "Whose Genes Are They? The Human Genome Diversity Project" (1999) 10 *Journal of Health & Social Policy* 51; M. Dodson and R. Williamson "Indigenous Peoples and the Morality of the Human Genome Diversity Project" (1999) 25 *Journal of Medical Ethics* 204; H. T. Greely, "Legal, Ethical, and Social Issues in Human Genome Research" (1998) 27 *Annual Review of Anthropology* 473; H. Cunningham, "Colonial Encounters in Postcolonial Contexts: Patenting Indigenous DNA and the Human Genome Diversity Project" (1998) 18 *Critique of*

In any case, the majority of the potentially susceptible groups and populations still need to be identified. To do so, extensive genetic research must be undertaken and carried out globally, sometimes with no clear focus on specific populations and without restrictions based on borders. Indeed, even if the vital and obvious importance of the group and population aspect in genetics is acknowledged—especially in research[109]—for the equitable development and distribution of the benefits of genetic, we need to broaden our focus in taking the health needs of individuals into account. In fact, it is our contention that a clear focus on the needs of specific populations would be too narrow for the purpose of the global justice framework that is required for genetics.[110] Thus, the universalistic/individualistic approach is preferable as it is compatible with the cosmopolitan focus of the methodology of this thesis.

Anthropology 205; M.H. Crawford, "Anthropological Genetics in the 21st Century: Introduction", (2000) 72 Human Biology 3; M.W. Foster, "Integrating ethics and science in the International HapMap Project" (June 2004) 5:6 *Nature Reviews Genetics* 467.

[108] For example, the genetic component of more common conditions like breast cancer and hypertension are being investigated in many centers, all around the world. D.H, Choi et al., "Incidence of BRCA1 and BRCA2 Mutations in Young Korean Breast Cancer Patients" (May 2004) 22:9 *J Clin Oncol.* 638; S. Sherwin, "BRCA Testing: Ethics Lessons for the New Genetics" (Feb. 2004) 27:1 *Clin Invest Med.* 19; S. Malander, "One in 10 Ovarian Cancer Patients Carry Germ Line BRCA1 or BRCA2 Mutations: Results of a Prospective Study in Southern Sweden" (Feb. 2004) 40:3 *Eur J Cancer* 422; B. Gorski et al., "A High Proportion of Founder BRCA1 Mutations in Polish Breast Cancer Families" (Jul. 2004) 110:5 *Int J Cancer* 683; N. Kato, "Genetic Analysis in Human Hypertension" (May 2002) 25:3 *Hypertens Res.* 319; H.C. Hendrie et al., "Alzheimer's Disease, Genes, and Environment: the Value of International Studies" (Feb. 2004) 49:2 *Can J Psychiatry* 92; R.T. Perry et al., "Investigation of Association of 13 polymorphisms in eight genes in southeastern African American Alzheimer disease patients as compared to age-Matched Controls" (May 2001) 105:4 *American Journal of Medical Genetics* 332;

[109] Especially for population studies where there is much debate on the necessity and relevance of group consent and protection from potential harm due to improper disclosure. For more details: National Research Council (Committee on Human Genome Diversity), *Evaluating Human Genetic Diversity* (Washington D.C: National Academy Press, 1997) at 4, 63-65, on line NAP <http://books.nap.edu/books/0309059313/html/index.html> (accessed June 4th, 2006); HGDP North American Regional Committee, "Proposed Model Ethical Protocol for Collecting DNA Samples" (1997) 33:5 *Houston Law Review* 1431; V. Arnason, "Coding and Consent: Moral Challenges of the Database Project in Iceland" (2004) 18:1 *Bioethics* 27; M.J. Smith, "Population-based Genetic Studies: Informed Consent and Confidentiality" (December 2001) 18:1 *Santa Clara Comput High Technol Law* J. 57.

[110] We refer the reader to the discussion on benefit sharing in the introduction for more details on this topic.

Some characterise the existing world order as a structure that institutionalises rather than eradicates oppression, self-interest, and deception on a global scale.[111] If valid, this clearly contradicts the universal conception of justice promulgated here. If we start with a cosmopolitan model of moral reciprocity in which all individuals are seen and treated as equals, we cannot adequately address the hierarchy and inequities present in the world.[112] Instead, the criteria of distributive justice actually prevailing domestically should be applied to the world for the satisfaction of the just interests of all individuals.[113] In practice, this should happen through the promotion of a cosmopolitan institutional reform that would directly influence the choice and design of the norms that regulate property and cooperation. Such an institutional approach to moral cosmopolitanism requires that the world as a whole provide the context for determinations of justice.[114] This certainly appears as a long-term goal in the actual global reality due to the limited enforcement capability of institutions on the international scene. However, this does not mean that we should not pursue such an ideal. As clearly stated by Buchanan,

> [a]lthough at present it is unrealistic to expect that the international legal order can do much directly to achieve distributive justice by formulating and implementing comprehensive principles of distributive justice, it is nonetheless an important element of the ideal moral theory of international law.[115]

This issue will be addressed all through this chapter as we assess the importance of an ideal theory.

Now that we have presented our context of analysis and demonstrated its relevance for our core question, some of the main objections to cosmopolitanism will be

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[111] O. O'Neill, *Face of Hunger: An Essay in Poverty, Development and Justice* (London: Allen and Unwin, 1986) at 145; K-C Tan, "Kantian Ethics and Global Justice" (Spring 1997) 23:1 *Social Theory and Practice* 53.
[112] K. Nielsen, "Global Justice, Capitalism, and the Third World" in J. Arthur & W. H. Shaw ed. *Justice and Economic Distribution* (Englewood Cliffs: Prentice Hall, 2001) at 236.
[113] C.R. Beitz, *supra* note 87.
[114] T.W. Pogge, "Cosmopolitanism and Sovereignty" *supra* note 84, at 97; R. Forst, "Toward a Critical Theory of Transnational Justice" (January 2001) 32:1/2 *Methaphilosophy* 26.
[115] A. Buchanan, *supra* note 25, at 203.

addressed. The analysis and critique of the objections will be followed by the argument for global distribution in health and the proposals for the justice claims upon which such distribution should be based.

1.2.1. Objections to cosmopolitanism

As indicated in the previous section, a cosmopolitan view does not give absolute priority to compatriots for the distribution of certain goods and services; instead it focuses on equality of individual needs, regardless of nationality or geographic location. For some, envisioning distributive justice in such a manner overlooks important elements of state autonomy and the special relationship that prevails between people from the same community. The purpose of this section is thus to consider and refute these criticisms, arguing that the importance of access to health transcends boundaries and that the universal aspect of health is demonstrated by the fact of global interdependence.

1.2.1.1. From the defenders of state sovereignty and autonomy

A common critique of cosmopolitanism is that it fails to adequately acknowledge the concept of state sovereignty. Many consider states to represent the principal independent ethical institutions in the world.[116] They are autonomous bodies that have the power to exercise control and enforce rights over their territory and over their citizens. The sovereignty of states is a basic principle of international law[117] which provides that all states are juridical equals, despite important differences in political and economic power. Consequently, states have the autonomy to set up their own domestic rules and exercise political coercion, but may concede part of their

[116] M. Frost, *Towards a Normative Theory of International Relations* (Cambridge: Cambridge University Press, 1986) at 177-183; M. Frost, *Ethics in International Relation: A Constitutive Theory* (Cambridge: Cambridge University Press, 1996) at 150-155.

[117] This concept has been codified in the Charter of the United Nations, 892 *U.N.T.S.* 119, art. 2(1): "The Organization is based on the principle of the sovereign equality of all its Members."

sovereignty by voluntarily agreeing to comply with international norms. Thus, often stimulated by self-interest, states can freely decide whether and how they choose to participate in the establishment and preservation of international norms that deal with issues arising beyond national boundaries and jurisdictions. Such a perspective exemplifies the concept of political freedom that accentuates the role of the nation-state and presupposes that every state is driven by its own national interests, such as preserving its political autonomy, its territorial integrity, and expanding its economic system.

However, this so-called realist vision of the state only represents one way of envisioning the role of nations. As they exist today, states lack unlimited sovereignty, notwithstanding any desire they may have to pursue their own interests in the creation or support of international obligations and institutions. International treaty obligations and the new existing global order confine nation-states to a more limited conception of sovereignty, the limits of which are partially determined by their respective political and economic positions. For example, nation-states may be restricted with respect to how they deal with other states, how they respect human rights, and how they enforce their international obligations depending on their political situation, their economic power and on the strategies adopted by other very powerful non-state actors.[118]

Advocates of state sovereignty accord significant ethical and moral weight to state boundaries and autonomy despite the cosmopolitan argument that they are "historically determined but morally arbitrary features of the earth's political geography".[119] Some *statists* believe that each sovereign and autonomous state has a certain responsibility for any underdevelopment and poverty, arguing that such conditions are often directly related to internal, structural, and political problems and traditions. They believe that the cosmopolitan ideal, which considers the global context as the basis for justice, is utopian and would violate the limited but important

[118] O. O'Neill, "Agents of Justice" (January 2001) 32:1/2 *Metaphilosophy* 180.
[119] C. Beitz, "International Justice: Conflict" in L.C. Becker & C. Becker, eds., *Encyclopedia of Ethics* (London: Garland, 1992) at 623.

degree of domestic, institutionalised social cooperation that some states have reached.[120] This leads some to believe that only states' citizens are entitled to be compensated for deprivation with the application of principles of distributive justice and economic egalitarianism. These same criteria do not apply on the international scene where they think that only some sort of minimal threshold of absolute deprivation should be compensated.[121] However, those opponents of cosmopolitanism do not seem to acknowledge the increasing economic and political interdependence among states at present, which causes states to lose part of their sovereignty due to globalisation.[122] Indeed, this is giving rise to an entirely new and sophisticated global order.

Another critique of cosmopolitanism originates from a sense of nationalism and is based on the idea that cosmopolitanism fails to recognise the value of individuals' rights and affiliations to their community as constituting a crucial part of the enjoyment and satisfaction of life.[123] Some, like Drahos, argue that even if we can observe interdependence between states in various sectors, it does not mean that those states are forming a system of mutual cooperation.[124] Indeed, various elements characterise nationality as compared to other sources of collective identity: the fact that nationality develops from a shared belief in its existence, distinct rules, cultural conceptions, and values; its origin in history; its connection to a specific geographic region; and its reflection in individuals' distinct and subjective identification.[125] Nations are thus viewed as major sources of solidarity, crucial in circumscribing specific duties of aid, assistance, and support to other citizens and therefore helpful for domestic justice. Nationalism thus allows individuals to forge bonds as they share

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[120] C. Jones, *supra* note 78.
[121] M. Blake, "Distributive Justice, Sate Coercion and Autonomy" (2001) 3 *Philosophy & Public Affairs* 257, at 264.
[122] E.R.Gold *et al.*, "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnology Innovation" (October 2004) *Public Affairs Quarterly* 299.
[123] C.R. Beitz, *supra* note 55, at 290-291.
[124] P. Drahos, A *Philosophy of Intellectual Property* (Adelshot: Darmouth Publishing Company, 1996) c.8, at 170-198.
[125] C. Taylor, *Reconciling the Solitudes* (Kingston & Montreal: McGill-Queens, 1993) c. 3; D. Miller, "The Nation-State: a Modest Defence" in C. Brown, ed., *Political Restructuring in Europe, Ethical Perspectives* (NewYork: Routledge, 1994) c. 7, 1367, at 141.

a similar sense of identity[126] and is also often perceived to be the guardian of distinct cultures that may not be recognised at the global level.[127] It therefore rejects the idea of a world group to which duties of distributive justice can be applied. Nevertheless, it is worth noting that cosmopolites do not necessarily argue for the abolition of states. What they oppose are boundaries that systematically inflict injustices on outsiders and the existence of restrictive domestic welfare schemes and citizenship rights "held by persons *qua* citizens rather than directly or exclusively *qua* human beings."[128]

A good illustration of an ideology that would counter cosmopolitanism is set forth by Rawls in his treatment of international relations and global justice obligations in his *Law of People*, which includes some of the critiques described above.

1.2.1.2. Rawls' *Law of People* and international justice

As discussed above, Rawls's *Theory of Justice* from 1970 is one of the most well-known treatments of justice in the last fifty years. His theory established the principles of distributive justice, but they were applicable only to individual states, a circumscribed context where it would be possible to identify social cooperation from which rights and duties arise. In *The Law of People*, Rawls offers an extension of his theory of justice beyond the individual state. Rawls changes his theoretical contract mechanism for the specific context of international justice and the parties become representatives of peoples, rather than individuals or persons, who make choices about terms of cooperation that are "fair to peoples and not to individual persons."[129] Individuals are not the relevant, moral players in the global setting since their

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[126] C. Brown, *supra* note 61, at 180; O. O'Neill, "Justice and Boundaries" in C. Brown, ed., *Political Restructuring in Europe: Ethical Perspectives* (London: Routhledge, 1994) at 85.
[127] J. Carens, "Migration and Mortality: A Liberal Egalitarian Perspective" in B. Barry & R.E. Goodin, eds., *Free Movement* (Hemel Hempstead: Harvester Wheatsheaf, 1992) at 23; R. Forst, *supra* note 116.
[128] D. Harris, *Justifying State Welfare: the New Right Versus the Old Left* (Oxford: B. Blackwell, 1987) at 147; S. Caney, "Cosmopolitan Justice and Equalising Opportunities" (January 2001) 32:1/2 *Metaphilosophy* 113.
[129] J. Rawls, *supra* note 81, at 17.

distributive justice claims have already been taken into account at the domestic level, where justice principles are constructed independently from principles of global justice.[130]

For Rawls, peoples are self-contained societies, but are not necessarily liberal democratic societies.[131] This means that hierarchical societies can be considered as people (qualifying as well-ordered societies) for the application of the law of people, a notion which is problematic.[132] Rawls views peoples rather than states as the primary agents of justice at the international level. He argues that peoples differ from states in three fundamental respects: peoples do not have the right to go to war to further their interests, they must meet certain minimal standards in their internal affairs, and they are fully prepared to grant the very same respect and credit to other peoples as equals.[133] However, his description of peoples is very similar to the definition one would give of states:

> Liberal peoples do, however, have their fundamental interests as permitted by their conceptions of right and justice. They seek to protect their territory, to ensure the security and safety of their citizens, and to preserve their free political institutions and the liberties and free culture of their civil society.[134]

The equality project supported by Rawls on the global scene is a political equality of just or decent peoples, mainly structured as states, not an equality of persons as typified by cosmopolitanism. The main objective of Rawls' theory of international justice is to push societies to the point where it becomes possible for them to support just and decent institutions. The focus is not on the material comfort and well-being of persons individually, but more on achieving a world of peaceful and decent societies. In such a world, justice issues are not triggered by inequities between

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[130] A Kupler, *supra* note 83.
[131] For interesting discussions on Rawls's international theory of justice, refer to: F. Teson, "The Rawlsian Theory of International Law" (1995) *Ethics and International Affairs* 79; T. Pogge, "An Egalitarian Law of Peoples" (Summer 1994) 23 *Philosophy and Public Affairs* 211; D. Moellendorf, "Constructing the Law of Peoples" (June 1996) *Pacific Philosophical Quarterly* 77.
[132] We will not analyse the scope of Rawls' definition of people here, but for an interesting discussion on this aspect, refer to F.R. Teson, *Ibid.* and A Kupler, *supra* note 83.
[133] J. Rawls, *supra* note 81, at 25, 26 and 35.
[134] *Ibid* .at 29.

individuals who live in different regions of the world. [135] The international redistribution Rawls calls for is not a consequence of the principles of cosmopolitan global distributive justice. It deals instead with the global institutional structure and with the political and economic effects it can have on states and on their ability to continue implementing their principles of national justice.[136] It arises from an ideal conception of an international order that would be composed of distinct and independent, decent and autonomous domestic societies that cooperate on the basis of a similar conception of international justice, which would include a duty of mutual aid.[137] In fact, Rawls argues for a simple duty of assistance toward burdened societies in cases of extreme emergency and to help them develop their economy and reach the minimum requisite standard of internal organisation for their basic development and satisfaction of their populations' interests.[138] Rawls refuses to transpose his domestic "difference principle" (any inequities should be to the greatest advantage of the least well off persons) at the global level as he considers it unacceptable for certain peoples to bear the burden of decisions made by other peoples.[139]

As clearly explained by Buchanan, Rawls likely adopted such international principles instead of principles of global distributive justice due to the lack of institutions and resources to implement the latter principles at the global level and the insufficient consensus on the nature of ideal principles of justice that exist among different peoples. [140] Also, Rawls believes that most obstacles to a society's sustainable economic and social advancement involve its own internal structure, culture, and tradition rather than its natural resource endowments or position in the international political economy.[141] Such arguments require prioritisation of national citizenship and a focus on individual societies as opposed to individuals who live in the global

[135] C.R. Beitz, *supra* note. 87
[136] P. Drahos, *supra* note 124, c. 8
[137] C.R. Beitz, "Social and Cosmopolitanism Liberalism" (1999) 75:3 *International Affairs* 515; W. Hinsch, *supra* note 137.
[138] J. Rawls, *supra* note 81, at 76.
[139] J. Rawls, *Ibid.* at 118-120; T.W. Pogge, "Moral Universalism and Global Economic Justice" (2002) 1:1 *Politics, Philosophy and Economics* 29; O. O'Neill, *supra* note 82; W. Hinsch, *supra* note 137.
[140] A. Buchanan, "Rawls's Law of Peoples: Rules for a Vanished Westphalian World", *supra* note 56.
[141] J. Rawls, *supra* note 79, at 74-77 and 105.

international order. More importantly, they also call for a limited duty of assistance to burdened societies with a clear starting and cut-off point.

1.2.2. Reasons for envisioning distributive justice on a global scale: a response

> *Certainly, once we accept the case for a rights-based "welfare state", we are, [...] morally constrained to go "beyond the welfare state" to respect the same rights to optimum need-satisfaction on a global scale.*[142]

The opposition to cosmopolitanism demands a focus on the domestic level and refuses to consider the global order as a superior context for distributive justice. In this next section, the limited *statist* focus of justice issues will be critiqued and compared to a scheme in which the principles of distributive justice are based upon global cooperation, which may emerge from increasing international globalisation and interdependence.

1.2.2.1. The limits of boundaries and the reality of the global order

A cosmopolitan account of justice requires the recognition of the limits of the existing global order and its failure to consider every individual's interest. If we believe that each human being is entitled to equal consideration, the prevalence of such great poverty in the world must be considered problematic. Therefore, the assumption that international justice necessarily presupposes the existence of states—and is simply an additional topic to justice issues arising within isolated well-ordered societies that are delimited by clear boundaries—overlooks the actual state of the

[142] L Doyal & I Gough, *supra* note 92, at 142 quoting G. Myrdal, *Beyond the Welfare State* (New Haven: Yale University Press, 1960).

world. Instead of recognising each person as a unit of moral concern, rights and privileges are granted to people according to their citizenship and where they are geographically located. Nevertheless, the actual international socio-political situation clearly shows that many states are not only very ineffective at protecting justice within their boundaries, but often are also very unsuccessful at securing it outside of their territory. Hence, states are not necessarily the only or best actors to protect justice; indeed, it would be inaccurate to describe the current international environment as various states united by voluntary mutual-assistance endeavours that are promptly undertaken. If each human being has a right to be free from the suffering and indignities of poverty, it is unacceptable to contain redistribution within nation-state boundaries, as such limited view threatens to leave many individuals from very poor societies in great deprivation.[143]

Our increasingly interdependent world is characterised by intense de-territorialisation, the spread of social relations across borders,[144] global capital and commodity markets,[145] and the rising power of multinational companies and other non-state authorities.[146] Therefore, foreigners are people with whom we do more and more business and trade in various sectors and with whom we collaborate and are involved in different economic, political, and cultural levels and settings. An unambiguous division between the national and international sectors becomes impossible and the vision of states as privileged actors in the realisation of normative ideals is also untenable. It is thus increasingly difficult to argue that considerations of distributive justice should be confined to existing state boundaries without referring to the broader context of their close connections with other foreign agents.[147] In other words, if we consider distant strangers as very involved in our politico-economic reality, we should not be entitled to adopt a different standard and ignore their presence when establishing a framework of distributive justice. Consequently, overemphasis on the importance of state sovereignty in considering justice issues may

[143] C. Jones, *supra* note 78, c.7, at 173 et ss.
[144] W. Scheuerman, *supra* note 98.
[145] T.W. Pogge, "Cosmopolitanism and Sovereignty" *supra* note 84, at 108.
[146] A. Woods, *Hegel's Ethical Thought* (New York: Cambridge University Press, 1990) at 30.
[147] S. Scheffler, *supra* note 89.

obscure the reality of our interconnected and heterogonous world: "compatriots, intimates and kin, with whom we may share much, do not form an 'ideal' united community that pre-empts plurality and the need for justice."[148]

As Kant has indicated, increasing international economic cooperation created, even 200 years ago, a new basis for international morality.[149] Indeed, the international picture is characterised by a basic global structure represented by various political and socio-economic rules and institutions involved in distributing burdens and benefits. This needs to be recognised in order to establish a theoretical framework for global distributive justice. The growing global disparity between rich and poor, increasing external control over domestic societies, and increasing global regulation and governance comprise a world that cannot be adequately restricted to the political theory of the nation-state.[150] States are active participants in this global structure, through the various international organisations and the states' respective influence over enforcement. As such, international organisations are responsible for the elaboration of various regional and international normative agreements, such as declarations and treaties on trade, human rights, and intellectual property and are at the centre of important collective initiatives, like international financial systems. Indeed, such organisations represent an important context for justice since their structural and normative characteristics influence the well-being of individuals and groups.

The elements of this international order play a crucial role in modeling the ways in which burdens and benefits of the existing international cooperation scheme are distributed between countries and individuals.[151] There is an economic debate as to whether the international interdependence caused by globalisation has overall negative effects on the economic situation of the poor. Some have argued that

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[148] O. O'Neill, "Justice and Boundaries" in C. Brown, ed., *Political restructuring in Europe, Ethical Perspectives* (NewYork: Routledge, 1994) 69, at 74-82.
[149] I Kant, *supra* note 99, at 124-129.
[150] C.R. Beitz, *supra* note 87, at 518.
[151] For example, section 28 of the Universals Declaration of Human Rights states that: "everyone is entitled to a social and international order in which the rights and freedoms set forth in the Declaration can be fully realized."

globalisation widens the revenue and welfare gap between rich and poor countries and individuals of the world and, consequently, that the living conditions of the poor have deteriorated. [152] Others believe that global economic integration and the openness to international trade contribute to better income distribution, which decreases poverty rates and global inequality.[153] In both cases, there seems to be agreement that globalisation could only improve such conditions if complemented by distinct institutional and policy reforms. Therefore, it seems that the distributional consequences arising from growing interdependence and justness of international social, political, and economic arrangements must be assessed morally by a distinct theory of justice. Indeed, as explained by Buchanan,

> [...] because the workings of the global basic structure have such profound and enduring effects on individuals and groups—and because these effects are for the most part neither chosen nor consented to by those affected—the global basic structure is subject to assessment from the standpoint of justice.[154]

A theory of global distributive justice should be concerned with the basic organisation of international society—that is, the basic structure of political and economic power relations that influence the global distribution of burdens and benefits. While voluntary international transfer and assistance measures might be of some help in redressing certain inequities, as discussed above, they are theoretically

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[152] J.E. Stigliz, *Globalisation and its Discontents* (New York, W.W. Norton, 2002); M. Weisbroth, "Growth May Be Good for the Poor – But are IMF and World Bank Policies Good for Growth?" Centre for Economic and Policy Research, May 11, 2001, online CEPR <http://www.cepr.net/globalization/Growth_May_Be_Good_for_the_Poor.htm> (accessed June 4th, 2006); C. R. Beitz, *supra* note 87; B. Ehrenreich & A. Russell Hochschild, *Global Woman: Nannies, Maids and Sex Workers in the New Economy* (London: Granta Books, 2002) at 8; S. Anderson, J. Cavanagh & L. Thea, *Field Guide to the Global Economy* (New York: New Press, 2000).

[153] D. Dollar, "The Poor Like Globalization but Institutions and Policies are Needed to Deliver the Hoped for Results" (June 23, 2003) YaleGlobal, online: <http://yaleglobal.yale.edu/display.article?id=1934> (accessed June 4th 2006); D. Dollar & K. Aart, "Growth *Is* Good for the Poor", The World Bank Development Research Group, March 2000; M. Wolf, "Kicking Down Growth's Ladder: Protesters Against the Word Bank and the IMF are in Effect Seeking to Deny the Poor the Benefits of a Liberal World Economy" (April 12, 2000) *Financial Times* at 23; World Bank, "Global Poverty Down By Half Since 1981 But Progress Uneven As Economic Growth Eludes Many Countries" News Release 2004/309/S, April 23 2004.

[154] A. Buchanan, Justice, *supra* note 25, c.2, at 76.

unjustifiable, unreliable, and unsupportive in terms of sustainable change.[155] What is required globally is a direct application of justice principles to the basic structure of the global regime to assess the moral character of international institutions.[156] This implies that justice might best be served by recognising that important institutions regulating human action do not all need to be territorially delimited.[157] Indeed, sovereignty should not be concentrated only at one level and may be differently envisioned, for example, as associated with functional tasks and non-territorial spheres of interaction.[158] In his article "Cosmopolitanism and Sovereignty" and his book "World Poverty and Human Rights," Thomas Pogge attempts to reconstruct the notion of sovereignty so that it may be compatible with a cosmopolitan vision and the existing global order.[159] He suggests a multi-layered institutional scheme in which government authority is "vertically dispersed" rather than concentrated almost completely within states[160] and where we find a number of political units governing individuals without hierarchy. This type of system would allow a shift from a domestic focus on justice to a global one, an essential step for moral cosmopolitanism. This is an interesting avenue for re-engineering the global political structure and it should be explored further.

Together with the problems encountered by the application of strict concepts of sovereignty and territorial boundaries, another reason for envisioning justice at the global level is the lack of logical justification for adopting a double standard of justice. We discuss this next.

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[155] For example, see C. Jones, *supra* note 78; S. Scheffler, *supra* note 89.
[156] C.R. Beitz, *supra* note 87; C. Jones, *Ibid.*
[157] O. O'Neill, *supra* note 148.
[158] Idem; A Kupler, *supra* note 83.
[159] T.W. Pogge, "Cosmopolitanism and Sovereignty" *supra* note 84, at 61 et ss; T.W. Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms* (Cambridge: Polity Press, 2002), at 168-195.
[160] *Ibid.* at 58; A. Kupler, *supra* note 83.

1.2.2.2. The problem of a double standard of justice

Many injustices and inequities arise from the existing global order. If we rely on theories like Rawls' approach to international justice, it is possible for unjust international conditions to be neglected as international society is not held to the same standards of justice as domestic societies. How can this be justified? How can we, at the same time, qualify the major national inequalities as injustices, yet find analogous inequalities morally acceptable in the global order?

The previous section posited the existence of a basic global structure shaped by complex international economic, political, and cultural relationships. This constitutes a global context for cooperation, analogous to its domestic counterpart and characterised by institutional inequities and justice violations. Such considerations are not acknowledged at all by Rawls, who clearly endorses two separate and distinct standards of justice at the domestic and the global levels. For example, in *Law of People*, he assumes that people will negotiate international free trade agreements without inquiring as to the fairness of the background institutions involved in those transactions. However, in *A Theory of Justice*, Rawls specifically requests the presence of a fair domestic background organisation as a prior condition for individuals to reach just agreements.[161]

Another example of Rawls' application of different morality to the same reality can be found in his assessment of the distributional effects of a basic structure. At the national level, Rawls establishes that principles of distributive justice are vital to redressing inequalities created by basic national structures. At the global level, where an analogous basic structure exists, Rawls' theory does not transpose the difference principle, as he calls for a principle of charity in the form of an arbitrary duty to help burdened societies build decent political and social regimes, rather than establishing similar enforceable principles of justice.[162] He justifies this position on the ground that it is unacceptable for people to bear the burden of decisions made by other

[161] A. Buchanan, "Rawls's Law of Peoples: Rules for a Vanished Westphalian World" *supra* note 56.
[162] Idem; J. Rawls, *supra* note 79, at 37.

people.[163] What he does not say is why it is different when one province, township, family, or person bears the burden of decisions made by another at the national level.[164] If we follow this reasoning, the imposition of a global economic order that generates great international inequality can be justified so long as the societies impoverished by this structure are charitably assisted to the extent of raising them above a certain minimum level.[165]

Rawls also argues that the great cultural differences between nations justify the different treatment of individuals from different nations and the establishment of domestic benchmarks of justice instead of global ones. [166] Even if different conceptions of domestic justice can lead to complex negotiations at the global level, some principles, such as equality in opportunities and democratic participation in the institutions of global governance, seem likely to receive a great deal of support from a majority of states. Furthermore, in practice, most countries' cultural and political traditions would likely not preclude preventive and curative genetic products and services from reaching their peoples. Indeed, in countries and communities where genetic testing and analysis are already used, there is evidence that they are widely accepted practices.[167]

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[163] J. Rawls, *ibid.* at118-120.

[164] T.W. Pogge, *Realising Rawls* (Ithaca: Cornell University Press, 1989) at 253-253; T.W. Pogge, "An Egalitarian Law of Peoples" (1994) 23 *Philosophy and Public Affairs* 195, at 211-213; T.W. Pogge, "Moral Universalism and Global Economic Justice" (2002) 1:1 *Politics, Philosophy and Economics* 29.

[165] T.W. Pogge, "Rawls on International Justice" (2001) 21 *Philosophical Quarterly* 246.

[166] J. Rawls, *supra* note 79, at 105.

[167] Indeed, as reported by Marshall and Koenig, it appears to be a common practice within some orthodox Jewish communities to use early preconception genetic testing to restrain partners' selection and marriage options. Another example can be observed in Cyprus, where broad prenatal testing for thalasemia is imposed and subsidized by the government and very well accepted by the members of the Cypriot community. P. Marshall & B. Koenig, "Accounting for Culture in a Globalized Bioethics" (Summer 2004) 32:2 The Journal of Law, Medicine & Ethics 252, at 256; S. Beck, "Genetic Transparency and Social Unpredictability: Remarks on a Genetic Screening Program in Cyprus" paper presented at the Stanford Center for Biomedical Ethics. Program in Genomics, Ethics, and Society, December 19, 2000; A. Alwan & B. Modell, Community Control of Genetic and Congenital Disorders. *EMRO Technical Publications Series* 24, World Health Organization, Regional Office for the Eastern Mediterranean, Cairo, 1997; I.C. Verma *et al.* "Genetic Counselling and Prenatal Diagnosis in India--Experience at Sir Ganga Ram Hospital" (April 2003) 70:4 *Indian J Pediatr* 293; *Guidelines for Control of Haemoglobin Disorders.* Geneva, World Health Organization, 1994 (WHO/HDP/HB/GL/94.1).

It is crucial to reiterate that the ability of a society to reach a higher stage of development and address national inequalities at different levels is not only a result of domestic economic and political factors, but is also a direct consequence of structures and events beyond its borders.[168] Indeed, a society's participation in global political and economic relations can wreak havoc at the domestic level, on its social, economic, and political situation. In fact, rather than representing voluntary mutual-benefit schemes, the basic global structure is characterised by unequal bargaining power, mainly driven by a few powerful state actors seeking to advance their own economic interests.[169] When economically advantageous for them, such powerful actors of the global economic order may recognise a corrupt or coercive government as the legitimate authority over a territory, or may do nothing while weak and powerless governments favour foreign interests over those of their own people.[170] Thus, the more powerful actors dictate terms that appear inescapable to those who are incapable of changing them. This conduct clearly influences how benefits and burdens are distributed globally and domestically. The growing global interconnectedness requires a critique of the fairness of the present global structure. If the global environment is one of justice, as argued here, domestic justice cannot take priority over global justice; both must be established in tandem.[171]

Applying lower moral standards to the basic global order involves arbitrary discrimination in favour of wealthy societies and against the global poor.[172] In fact,

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[168] A. Kuper, "Debate: Global Poverty Relied, More than Charity: Cosmopolitan Alternative to the "Singer Solution" (2002) 16 (1) *Ethics and International Affairs* 107.

[169] This can be observed among the states participating in international trade negotiations under the auspices of the WTO: J. M. Finger and P. Schuler, *Implementation of Uruguay Round Commitments: The development challenge*, 1999, World Bank,Geneva; C. Beitz, *supra* note 80, at 279-280; T. W. Pogge (2002) *supra* note 139.

[170] For example, many of the provisions of TRIPs, a document that has to be ratified by every member state of the World Trade Organization, reflect the views and demands of countries with powerful industrial lobbies for high levels of intellectual property protection. We will be coming back to this specific issue later in the dissertation. Also refer to: T.W. Pogge, "Cosmopolitanism and Sovereignty" *supra* note 84, at 108.

[171] H. Shue, "The Burden of Justice" (1983) 80 *Journal of Philosophy* 600, at 603; R. Frost, *supra* note 116.

[172] Needless to say, the location of the world's valuable natural, wealth-creating resources is a matter of sheer luck. It therefore seems unfair that some people, because of a different control over resources, would prosper more and be less subject to discrimination than others. T. W. Pogge (2002) *supra* note 139; C Jones, *supra* note 78, at 73.

such global oppression by certain countries on the rest of the world does not meet minimum domestic standards of justice. Thus, rich and powerful countries impose a global economic order under which millions die each year due to poverty, and in which the gap between the rich and poor continually increases.[173] Since this would not be acceptable domestically, it therefore gives rise to a double standard for which there is no reasonable justification.

1.2.2.3 The place and role of States in the application of a theoretical framework of global distributive justice

Who owes justice to whomever it is justice is owed?

Notwithstanding our shift in emphasis with respect to the role of states in evaluating justice, the rationale for envisioning distributive justice globally still allows states the possibility to remain vital actors in such distribution. One of the crucial elements of the argument presented here is that equality between individuals should be considered the moral standard that would justify equitable access to genetic innovations when required. Can states have a role to play in this framework? What is a possible role for them within our cosmopolitan framework of global distributive justice?

To understand cosmopolitanism, the difference between moral and political structures must be clearly delineated. As demonstrated above, the main objective of our moral conception of justice is to attain some form of equality with regard to normal functioning and opportunity of every individual affected by institutional distributive arrangements. This does not mean that justice demands a total abrogation of sovereignty or the elimination of states. It instead requires an interpretation of sovereignty that does not constitute an arbitrary limit to the scope of justice.[174] Cosmopolitanism does not propose a best institutional structure for doing international politics. Indeed, principles of justice can continue to impose obligations

[173] T. W. Pogge (2002) *supra* note 139.
[174] O. O'Neill, "Justice and Boundaries" in C. Brown, ed., *Political Restructuring in Europe, Ethical Perspectives* (NewYork: Routledge, 1994) at 69.

for the satisfaction of individuals' rights on states and other institutional actors that may also be viewed as agents of international justice obligations.[175] Cosmopolitan justice does not rule out the importance of communities, as they may cultivate special bonds of sentiment, identity, and obligation among individuals. Thus, the fact that loyalties and connections are often associated with membership in a community is very important for some individuals and may still be taken into account under a cosmopolitan view of distributive justice. Special internal responsibilities can be significant if they do not take our attention away from the people who stand outside of the special relationship.[176] In this sense, a state-based world order may better serve human interests, with a perspective that includes everyone and can include special responsibilities for others' needs, insofar as the global theoretical basis of justice is acknowledged and respected.[177]

In attempts to draw connections between the moral aspects of cosmopolitanism and the political reality in which states are major actors, different propositions for more porous boundaries have been promulgated. For example, Charles Jones proposes *qualified sovereigntism*, in which states and organisations of states maintain elements of their authority and sovereignty, but higher powers may supersede such authority if it does not meet the requirements of cosmopolitanism.[178] Wilfried Hinsch, by contrast, presents an international order with more or less independent states, united by contracts and mutual agreements that are governed by principles of global distributive justice and which apply directly to citizens of the world rather than to states.[179] As mentioned above, another proposition comes from Thomas Pogge, who suggests a form of vertical sovereignty in which governmental functions and areas of competence would be reallocated by their division and distribution to various coordinated political units. A form of centralisation would thus be established, but

[175] C.R. Beitz, *supra* note 55, at 271.
[176] C.R. Beitz, *supra* note 101, c. 6 123, at 130-131; C Jones, *supra* note 78; S. Scheffler, "Liberalism, Nationalism, and Egalitarianism" in R. McKim & J. McMahan, eds., *The Morality of Nationalism* (New York: Oxford University Press, 1997); S. Scheffler "Relationships and Responsibilities" (Summer 1997) *Philosophy and Public Affairs* 26; A. Mason, "Special Obligations to Compatriots" (1997) *Ethics* 107.
[177] C.R. Beitz, *supra* note 80, at 285.
[178] C. Jones, *supra* note 78, c.8, at 225 et ss.
[179] Hinsh, "Global distributive Justice", *supra* note 97

this structure could, at the same time, lead to the scattering of political allegiances and loyalties over both the new and the traditional groupings such as neighbourhoods, towns, counties, provinces, states, regions, and the world at large. [180]

Nevertheless, there does not seem to be any contradiction in holding both that the ultimate moral focus for the analysis of international justice should be the interests of individuals and that justice development may take place within the basic structure of a decentralised order like the state system rather than a world government. As suggested by Andrew Kupler, normative cosmopolitan principles should consider "individuals to be the normative epicentre of a system of functionally plural sovereignty."[181]

In our specific context of analysis, states remain very important actors. In fact, in the field of genetics, once products and services are available, further complex diagnostic testing steps will often be required to identify needs, genes, susceptibility to diseases, and to target treatment. This type of procedure will likely be undertaken at a population level, so states' health care representatives, in their role as the existing present authority, will be important players in the distribution and allocation of genetic benefits to individuals in need. Moreover, the significant involvement of the private sector in genetics, especially from multinational pharmaceutical and biotechnology companies, calls for effective national intervention. In fact, the possibilities, in certain cases, for state to impose some sort of control over corporate conduct (for example, through price fixing, technology transfer, and corporate taxation policies) could have dramatic effects on the international distribution of the gains arising from genetic research. As such, states remain significant for our theoretical framework. Indeed, they would, at least in the actual world order, provide the agency required to perform obligations of international justice, whereas individuals, not just citizens, would represent the standard for consideration in determining how states ought to act.

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[180] T.W. Pogge, "Cosmopolitanism and Sovereignty", *supra* note 84, at 99-108.
[181] A Kupler, *supra* note 83.

Conclusion

To conclude, we have now set forth the methodology and context for the theoretical analysis undertaken in this thesis. As such, we made the argument for considering the global environment as the context of application for our framework of distributive justice. We analysed and adopted a cosmopolitan perspective that justifies the focus on individual human beings as the ultimate determinative basis, a standpoint particularly relevant for dealing with our specific issues of concern. Analysing some critiques of the global perspective on justice and refuting them with evidences on the limits of strict sovereignty and boundaries in today's rising global order have been very informative for us. Indeed, it gave us the perspective we needed to determine how institutions involved in the distribution of the benefits of genetic research should operate and on what scale distribution should be handled.

We are now ready to approach our second chapter which presents a specific argument for global distribution in health and genetics by setting up a scheme of health/health care justice at the global level.

Chapter II: An Argument for Global Distribution in Health

What are the reasons for intervention in health (in the process of accessing the good life)?

Introduction

After presenting some justification for our global contextual focus in the first chapter, the second chapter of this first theoretical part is dedicated to elaborating an ideal conception of distributive justice in health as a way to justify global access to genetics. Having established our global contextual focus for the application of distributive justice principles in health and genetic technology, we are now ready to analyse the specific reasons why genetic research benefits should be distributed and the normative basis for such a determination. This argument relies on the premise that health is a basic and essential good and that any reasonable account of justice must address the distribution of health care, resources, and services in the global order.

We will begin by presenting the rationale for a special treatment of health, referring to some unique characteristics of health and to the direct link existing between health, avoidance of harm, well-being, and range of opportunities. More specifically, this analysis will highlight the need for equitable access to genetic advancements based on its potential for improving human normal functioning and accessibility to normal range of opportunities. Then, we will extend our discussion to the global perspective on health required by our conception of cosmopolitan justice as a way to propose some normative grounds for global distribution in health and genetic innovation.

This thorough analysis will provide us with the needed rationalisation for an equal treatment of everyone's health, for using our global distributive justice framework to resolve health inequalities over which we can have some control, and for fostering equitable access to the benefits of genetics.

2.1 Conception of Health Justice

Some have argued that the pursuit of health should be embedded in social justice's broader quest to provide it with a stronger focus and a better understanding of the underlying social processes of health, and their fairness.[182] This view is based on the argument that social inequalities in health essentially find their source in the basic structure of social, political, and economic institutions, as well as from consequent inequalities in poverty, income, and opportunity.[183] As demonstrated below, a theory of health justice remains linked in many ways to a more general all-purpose theory of justice. Nevertheless, health and, more specifically, genetics, raise unique issues that should be approached within a specific sphere of justice.

One very broad and idealised vision of health is "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity."[184] This definition is problematic in that it is so broad as to encompass many subjective conceptions of well-being and leads to a perfectionist conception of healthy human being. Like Daniels and Borse, we agree to define health as the absence of disease in a broad sense, which includes disabilities,[185] loss of abilities due to trauma and environmental harms, as well as other functional deficits.[186] In that sense, disease means any deviation from the normal functional organisation of a typical member of

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[182] F Peters & T Evans, "Ethical Dimensions of Health Equity" in T Evans *et al.*, eds., *Challenging Inequities in Health: From Ethics to Action* (New York: Oxford University Press, 2001) at 24-33; S. R. Benatar, A. S. Daar & P. Singer, "Global Health Ethics: The Rationale for Mutual Caring" (2003) 79:1 *International Affairs* 107, at 122; N. Kriege & A-E. Birn, "A Vision of Social Justice as the Foundation of Public Health: Commemorating 150 Years of the Spirit of 1848" (1998) 88:11 *American Journal of Public Health* 1603.

[183] O. O'Neill, "Justice Gender and International Boundaries" in: M.C.Nussbaum & A. Sen, eds, *Quality of Life* (Oxford: Clarendon, 1993) 303, 315.

[184] Preamble to the Constitution of the World Health Organization. Adopted by the International Health Conference held in New York, 19 June-22 July 1946, and signed on 22 July 1946. *Official Record of World Health Organization* 2, no. 100.

[185] Which, in Doyal and Gough's terms, mean the "consequent restriction or lack of ability to perform an activity in the manner or within the range considered normal for human beings" L. Doyal and I. Gough, *supra* note 92, at 172.

[186] N. Daniels, *Just Health,* Forthcoming, c. 2, at 12.

a species which comprises all impairment of functions.[187] Health therefore closely relates to *normal functioning*, a notion that will be analysed in greater details in the next subsection.

Health is unlikely to ever be uniformly distributed among individuals. It can be influenced by various factors like individual biological variations, adequate nutrition, sanitary hygienic living and working conditions, chance, free and informed consent, and availability of preventive, curative, and rehabilitative medical resources and services.[188] Even if health and diseases are often thought to be beyond individual responsibility as the result of a natural lottery, namely environmental and socio-economic factors, some argue that the determinants of health over which we have control should be taken into consideration for distribution.[189] This argument calls for the elimination of only random inequalities that are not subject to choice, and has been called the *level playing-field* ideal.[190] Advocates of such a vision, *luck egalitarians*, consider responsibility to be at the centre of moral concerns, arguing that distribution should apply only to things over which individuals lack control and that are unrelated to free and informed choices. This position is controversial and does not always present the full picture. Indeed, ostensibly voluntary health-related behaviours are often driven by other socio-economic factors over which people frequently lack control. In fact, studies show that detrimental health habits do not

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[187] N. Daniels, "Health Care Needs and Distributive Justice" (1981) 10 *Philosophy and Public Affairs* 146; N. Daniels, "Equality of What: Welfare, Resources, or Capabilities?" (Autumn 1990) 50 (supplement) *Philosophy and Phenomenological Research* 273, at 280; C. Boorse, "Health as a Theoretical Concept" (1977) 44 *Philosophy of Science* 542; C. Boorse, "On the Distinction between Disease and Illness" (Fall 1975) 5:1 *Philosophy & Public Affairs* 49.

[188] N. Daniels, *Justice and Justification Reflective Equilibrium in Theory and Practice* (Cambridge: Cambridge University Press, 1996) c. 9, at 179.

[189] L. M. Fleck, *supra* note 71; D. Wikler, "Personal and Social Responsibility for Health" (2002) 16:2 *Ethics and International Affairs* 47.

[190] J. Roemer, *Equality of Opportunity* (Cambridge: Cambridge University Press, 1998); R. Arneson, "Equality and Equality of Opportunity for Welfare" in L. Pojman & R. Westmoreland, eds., *Equality: Selected Readings* (New York: Oxford University Press, 1997); E. Rakowski, *Equal Justice* (New York : Oxford University Press, 1991); R. Arneson, "Equality of Opportunity" *The Stanford Encyclopedia of Philosophy (Winter 2002 Edition)*, E.N. Zalta, ed., online: <http://plato.stanford.edu/archives/win2002/entries/equal-opportunity> (accessed: May 30th, 2006).

necessarily always arise from free and informed will, but are often foreseeable results of poverty in childhood and beyond.[191]

This is why, even if personal responsibility for health and genetic characteristics can, in certain cases, be an interesting and complex argument, we will leave it out of our moral focus for the purposes of this dissertation. Indeed, we argue for health equity as a way to achieve equality in opportunities, regardless of the cause of disease and how responsibly ill individuals can handle available opportunities. Our vision of the international and national orders is more compatible with a system of cooperation that guarantees, in certain crucial areas, a "*safety net through which even the imprudents are never forced to fall.*"[192] This secures a range of basis needs which allows individuals to function in a community and choose from available opportunities.

It has been suggested that health inequalities may be considered inequities when they are unavoidable, unnecessary, and unfair.[193] Social inequalities in health can be perceived as a responsive indicator of the fairness of the basic social order. Unavoidable individual health variations rooted in biological differences could be seen as acceptable if they were indiscriminately spread between social and geographical groupings and had nothing to do with education, income, or economic factors.[194] However, this is clearly not the case. Wealth and health disparities are constantly expanding within and between nations, both in terms of access to health care for individuals and of development and availability of adequate and population-specific treatments.[195] Health differences among individuals within different populations of the world are great and are often related to socio-economic factors such as income and education levels, the gap between rich and poor, public health measures, and access to health care and technologies. Since health is not a good that

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[191] J.W. Lynch, G.A. Caplan & J.T. Salonen, "Why Do Poor People Behave Poorly? Variation of Adult Health Behaviours and Characteristics by Stages of the Socioeconomic Life course" (1997) 44:6 *Social Science and Medicine* 809.

[192] E. Anderson, "What is the Point of Equality?" (Jan. 1999) 109:2 *Ethics* 287, at 325.

[193] G. Dahlgren & M. Whitehead, *Policies and Strategies to Promote Social Equality in Health* (Stockholm: Institute of Future Studies, 1991).

[194] F. Peter & T. Evans, "Ethical Dimensions of Health Equity", *supra* note 182, at 28.

[195] J. Sach, *The End of Poverty: Economic Possibilities for Our Time* (New York : Penguin Press, 2005)

can be directly transferred or allocated by distributive measures, the normative framework here will focus on the factors that have a direct influence on individual health inequalities.[196]

In the introductory part of this dissertation, we demonstrated how human genetic research is a very promising field for improving health globally. Many new products, including vaccines and drugs for common diseases, may eventually be based on genetic research. The human genome undeniably offers exceptional opportunities for understanding mechanisms of disease and developing new drugs and vaccines. Indeed, it is believed by some that advances in genomics and genome-related biotechnology could, if applied correctly[197], instigate important changes in the field of medicine and health care in the near future.[198] However, new technology and health care innovations are simply beyond the financial reach of much of the world's population and could end up benefiting only a privileged minority, thereby increasing inequities in global health, as has been the experience thus far with certain drugs and vaccines.

Furthermore, in the field of genetics, the limits of what is unavoidable are unclear. Enduring biological/genetic characteristics can be directly caused by socio-economic factors. In fact, it would be unfair to acknowledge that individual members of a population are affected with unavoidable biological differences and diseases when the technology to prevent or cure those genetic predispositions and conditions exists, but

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[196] D. M. Hausman, Y. Asada & T. Hedemann, "Health Inequalities and Why They Matter" (2002) 10 *Health Care Analysis* 177; S. R. Benatar, A. S. Daar & P. Singer, *supra* note 182.

[197] Many fear that genetics could also give rise to rampant abuses, like eugenics, and undesirable perspectives, like genetic determinism. Because of the many possible excesses and serious consequences they can have, a strict normative framework is needed to regulate genetic research and applications. These fascinating issues are not addressed in this dissertation as we are starting from the premise that the benefits arising from genetics and relevant for global health will be the result of good quality scientific research undertaken and applied in strict compliance with appropriate legal and ethical principles.

[198] As we have seen earlier, some, on the other hand, consider that this is an overstatement and that excess of optimism towards genetics should be moderated. For our part, we decided to focus on the positive impact that genetics is likely to have on global health in the future. For arguments in favor of this position, see: P. A.Singer & A. S. Daar, "Harnessing Genomics and Biotechnology to Improve Global Health Equity" (October 5, 2001) 294 *Science* 87; S. R. Benatar, A. S. Daar & P. Singer, *supra* note 182. For arguments calling for moderate enthusiasm, see: T.M. Bubela & T. Caulfield, *supra* note 36 L. B. Andrews, *supra* note 36.

is neither available nor affordable. Genetics is one field in which it has become vital to develop measures that will acknowledge the inequalities existing between individuals living in different countries of the world in terms of access and availability of the technology, undertake efforts to reduce them, and build safeguards for investment and research. To justify such distributive actions, we argue for a form of egalitarianism that asks for equal treatment of every individual in terms of bringing them to a level of normal functioning. In this framework, genetic benefits that can play a role in normal functioning should therefore be developed and made available to every individual in need, in line with a cosmopolitan vision insisting on equal consideration of individuals in the pursuit of global health.

2.1.1 Importance of health for avoiding serious harm/crucial link with normal functioning

The elaboration of this framework for global distribution in health requires an examination of the rationale for the special treatment of health. In his *Discourses on Method*, Descartes wrote that the preservation of health was no doubt the chief of all goods and the foundation of all other goods of life.[199] The Millennium Development Goals (MDGs), adopted at the Millennium Summit of the United Nations in September 2000, call for dramatic improvements in the health of the poor. Indeed, health is central to the MDGs: three of the eight objectives, eight of the eighteen targets, and eighteen of the forty-eight indicators are health-related.[200] Furthermore, in a recent global consultation undertaken by the UN Secretary General Kofi Annan, people around the world consistently indicated that good health was what they most desired[201] Health's unique importance is acknowledged by many societies through

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[199] R. Descartes, *Discourse on Method*, L. Lafleur, trans., (New York : Macmillan, 1960) at 85.

[200] UN General Assembly Resolution, *United Nations Millennium Declaration*, September 2000, A/RES/55/2, online: UN <http://www.un.org/millennium/declaration/ares552e.pdf> (date accessed: May 30th, 2006);
Executive Board Members, *Millennium Development Goals and Health Targets*, EB/Retreat/03/Discussion Paper 1, November 11, 2003, online: UN <http://www.who.int/gb/ebmr/PDF/E/Millenium%20development%20goals%20and%20health%20targets.pdf> (date accessed May 30th, 2006).

[201] Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development*, Dec. 2001, at 21, online on the WHO website:

special institutions and systems that ensure a more equitable distribution of health-related goods in comparison with other goods.[202]

Before saying more on the importance of health as a basic need, it is crucial to place it in a broader context where the avoidance of harm is the primary goal. In this context, the satisfaction of basic needs is an essential precondition to ensuring that serious harm is avoided. To qualify as serious harm, something has to prevent the pursuit of important individual goals. In Doyal's words, serious harm can be defined as "the fundamental and sustained impairment of social participation and of basic needs for physical health and autonomy [...] which block new achievements which would otherwise have been real possibilities for the individual concerned."[203] In this section, we argue that when serious health impairments can be avoided or prevented with existing products and services like, for example, vaccines, drugs, and diagnostic tests, refusing or neglecting to provide them to individuals in need, wherever they are, is equivalent to inflicting serious harm.

Health needs sometimes vary between countries and geographical regions of the world because of environmental, nutritional, housing, and other socio-economic factors (as opposed to natural misfortune) and because the perception of health and illness can differ from one culture to another. In that way, therapeutic and preventive measures necessary to meet health needs can vary.[204] However, health as a basic human need can nevertheless be viewed as having a unique universal and objective significance.[205] In fact, as mentioned above, humans share similar genetic makeup and are physiologically alike although minor genetic variations can also entail important differences between individuals which may require specific medical attention. This makes us all vulnerable to disease and health problems to different

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<http://www3.who.int/whosis/cmh/cmh_report/report.cfm?path=cmh.cmh_report&language=english> (accessed, May 30th, 2006); M. Johri & C. Barry, "Health and Global Justice" (2002) 16:2 *Health and International Affairs* 33.

[202] N. Daniels, *supra* note 188.

[203] L. Doyal & I. Gough, *supra* note 92, at 50-51.

[204] K. Lederer, *Human Needs* (Cambridge: Oelgeschlager, Gunn and Hain, 1980).

[205] That is why health is enshrined as basic human right in international law, for example in the Universal Declaration of Human Rights, 1948, art.25 and in the International Covenant on Economic, Social and Cultural Rights, 16 December 1966, art. 12.

degrees, but because of the common characteristics we share with other human beings, we can say that "universal and objective human needs do exist."[206] In others words, even if each individual's unique genetic makeup might influence his precise health condition and his response to treatment in certain cases, in most cases, existing preventive and therapeutic methods will have similar effects on sick individuals and different degrees of health and disease will have comparable significance for almost everyone, anywhere. [207] As explained by Acharya, "[e]mpirically we are not likely to observe dramatic differences in the assessment of health in terms of what can be achieved with particular physical conditions across cultures."[208] The objectivity of health-needs satisfiers can be demonstrated in genetic applications, with reliable diagnostic tests, for example; they could prove to be universally appropriate to test for the presence of a specific disease gene in susceptible populations anywhere. Another example of universality in health relates to physical pain, which, at a certain level, is objectively considered by almost everyone as something negative to be avoided.

Therefore, there seems to be a strong moral objection to the prevalence of different standards for health between different populations, particularly when these differences arise from socio-economic factors. As a result, some argue for universal agreement on some principles of justice and specific egalitarianism in the distribution of basic and universally important goods and services like those related to health. Basic needs like health care, food, water and shelter, all directly related to health, should therefore be regulated by special standards of egalitarian justice, different from those used to regulate the distribution of income and wealth. [209] Indeed,

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[206] L. Doyal & I. Gough, *supra* note 92, at 2.

[207] There are some exceptions to this, as if we take, for example, some physically impaired people who learn to develop amazing artistic skills and sensitivity, and for whom being ill probably does not have the same meaning and negative effects that it would have for a majority of people.

[208] A. K. Acharya, *supra* note 5, at 74.

[209] It is important to mention here that since we are establishing an ideal theory of justice, we can consider all of those needs as universally basic and crucial. However, when we transpose this at the intermediate level of the non-ideal world, the lack of resources requires rationing the different basic needs like health, subsistence, education, etc. Fried clearly explains this dilemma and argues that focusing only on health care needs-satisfaction would prevent societies from pursuing other crucial social goals in C. Fried, *Rights and Wrongs*, (Cambridge: Harvard University Press, 1978) c. 5; see

following this position, inequalities in health should be repaired without taking individuals' ability to pay for health care and services into consideration.[210]

But how and why is health a special good with an intrinsic value? Health is viewed as essential because it has a direct affect on every individual's normal functioning. "Normal functioning" is a very broad concept and it is somewhat challenging to try to establish precise criteria for it. We cannot use this notion as a basis for global distribution if we consider it a subjective concept, adjustable to individuals' personal circumstances and variable depending on each individual's perception. For the purposes of this framework, we need a narrow standard of normal functioning, abstracted from personal choices and preferences. Aiming to define normal human functioning, Anderson says that:

> [t]o be able of functioning as a human being requires effective access to the means of sustaining one's biological existence, food, shelter, clothing, medical care and access to the basic conditions of human agency, knowledge of one's circumstances and options, the ability to deliberate about means and ends, the psychological conditions of autonomy including the self confidence to think and judge for oneself, freedom of thought and movement.[211]

As it appears from this quote and as clearly explained by Daniels in his forthcoming book,[212] a thorough analysis of the concept of normal functioning requires that we look through a broader lens, not just referring to biomedical determinants but also

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also A.J.Culyer & A. Wagstaff, "Equity and Equality in Health and Health Care" (1993) 12 *Journal of Health Economics* 431; D. Braybrooke, *Studies in Moral Philosophy* (Oxford: Blackwell, 1968).

[210] However, again, in front of the limited resources available in the non-ideal world, rationing within the broad field of health is also unavoidable. Although it is not the focus of this dissertation, we will come back to how distribution of genetics' benefits could be undertaken to respect, as much as possible, our ideals of justice under section 2.3.2.4. of this chapter. J. Tobin, "On Limiting the Domain of Inequality" (1970) 13:2 *The Journal of Law and Economics* 263; S. Marchand, D. Wikler & B. Landesman, "Class, Health and Justice" (1998) 76:3 *Milkbank Quarterly* 449; on rationing criteria in health: R. Plant & N. Barry, *Citizenship and Rights in Thatcher's Britain: Two Views* (London: IEA Health and Welfare Unit, 1992) at 27-30; T.W. Pogge, *Realizing Rawls* (Ithaca: Cornell University Press, 1989) at 178-188; J. Sabin & N. Daniels, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* (Oxford: Oxford University Press, 2002); N. Daniels & J. Sabin, "Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers" (1997) 26:4 *Philosophy and Public Affairs* 303.

[211] E. Anderson, *supra* note 192, at 317.

[212] N. Daniels, *supra* note 186.

interpreting it in the context of the different social, environmental, and genetic determinants of health distribution. However, for the needs of this dissertation, we focus primarily on a form of egalitarianism that links biomedical and genetic resources with human beings' normal functioning to justify global distributive justice principles.

Being totally objective in defining normal functioning appears very difficult. In fact, as clearly explained by Boorse, values inevitably get involved when deciding which diseases impede normal function the most and therefore require more care and resources. There are many criteria that can be used to assess the priority of health care measures in pursuit of normal functioning as, for example, a treatment's potential for pain alleviation or death postponement. Our *objective* measure of individuals' normal functioning is directly related to the decent range of opportunities that are actually available to them. We argue that individuals should have access to the genetic products and services they objectively need to get to a level of normal functioning, which will allow them to take advantage of a decent range of opportunity (a concept to be analysed further in the next subsection).

Hence, health directly contributes to a person's basic ability to function in society, to interact in meaningful ways with other agents, and to live a life in which the pursuit of significant objectives and projects can occupy an important place.[213] Good health enables people to become educated, work, be productive, earn a salary, pursue personal and familial goals, and gain a certain degree of economic security, when possible in a given economic context. As indicated by Amartya Sen, health and education are constituents of development and are among the basic capabilities that give value to human life.[214] As it is not rare to see life plans compromised or considerably reduced by disease and poor health, good health is considered essential to a good life, one that is somewhat adequate in length and activity.[215] Good population health is also very important for poverty reduction and sustainable

[213] S. Anand, *supra* note 73.
[214] A. Sen, *Development as Freedom* (New York: Knopf, 1999) Introduction and c. 1.
[215] L. M., *supra* note 70; A. K. Acharya, *supra* note 5, at 73.

economic development, as societies affected by serious disease also experience considerable economic struggles and obstacles.[216] Therefore, since health can be characterised as a condition for normal species functioning,[217] it can be considered an objective need rather than a subjective preference or desire.

With respect to distributive justice, therefore, an *objective* criterion for health requires a standard independent from an individual's own evaluation, which might otherwise be representative of desires and preferences.[218] As such, if we consider that health is an objective need, vital to normal functioning, we could argue that many existing and future genetic technologies are equally necessary. Indeed, if genetics lives up to its great potential and proves useful in overcoming many serious and life-threatening health problems, those without access to genetic services and technologies might be denied health benefits crucial for normal functioning. In fact, without access to genetic testing and screening technologies, individuals in deprived populations could lack the ability to prevent, cure, or reduce the severity of their conditions. Therefore, the more scientific developments in genetics lead to genetic testing and therapies for global health improvement, [219] the more disparities between the health condition of individuals with and without access to such technology will increase.[220] This will also likely create differences in the range of opportunities effectively available to individuals from those different groups.

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[216] Commission on Macroeconomics and Health,„*supra* note 201 at 22 & table 5 at 23.
[217] D. Braybrooke, *Let Needs Diminish the Preferences May Prosper in Studies in Moral Philosophy*, American Philosophy Quarterly Monograph Series, No.1 (Oxford: Blackwells, 1968) at 90.
[218] N. Daniels, *supra* note188, c. 9 (health-care needs and distributive justice) at 179.
[219] As it is planned in this report, which presents 4 top genetic biotechnologies that could improve health in developing countries: Program in Applied Ethics and Biotechnology and Canadian Program on Genomics and Global Health (University of Toronto Joint Center for Bioethics) *supra* note 25.
[220] M.J. Mehlman & J.R. Botkin, *Access to the Genome: The Challenge to Equality* (Washington D.C: Georgetown University Press, 1998).

2.1.2. Avoidance of harm and normal functioning: crucial aspects of equality of opportunities

Having established that health is a central aspect of normal functioning, the argument now shifts to the role of wellness and normal functioning in the lives of individuals as a basis for distributive justice in health. The *equality of fair opportunity* has been popularised in Rawls' theory of justice as one of the main three principles, specifically that of "justice as fairness."[221] In short, it requires that persons with similar skills, talents, and ambitions have equal access to equivalent professional positions.[222] This concept does not require that opportunities be equal for all persons. In fact, unequal talents and skills among individuals are supposed to be covered by the application of the difference principle (inequalities have to be most advantageous to the least well-off). Rawls' theory of justice assumes a completely healthy population. It is therefore not designed to deal specifically with issues of health inequalities and health care distribution, and sets aside individual differences resulting from disease.[223] Rawls only requires a fair distribution of basic liberties, opportunities, and economic resources. One's health, positive freedom, and actual capacity to convert such factors into normal functioning and well-being (professional advantages, well-being, wealth, etc.) do not figure directly into his view.[224] It can be understood as setting up the justice framework for regulating distribution of key health determinants that are subject to social control, such as the structure of social organisation, government policies, wealth distribution, income inequality, poverty, and so on. Some also argue for the application of Rawls' difference principle to

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[221] Indeed, Rawls argues that rational individuals who would not know their position in a society would desire, after ensuring equal distribution of basic liberties, that two basic principles govern distribution in their institutions: equality of opportunity (professional) and the difference principle (that all inequalities in the remaining social goods be to the greatest advantage of the least well-off). J. Rawls, *supra* note 75; J.Rawls, *supra* note 61, at 63, 72-73; J. Rawls, *supra* note 79, at 115.

[222] N. Daniels, B. Kennedy & I. Kawachi, "Justice is Good for Our Health: How Greater Economic Equality would Promote Public Health" (February/March 2000) 25 *Boston Review*, online:Boston Review <http://www.bostonreview.net/BR25.1/daniels.html> (accessed May 30th, 2006).

[223] *Ibid.*

[224] He has been criticized on this point by Amartya Sen, who argues that Rawls' focus obscures the difference between sick and healthy individuals in terms of capability of functioning. For more details refer to: A. Sen, The Standard of Living, The Tanner Lectures (Cambridge: Cambridge University Press, 1987); A. Sen, *Commodities and Capabilities* (New York: Elvier Science Pub., 1985); A. Sen, *supra* note 214.

health concerns, which would require granting priority to the least-favoured groups in society with respect to health matters and to improve the health of the poorest in society in order to justify health inequalities.[225]

However, the pursuit of the kind of distributive justice promulgated here requires a system of distribution that meets health needs fairly at the "point of delivery."[226] This vision is that of Norman Daniels, who extends the theory and notion of equality of opportunity to cover health care and adapt it to the reality of disease and disability.[227] He believes that health care should be something to which we should have equal access in order to improve our health status and attain a level of normal functioning that allows access to a normal range of opportunities in other spheres of activities; or, in other words, to become efficient "converters of primary goods."[228] For Daniels, opportunity not only refers to the professional area but should also be considered as the portion of an individual's autonomy and liberty available for the achievement of various goals and undertakings, plans of life, and conceptions of the good.[229] In fact, when we argue for the moral equality of individuals, it means that we believe that everyone should have equal prospects to plan for a good life, should be entitled to participate and take part in their community's life and develop their individuality,[230] and that disparities in possibilities over which we have control should be eradicated. Many external factors like lack of water and food, severe poverty, political and socio-economic instability, and lack of access to health care goods and services can influence opportunities. Taking the example of health, if people with equal skills, talents, and ambitions are entitled to fair, equal opportunities and yet different degrees of access to health-care technologies and resources are tolerated, some individuals will accordingly lack the same advantages with respect to those

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[225] S. Marchand, Daniel Wilker & B. Landesman, *supra* note 210.
[226] N. Daniels, B. Kennedy & I. Kawachi, *supra* note 222.
[227] N. Daniels, *Just Health Care* (New York: Cambridge University Press, 1985) at 36-48; N. Daniels, *supra* note 188.
[228] N. Daniels (1990), *supra* note 187, at 279.
[229] N. Daniels (1990), *supra* note 187; see also A. Sen, *The Standard of Living*, *supra* note 224.
[230] L. Doyal and I. Gough, *supra* note 92, at 91.

opportunities, since disease can considerably diminish one's capacity to take advantage of available opportunities.[231]

Even if health problems will not always impact negatively on individuals' goals, projects, and level of happiness, it appears that individuals must possess a certain degree of physical health to participate in life, and accomplish projects in a cultural, personal, or professional context. They therefore ought to have an equal chance to obtain health care/genetic technologies and services to attain a level of objective normal functioning that will then allow them to profit from a decent range of opportunities, given their skills and talents. Indeed, even when societies establish measures to help and include people with disabilities, serious health impairments can still mean major limits on the range of opportunities that would otherwise have been available to someone with particular talents and skills.[232] Daniels' view follows from Rawls' theory of justice but does not depend upon it. Instead, Daniels adopts a notion of opportunity that is far broader than Rawls'. Rawls is interested only in access to professional positions and careers. Daniels goes one step further and associates the right to health care resources with the personal and social factors required for a good life.[233]

In the context of this analysis, the expression *health care* includes genetic technologies, tests, drugs, vaccines, and services available for preventing diseases and providing early diagnosis and treatments to improve the health status of individuals affected with specific diseases. Health care can have many functions for sick individuals, such as improving life expectancy, decreasing pain and suffering associated with their conditions, and providing tools for the prevention and treatment of diseases. In other words, "it maintains, restores or compensates for the loss of

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[231] N. Daniels (1990), *supra* note 187.
[232] A. Buchanan et al., *From Chance to Choice: Genetics and Justice* (Cambridge and New York: Cambridge University Press, 2000) c.7.
[233] Idem; L.M. Fleck, "Just Health Care (II): Is Equal*ity Too Much*?" (1989) 10 *Theoretical Medicine* 301.

functioning that is normal for a member of our species."[234] If our vision of justice requires the protection of fair equality of opportunity in health, it follows that every individual should have a fairly equal opportunity to access health care resources, technologies, and services that would allow for normal species-typical functioning, a central element required for equal prospects for a good life.[235] Therefore, health care should be distributed on a more equal basis rather than according to an individual's motivation and ability to pay.

Unlike preferences, tastes or desires, health relates to objective needs, the fulfillment of which allow an individual to access a normal opportunity range, to build up life plans for which he is suited, to establish relationships with others, and to develop different interests. As such, the crucial difference between treatment and enhancement in genetics is important. In referring to equality of opportunity in the framework of justice required for this thesis, it is not intended that genetic research should bring everyone to the same wellness and happiness level since medicine does not exist to make everyone happy and equal in terms of their skills and talents. Instead, it means equality in terms of access to genetic services and technologies that can be used for treatment of those who have an *objective medical need*, or in other words access to what is needed to attain *normal functioning* as an objective measure of health. This way, genetic technologies and services can be employed to bring individuals as close to the *normality level* (being healthy) as possible by removing obstacles in the way of access to a normal opportunity range.[236] One example of genetic intervention that has been proposed to ensure fair access to a normal opportunity range is germ-line and somatic genetic engineering in embryos to correct serious genetic defects before birth.[237] Notwithstanding the numerous ethical and

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[234] N. Daniels, "The Genome Project: Individual Differences and Just Health Care" in: T.F. Murphy & Marc A. Lappé, eds., *Justice and the Human Genome Project* (California: University of California Press, 1994) c. 7, at 110.
[235] Abstracting from individuals' subjective idea of what should be their normal opportunities in terms of life plans, careers, etc. N. Daniels, *supra* note 186.
[236] N. Daniels (1981), *supra* note 188; M. Leonard, *supra* note 677.
[237] M. Leonard, *ibid.* at 133.

scientific problems that could arise with this technology,[238] it may have considerable potential for the protection of fair equality of opportunities in our global structure if made available to everyone in cases where there is absolutely no doubt that the defective genetic makeup would lead to serious disease.

To conclude this section, in order to support the foundation for a specific theoretical framework for global distributive justice in health and, more specifically, in genetics, it has been established that health, as a vital element for normal functioning, greatly influences the range of normal opportunities available to individuals. Indeed, the impairment of normal species functioning reduces the range of opportunity in which we may construct our life plans. Therefore, the needs associated with normal species functioning can be qualified as objectively important since they correspond to the great interest people have in maintaining a normal range of opportunities. Attaining normal functioning to be in a position to benefit from equality of opportunity is thus crucial and is supposed to be protected against interferences from persisting inequalities. Having presented the reasons why health warrants special treatment, we now need to expand our discussion to the global aspect of health, in accordance with the concept of cosmopolitan justice supported in this dissertation.

2.1.3. Global perspective on health

The argument presented above in regards to equality of opportunity and its application to health had originally been developed to apply only to citizens of a given society. As such, it depended on the idea that opportunities available to individuals are unique to a given society since they depend on specific characteristics of that society, such as its level of material wealth, its economic and technological development, its cultural particularities, its conception and shared understanding of justice, its administrative and institutional structures and regulations, and so

[238] Arising problems could, for example, be related to the fact that the technology is not at all yet safe and usable, that it would be extremely expensive (read impossible) to make it available to everyone, that it could lead to eugenic applications, etc.

on.[239] Therefore, it is argued that the same disease in two different societies will likely reduce opportunities in different ways, with the result that their significance would be differently assessed.

However, to support the argument that equality of opportunity should prevail within states but not at a global level would be to attribute certain rights to members of a society while denying them to others who are not part of a national system of cooperation. As discussed at length in the previous chapter, we do not agree with such view that prioritise a domestic conception of distributive justice where states are the primary agents of justice and where members of a political community are entitled to special rights by virtue only of their membership in this society.[240] This argument provides a good basis for domestic equality of opportunities, but how does it justify rejecting a similar concept at the global level? Those in favour of a domestic application of this principle to health often argue that the major financial contribution of societies' members to support their health system (programs, services, therapeutic products, etc.) justifies limiting equality of opportunity to the national level. However, potential holders of a right to equality of opportunities within a society have not necessarily begun to participate in the system of mutual cooperation. In fact, like non-citizens, children and teenagers often did not engage in the economic system that allowed the creation of the goods and services that would be subject to equality of opportunities.[241] Moreover, if the enforcement of domestic equality of opportunity would oppose situations where people have fewer prospects due to their class or income, it would seem to follow that analogous situations in which people have fewer prospects according to their nationality, citizenship, or geographic location should also be opposed.[242]

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[239] N. Daniels (1981), *supra* note 188; N. Daniel, *supra* note 187, at 33; M. Walzer, *supra* note 79.
[240] D. Harris, *supra* note 128, at 56-57, 86, 103-104; M. Walzer, *ibid*, at 314.
[241] T.W. Pogge, "Cosmopolitanism and Sovereignty", *supra* note 84.
[242] S. Caney, *supra* note 128; S. Anand, *supra* note 73.

The cosmopolitan perspective of justice proposed in the first chapter is very relevant in the health sector, where different societies interact within a rich global structure of political and economic institutions that considerably affect health prospects for everyone. Therefore, the moral reasons to take responsibility for non-citizens' health problems caused by the global economic order are of similar importance when compared to co-citizens' health problems resulting from the domestic economic order.[243] This argument derives from the principle defended in the first chapter, that individuals, wherever they are, should be the most important standard of concern in establishing basic principles of justice. Therefore, it follows that we should not determine the significance of disease and lost opportunities on a society-based model. This application of the cosmopolitain perspective to global health and justice is one important contribution of this dissertation.

The normal opportunity range can vary between countries in terms of the nature of the actual opportunities, which include the types of careers available, the most rewarded physical and intellectual talents and skills, and the nature of possible undertakings and life plans in a given environment. Consequently, some, like Daniels, argue that since different societies call for different health care measures, the normal opportunity spectrum is relative to each society.[244] However, like the ability to function normally, the general types of opportunities to pursue life and career undertakings, to use some form of language and basic social ability, or to engage in some form of labour, should be the same for everyone regardless of their nation, state, or ethnic group.[245] The evaluation of the range of opportunities at the global level, as at the national level, may be generalised from an examination of the variety of possible prospects and from a subjective perspective regarding such opportunities. As Martha Nussbaum indicates, certain objectively important needs, like health, are valued by everyone since they relate to universally shared priorities. This can allow

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[243] Refer to Pogge's interesting discussion on this point: T.W. Pogge, *Justice in Health Care: Reflexions on the Foundations of Health Equity*, Working Paper Series, Cambridge, MA, Harvard Center for Population and Development Studies, 1999.
[244] N. Daniels, *supra* note 187.
[245] H Shue, *Basic Rights: Subsistence, Affluence and US Foreign Policy* (Princeton: Princeton University Press, 1996) at 59-60, 159 et ss; L. Doyal & I. Gough, *supra* note 92, at 181.

the creation of an international standard for evaluating opportunities on a global scale.[246] Consequently, the rationale for accepting the principle of equality of opportunity within the state also requires that we endorse a principle of global equality of opportunity, the whole of which contributes to the framework for global distributive justice. Indeed, the goal of global equality of opportunity in health is becoming increasingly essential, especially in light of the critical health problems affecting individuals who live in poorer countries where genetic technologies and services may not be adapted, available, or affordable. This leaves millions of individuals with reduced access to a normal range of opportunities in many spheres. This quote from Acharya summarises our position on the importance of the global aspect in equality of opportunities:

> It will be most likely agreed that children should be afforded the same chances for all possible future jobs, political offices, and opportunities. Nearly all children should be given an equal chance of survival conditional on their congenital status. A child should be considered to be especially disadvantaged if he or she, as an adult, will not be capable of qualifying for most types of employment in a given region when another child in a different region with a similar condition could obtain employment.[247]

However, it is important to mention that although we should ensure that, on the global scene, every individual of comparable skill and talent should be healthy enough to access similar sorts of opportunities, it does not mean that they should all be provided with identical medical attention and health care. Indeed, since uniformly broad categories of opportunities will actually give rise to different opportunities in different settings and environments, adapted health care standards will be required to bring individuals to a level of normal functioning in different societies. For example, if we consider the opportunity to pursue career undertakings or, even more generally, to engage in some form of labour, it appears that bringing people to a level of normal functioning will require different types of health care

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[246] M. Naussbaum, "Human Functioning and Social Justice: in Defense of Aristotelian Essentialism" (May 2nd 1992) 20 *Political Theory* 202, at 216-223.
[247] A. K. Acharya, *supra* note 5, at 74.

measures depending on the context of their respective societies. Indeed, a normal functioning standard in career and labour opportunities could mean something different in an industrialised context with established resources and infrastructure to treat people with disabilities than in a poorer, more rural/agricultural reality that lacks those same resources, and where the same diseases consequently lead to considerable burdens. Although the basic framework for distribution remains the same, genetic technologies could be harnessed in specific ways to respond to different countries' health needs and to bring individuals to the level of normal functioning they need in order to be able to take advantage of given opportunities and be functional in the environment in which they live.

2.2. Normative Grounds to Operate Distribution and Premises Upon which to Claim Health Equity and Fairness.

What can constrain distribution in health? What kinds of responsibilities do the affluent of the world have towards the global disadvantaged?

The concept of global equality of opportunity as applied to health is an essential stand point for analysing the global distribution of health care, technologies, and services within a framework of justice. Having established an argument for the rationale of the global distributive theory, the normative grounds upon which distribution in health and genetic innovation should be operated will be presented. The role of the principles of distributive justice is to determine the fair distribution of genetic benefits that may be produced by global cooperation. Having established a rationale for fair distribution in this specific area, we will now address how it should be undertaken. To this end, various normative tools are available, such as right- and duty-based theories and the global application of Rawls' difference principle.[248] This needs to be discussed to resolve the ambiguity that prevails with regard to the moral grounds of any requirement to assure global health.[249]

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[248] C. Jones, *supra* note 78.
[249] L.M. Fleck, *supra* note 71.

2.2.1. Rights (to equality in opportunities)

According to Feinberg:

> Legal claim-rights are indispensably valuable possessions. A world without claim-rights, no matter how full of benevolence and devotion to duty, would suffer an immense moral impoverishment... A world with claim-rights is one in which all persons, as actual or potential claimants, are dignified objects of respect, both in their own eyes and in the view of others.[250]

From a theoretical point of view, the nature and the underlying justification of the concept of rights have undergone considerable changes.[251] During the 19th and 20th centuries, the notion of rights as described by Hobbes, Kant, Hegel, and many other philosophers was strongly criticised, both from the right and the left, reducing the concept of rights to *social constructs*.[252] Consequently, rights had been absent from the vocabulary of political philosophy for decades before coming back into political, legal, and philosophical discourse just after the Second World War.[253] The human misery and atrocities exposed by the media during and following the War were a turning point leading to the re-introduction of the language of rights.[254] Then, welfare liberalism developed into the dominant ideology and became increasingly associated with the new, developing body of international human rights, including social and economic rights.[255] Still, many scholars denounce the use of rights as a way to structure and regulate a society, arguing that it creates entitlements without envisioning them within the context created by the society's structures and

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[250] J. Feinberg, *Social Philosophy* (New-Jersey: Prentice Hall, 1973) at 58-59.
[251] For a comprehensive analysis of the evolution of the concept of right, see G.B. Herbert, *A Philosophical History of Rights* (New-Brunswick: Transaction Publishers, 2002).
[252] J. Bentham, *Rights, Representation, and Reform : Nonsense Upon Stilts and Other Writings on the French Revolution* (New York: Oxford University Press, 2002); K. Marx, "Capital", in F. Engels, ed., *Manisfesto of the Communist Party,* Trans. from the 3d German ed. by S. Moore & E. Aveling. Rev. (Chicago: Encyclopædia Britannica, 1955); G.B. Hebert, *A Philosophical History of Rights* (London: Transaction Publishers, 2002) at 277.
[253] G.B. Hebert, *ibid* at 286.
[254] *Ibid,* at 287; T. Ball & R. Dagger, *Ideals and Ideologies: a Reader* (New York : Pearson Longman, 2004).
[255] T. Ball & R. Dagger, *ibid.*, at 11-23 & 74-80.

institutions.[256] The purpose of this section is not to present a comprehensive analysis of the notion and desirability of rights, but to refer to a framework in which rights can be conceived as a potential basis for the requirements of our theory of global justice in health. We will return to rights discourse later in the dissertation, when we analyse the legal framework and system of international socio-economic human rights.

The acknowledgement of rights is an important aspect of a theory of justice. It is, in fact, what often justifies the restrictions on action or the imposition of duties to act in certain ways. If we consider rights an important factor in a global distributive justice theory, they will accordingly impose restrictions on distributive arrangements (social, political, and economic) supported by the global order. In fact, we can consider that a just distribution is one in which each individual obtains what he or she can claim by right. When rights are established and recognised, they shift the burden of proof onto those who decide not to respect them. Indeed, as indicated by Will Kymlicka, justice can be considered the system of entitlements upon which people can base their demand for recognition of legitimate claims for resources and opportunities.[257]

The need to rectify injustice created by inequitable distributions can find its source in rights. Rights must be based on property or on something of crucial importance for its possessors.[258] They are often envisioned as a basis for justifying demands and imposing obligations. A right-holder can require that the content of his or her right be guaranteed. Rights are recognised and understood as being grounded in the basic interests that individuals have in the content of those rights. An argument for a right "is an argument showing that an individual interest considered in itself is sufficiently important from a moral point of view to justify holding people to be under a duty to promote it."[259] Some argue for the protection of basic rights associated with the

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[256] For a comprehensive exposé on the criticism of the character and the desirability of rights refer to: M. Sandel, *Liberalism and the Limits of Justice* (New York: Cambridge University Press, 1998); A. Petter, "Immaculate Deception: The Charter's Hidden Agenda" (1987) 45 *The Advocate* 857, at 860.
[257] W. Kymlicka, *Liberalism, Community and Culture* (Oxford: Clarendon Press, 1989), at 234; C. Jones, *supra* note 78.
[258] C. Jones, *ibid.*
[259] J. Waldron, *The Right to Private Property* (Oxford: Clarendon Press, 1988) at 3; On the interest notion see also: J. Waldron, *Liberal Rights: Collected Papers 1981-1991* (Cambridge:

primary necessities and preservation of human life. Such basic rights can emerge from needs shared by every human, like food, water, shelter, and health care.[260] Rights allow us to associate human well-being and related obligations. They can be ranked according to the nature of the interest they help to defend, as well as by their normative weight.[261] We will return to the related duties and obligations in the next part of this chapter.

As discussed above, health is critically important for individuals and represents a basic human interest. As we will see in more details in the fourth chapter of this dissertation, the right to health is controversial but is recognised as a human right in international law treaties[262] and requires positive actions in terms of resources or actions. Interpreted broadly, the right to health can include the right to health care and the right to genetic technologies, especially if we consider that they could become the new standard of care needed to achieve acceptable standards of health and a broader and universal right to equality of opportunity. In fact, in the field of health, it is inadequate to refer only to a basic right to emergency health care and subsistence if access to adequate and adapted health care remains reserved for a privileged few.[263]

The very concept of rights is not accepted by everyone and is, in fact, often criticised. One reason for this is that rights remain meaningless in cases where taking advantage

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Cambridge University Press, 1993) at 11 & 212; J. Raz, *The Morality of Freedom* (Oxford: Clarendon Press, 1986) at 166; N. MacCormick, "Rights in Legislation" in P. M. S. Flacker & J. Raz, eds., *Law, Morality, and Society: Essays in Honour of H. L. A. Hart* (Oxford: Clarendon Press, 1982).

[260] H. Shue, *Basic Rights, supra* note 245; O. O'Neill, *supra* note 82, at 155 et ss.

[261] O. O'Neill, "Hunger, Needs and Rights", *supra* note 88; P. Jones, *Rights* (London: MacMillan, 1994) at 13-15.

[262] For example, the right to health has been codified in: Universal Declaration of Human Rights, art. 25; International Covenant on Economic, Social and Cultural Rights (ICESCR), G.A. Res. 2200 (XXI/, UN GAOR, 21st Sess., Supp. No. 16, at 49, UN Doc. A/6316 (1966) art.12; (find exact ref.); *Convention on the Elimination of all Forms of Discrimination against women*, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, entered into force Sept. 3, 1981, art.12; *Convention on the Rights of the Child*, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), *entered into force* Sept. 2 1990, art.24; See also, *African Charter on Human and People's Rights*, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), *entered into force* Oct. 21, 1986 art. 16; *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights*, 1988, art. 10.1.

[263] S. Caney, *supra* note 128.

of them is not a real option for the right holders.[264] This objection seems to apply more to civil and political rights. In fact, even if it appears easy to grant rights such as the right to vote, the right to freedom and to security, or the right to free speech, if personal health, material, and economic conditions of the right holders are such that they cannot take advantage of them, these rights lose much of their value. While some argue that the strong socio-economic component of many traditional civil and political rights justify their extensive protection,[265] it may make more sense to eliminate what is now a clear separation between civil and political rights and economic, social, and cultural rights.[266] In fact, since poverty and ill-health are considerable obstacles to a satisfying human existence, economic and social rights should rank alongside civil and political rights,[267] and all of these rights should therefore be envisioned as required values for a better world.[268] This has a critical importance with respect to health issues since it seems essential to ensure that each individual have equal access to appropriate health care, technology, and resources in order to achieve a normal range of opportunities in other spheres and therefore be able to take advantage of other civil and political rights.

Another objection to rights discourse relates to the notion of solidarity, which holds that granting rights to people can have the effect of isolating them from each other.[269] In fact, proponents of this view argue that a focus on individual rights allows neglect of collective responsibilities—for example, in allowing some individuals to control the majority of wealth while many others, though possessing rights, end up with a lot

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[264] In *A Theory of Justice*, Rawls recognizes that the value of liberty is directly linked with the material conditions necessary to experience it.

[265] J. Waldron, *supra* note 259 at.7-8; M. Jackman, "Poor Rights: Using the Charter to Support Social Welfare Claims" (1993) 19 *Queen's Law Journal* 65.

[266] The strong connection between the two categories of rights and the fact that there is no hierarchy between them has been specifically emphasized by the UN: United Nations Committee on Economic, Social and Cultural and Economic Rights, *General Comment No. 3(1)*, 2002, online: UN <http://www.unhchr.ch/html/menu2/6/cescr.htm> (date accessed: May 30th, 2006)

[267] B. Terence & R. Dagger, *Political Ideologies and the Democratic Ideal*, 5th. ed. (New York: Addison Wesley, 2004)

[268] J. Waldron, *supra* note 259 at 7-8; G.B. Herbert, *A Philosophical History of Rights* (London: Transaction Publishers, 2002).

[269] J. Waldron, *Nonsense upon Stilts: Bentham, Burke and Marx on the Rights of Man* (London: Methuen, 1987); R. Vincent, *Human Rights and International Relations* (Cambridge: Cambridge University Press, 1986) part 1; A. Renteln, *International Human Rights: Universalism vs Relativism* (Newbury Park: Sage, 1990).

less than they need. This creates social division that can prevent the establishment of a truly solid community. In response to this argument, others assert that any defensible account of rights demands a strong social framework that would facilitate mutual sharing of the benefits of rights and burdens of duties. For advocates of this view, rights are part of a "reciprocal universality" and thus it is impossible to see right-holding as a totally selfish and individual experience.[270] As Bowles and Gintis maintain, "the discourse of rights has served as a source of bonding and a framework for the expression of group demands, rather than reflecting a social philosophy or a political ideology.[271] The cosmopolitan perspective holds that where the importance of vital interests of each individual should be acknowledged, regardless of his or her location, nationality, or citizenship, rights are essential to achieving the moral distributive ideal. In fact, when they are recognised, integrated within a society's functioning structure, and taken seriously, they can provide a basis for impartial and equal individual recognition, as well as for community solidarity and cohesion. As such, from the cosmopolitan perspective, rights cannot remain based on individual experiences, but must be integrated in a collective framework where the structure in place imposes global respect and recognition. This aspect will be treated later in the dissertation when we discuss the existing human rights framework.

Also, the enforcement aspect of rights gives rise to scepticism about the concept of a right to health care, genetic technologies, and resources. Critics emphasise the material obstacles to supporting and implementing welfare claims, that mainly relate to the scarcity of resources and the identification of accountable actors and institutions.[272] They maintain that rights should not only cover the essence of what should be granted, but should also talk about what would be necessary to achieve them and by whom they should be respected. By focussing on enforcement, such critiques emphasise the abstract aspect of rights. Onora O'Neill for example, argues

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[270] For example refer to: C. Jones, *supra* note 78, at 80-83; A. Gerwirth, "Rights", in L.C. Becker & C. Becker, eds., *Encyclopedia of Ethics* (London: Garland, 1992) at 1108.
[271] S. Bowles & H Gintis, *Democracy and Capitalism: Property, Community, and the Contradictions of Modern Social Thought* (New York: Basic Books, 1986) at 170.
[272] R. Nozick, *supra* note 71, at 112-114.

that "if the claimants of supposed 'rights' to food or development cannot find where to lodge their claims, these are empty "manifesto' rights' which would be equivalent to having no right at all."[273] She argues that rights-talk is rhetorically powerful, but is not ethically founded because it does not deal with the powerful actors who could do something about international injustice.

However, with this type of argument about legal enforcement, the inherent normative importance of a focus on welfare rights is often ignored as it assumes a strict legalist *Hohfeldian* vision of rights. In the early twenties, Hohfeld published a very influential text in the field of rights, *Fundamental Legal Conceptions*,[274] in which he approaches diverse theoretical differences informing rights discourse. According to Hohfeld, the concept of 'rights' gives rise to correlated duties and is thus best defined as *claim-rights* against another party who, as a consequence, becomes legally obligated.[275] However, this is not the only way to envision rights, especially not human welfare rights, the substance of which should not be subject to the same restrictive juridical conceptualisation.[276]

The types of rights on which we could establish our justice framework (rights to health and health care, to genetic technologies and resources, to opportunities) relate to human values that are essential to people's welfare. Rights can give rise to different types of duties, some positive (like, for example, to perform actions, to assist) and others negative (like to refrain from performing certain actions).[277] Therefore, a restrictive conceptualisation of rights, with required correlative positive duties, is not necessarily always applicable to health, health care and technologies, or to the right to equality of opportunities in practice. Indeed, they can exist without the actual claim of specific positive duties against identifiable actors as they are associated with the justice values and principles to which we aspire globally.

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[273] O. O'Neill, (2000), *supra* note 82, c.7, at 115 et ss; O. O'Neill, *supra* note 82, at 117-120.
[274] W. Hohfeld, *Fundamental Legal Conceptions (New Haven: Yale University Press, 1923 and* Aldershot: Ashgate, 2001).
[275] *Ibid* at 38 & 46.
[276] G.B. Herbert, *supra* note 253, at 280.
[277] J. Narveson, *The Libertarian Idea* (Philadelphia: Temple University Press, 1988) at 57; R. Cruft, "Human Rights and Positive Duties" (Spring 2005) 19:1 *Ethics and International Affairs* 29, at 30.

However, some argue that human rights, like the right to health, certainly give rise to negative duties not to harm, and these commentators refuse to endorse an institutional order that entails avoidable and foreseeable violation of those rights.[278] The rights to health/health care, technologies, and resources are inherently important to protecting individuals' welfare and vital interests; this alone justifies their recognition as normative grounds for justice in a just global structure. The fact that the related positive duties associated with these rights are sometimes contested (or not yet allocated to particular actors or institutions) does not mean that those rights do not exist and cannot be an important part of our ideal justice theory. As Gewirth puts it, "[i]t is not enough to say that rights-enforcement incurs costs; there is the prior question of what there is about rights that makes them worth the cost."[279]

This being said, in order for the distributive justice theory for health care to have political significance, it needs to have an institutional component. Justified rights must be adequately protected by required duties and obligations to refrain to harm, defend the interests of rights-holders, and facilitate the enforcement of their rights against particular agents.[280]

2.2.2. **Obligations /Duties** (to redress distributive injustice)

Who owes justice to whomever it is justice is owed?

The practical and institutional aspects of obligations require examination, particularly in connection with the concept of obligation and duties in relation to justice. We have seen that Daniels' theory allows us to consider health care access as directly related to the normal range of opportunities. Health care and genetic resources and services should thus be distributed in a way that allows normal functioning and consequently

[278] T.W. Pogge, "Severe Poverty as a Violation of Negative Duties" (Spring 2005) 19:1 *Ethics and international Affairs* 55, at 66-68.
[279] A. Gewirth, "Are All Rights Positive?" (2001) 30:3 *Philosophy and Public Affairs* 321, at 330.
[280] J. Feinberg, *supra* note 250, at 59; J.W. Nickel, "How Human Rights Generate Duties to Protect and Provide" (1993) 15 *Human Rights Quarterly* 77.

ensures equality of opportunities. This may give rise to a right to equality of opportunities and to correlative obligations.

2.2.2.1. What duty/obligation?

Following Henry Shue's classification, obligations can arise from three different kinds of duties, which are either positive or negative: the negative duty of avoidance, the positive duty of protection and the positive duty of aid.[281] The global distributive justice theory would include several related duties such as avoidance of harm to global health, institutional protection against harm, provision of relief, provision of aid development, and redistribution of genetic resources. The aim, purpose and responsibility of the different actors involved will determine the nature of the duties that will be assigned to them. For example, as multinational corporations are not designed to protect human rights, but to make profits and gain power in their sphere of activity, they may merely have to act so as to avoid violating human rights (negative duty of avoidance) without necessarily having to promote human rights, as other actors might be otherwise compelled to do.

Health deprivation and aggravation may be caused by many actors because of a variety of factors. This is why it can be tempting to say that since health deficiencies are the responsibility of so many agents, they are not specifically anyone's responsibility. There are different arguments as to how we should allocate duties in health-related spheres. Shue's response is to propose prioritising rights' protection. He gives the fulfillment of basic rights priority over all other non-basic rights, which he, in turn, gives priority over satisfaction of preferences and cultural advancement.[282] If we apply this priority principle to the access to health, health care, technologies, services, and resources, duty-bearers could find themselves obligated to fulfill those rights before anything else. As discussed above, equitable access to good health is a prerequisite to equality of opportunities in many crucial spheres of life. It

[281] H. Shue, *Basic Rights supra* note 245, at 52.
[282] *Ibid.*, at 118.

is critical to every individual's complete personal development; as such, the actual level of inequality in this area contributes to the preserving a degrading and unfair level of inequality. Other important factors to consider in determining the scope of justice obligations are the urgency of the condition and the cost to deliver the required assistance. In other words, Shue makes special responsibilities for health depend on emergency and seriousness of interests without necessarily taking responsibility for health into account. This demands positive distributive duties even in cases where no responsibility can be attributed. This is particularly relevant for global health since the actual situation has become worse for so many years for so many different political, environmental, and socio-economic reasons—a context that makes it very hard to attribute direct responsibility to specific actors. Where the more fortunate can do something about serious diseases and suffering without unduly burdensome costs, they should do so.[283]

Another way to envision duty allocation is to focus on responsibility for deprivation, giving rise to a duty to avoid causing harm to others. This can be considered in many different ways, one being that everyone who supports an unjust global structure is responsible for the injustice it creates,[284] and another being that a failure to secure universal and basic needs (health-related needs for example) implies failing in meeting one's duty to refrain from harm.[285] We can cause harm by exposing others to extreme poverty and health deficits, and failing to intervene when, for example, life-saving knowledge and products are available but inaccessible for structural reasons. In such cases, the negative duty to avoid harm can require positive obligations, i.e., that we take positive steps to ensure that the legal structure we support is not

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[283] H. Shue, *Basic Rights supra* note 245 at 17, 59-60, 159-161, 164-166, 168-180; T.Pogge, "Eradication Systematic Poverty: Brief for a Global Resources Dividend" (2001) 2 *Journal of Human Development* 59; T. W. Pogge, "Responsibilities for Poverty-Related Ill Health" (2002) 16:2 *Ethics and International Affairs* 71, at 73; C.R. Beitz, *supra* note 55. C. Jones, *supra* note 78

[284] T. W. Pogge, *World Poverty and Human Rights*, "Symposium on World Poverty and Human Rights" (2005) 19:1 *Ethics & International Affairs* 1; N. E. Kass, "Public Health Ethics: From Foundations and Frameworks to Justice and Global Public Health" (2004) 32 *Journal of Law, Medicine and Ethics* 232, at 238-239; T.Pogge, "Eradication Systematic Poverty: Brief for a Global Resources Dividend" (2001) 2 *Journal of Human Development* 59; T. W. Pogge, "Responsibilities for Poverty-Related Ill Health" *supra* note 283, at 73; C.R. Beitz, *supra* note 80; C. Jones, *supra* note 78.

[285] L. Doyal & I. Gough, *supra* note 92

encouraging these health gaps. Individuals can also be harmed if others fail to recognise the importance, objectivity, and universality of their crucial health needs, and consequently restrict them in the pursuit of his life goals, as discussed above. Again, the duty not to harm extends to agents and implies that individuals should participate in creating and supporting institutions that can help meet basic needs and relieve major suffering.[286] The ideal just global structure we argue for must adhere to global distributive mechanisms to avoid such harm.

In addition to the basic need and to the responsibility views, a third way to allocate duties for health improvement is Buchanan's natural duty of justice, which requires the creation of mechanisms to provide universal access to just institutions, even outside established schemes of cooperation.[287] This idea is based on a cosmopolitan vision that treats all human beings with equal consideration by respecting and protecting their most basic needs and helping to create a global context where individuals will have access to institutions that secure their fundamental rights. It is similar to the duty not to harm, but requires positive duties to establish institutions and legal principles to regulate the global structure and ensure that everyone's needs are given consideration.

This discussion on duties and obligations calls into question the very system of exclusive property rights which allows extensive control over knowledge, goods and technology that, if otherwise available, would be crucial in meeting individuals' basic needs and rights. With respect to property rights, individuals generally have the right to dispose of their own property as they wish.[288] Under what conditions would it be fair to violate property rights? Should bringing people to a common health standard, by which they could have access to equal opportunities, be a reasonable threshold? If property rights increase health innovation, promising discoveries, and ultimately the production of therapeutic products and services in certain cases, would it be fair to

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[286] *Ibid.*, at 104.
[287] A. Buchanan, *supra* note 25, c. 2, at 73-85.
[288] H.T. Engelhardt Jr. *The Foundations of Bioethics* (New York: Oxford University Press, 1986) at 342-343.

restrict those rights? Could it lead to greater harm? Should researchers wanting to do research to advance the health of deprived people be entitled to use other people's property to further their goals? Should property enforcement institutions be responsible for guaranteeing other important rights as well? If yes, to what extent? It seems that the theoretical foundation of the legal property rights needs to be questioned in our process to establish a duty to global distributive justice. This will be addressed later in the dissertation, in chapter three, when we analyse the existing intellectual property system and its compatibility with distributive justice ideals.

Duties are part of an institutional strategy to ensure that people around the world receive their basic health entitlements and profit from global equality of opportunities. Thus, a clear distinction must be made between duties of justice and acts of benevolence or charity. O'Neill sets forth an interesting perspective using the Kantian universal maxim[289] to defend far-reaching justice obligations to individuals and to state that actions, policies, and institutions not be based on fundamental principles of coercion or deception within states and across borders. O'Neill asserts that there is an obligation to help, but denies that this obligation corresponds to a human right to be helped.[290] This approach fails to generate any positive duties to help those whose fundamental interests need protection through positive action. According to this approach, only non-deception and non-coercion would qualify as required conditions for justice, since positive obligations to assist others would seem to fall into the realm of beneficence rather than justice.[291]

Moreover O'Neill's approach presents only a limited perspective on obligations. In fact, as argued above, the ideal of global distributive justice involves direct help to the individuals in need of health care, resources, and technologies to bring them to a level where they can enjoy equality of opportunities. Duties of

[289] Kant's categorical imperative asks to "act only according to that maxim by which you can at the same time will that it should become a universal law" I. Kant, *Foundations o/ the Metaphysics of Morals,* 2nd ed., tr. Lewis White Beck (London: Collier Macmillan, 1990) at 39.
[290] O. O'Neill, *supra* note 88, at 70; O. O'Neill, *supra* note 82, at 164.
[291] O. O'Neill, *supra* note 144, at 119-120.

benevolence or charity are often proposed as forms of positive obligations but are not sufficient. In fact, the obligations of justice proposed here are more demanding: they require more sustained efforts, greater sacrifices, enforceable commitments from the identified duty-bearers, and the reorganisation of global institutions. Such obligations were proposed more than thirty years ago in the UN General Assembly's *Declaration on the Establishment of a New International Economic Order*,[292] which required developed countries to work toward eliminating the ever-widening gap between rich and poor countries, and to restructure the world's economic system in order to promote the economic advancement and social progress of all people. As we know, those obligations have not been fulfilled, but some actors have instead attempted to propose random and sporadic philanthropic initiatives to replace them. For example, we have seen several multinational companies offering free medication to specific countries: sometimes as an act of charity in cases of extreme health crisis, sometimes more as a result of negotiations to avoid the production of generics with the system of compulsory licenses, and other similar initiatives. Besides their sometimes doubtful safety and long-term effectiveness[293] such initiatives are not a sustainable solution, and their theoretical foundations are open to criticism. In fact, the initiatives described above can contribute to the flawed characterisation of the nature of the responsibilities of the more privileged, disguise their abusive behaviours, and obstruct in-depth institutional reforms.[294] Since they are freely and voluntarily performed, no one can claim a right to such acts as a consequence of justice. Also, no one can be forced to perform such charitable actions as generosity is voluntary and property rights over resources give owners total freedom over their management and disposition. Acts of charity that

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[292] GA Res. 3201 (S-VI), 2229th plenary meeting, 1974.

[293] P. Berckmans et al., "Inappropriate Drug Donations in Bosnia and Hezergovina, 1992-1996" (1997)1842:5 *New England Journal of Medicine* 337; WHO, *Essential Drugs and Medicine Policy, Guidelines for Drug Donation,* Interagency Guidelines, revised in 1999, WHO/EDM/PAR/99.4, Geneva, 1999; K. Godfrey, "Charity Aims to Distribute Donated Drugs to Developing Countries" (20 November 2004) 1206 *BMJ* 329.

[294] Oxfam, *Patent injustice: How the World Trade Rules Threaten the Health of Poor People* (Oxfam briefing paper London, 2001, online on the website of oxfam <http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf> (accessed: May 18th, 2006); C. Barry & K. Raworth, "Access to Medicines and the Rhetoric of Responsibility" (2002) 16:2 *Ethics and International Affairs* 57.

result from some sense of kindness and compassion are thus not the appropriate vehicle for achieving justice. They can be defined as moral obligations, but should not be invoked to replace legal positive obligations and duties. In fact, beneficence allows agents to withdraw from discretionary charity endeavours at any time; they can also help very limited number of individuals globally, which would leave many people in need of health care and resources. From a global distributive justice perspective, this would be unacceptable, whereas from a beneficence perspective, such inequalities between individuals are simply unfortunate.[295] Indeed, Thomas Nagel makes a similar point when he indicates that "aid should not be regarded as a voluntary contribution of a portion of a state's own wealth, but rather as a transfer of wealth required to redress distributive injustice".[296]

2.2.2.2. Who should act?

Another important aspect of obligations and duties is the identification of duty-bearers and agents of justice. After the recognition of clear obligations, the next step is to identify who should be required to act. The purpose of this section is not to proceed in the identification of specific obligation-holders, but rather to propose generally what kinds of actors or groups should be handling such duties. Individuals, states, and other institutions and organisations may thus all be responsible for performing given duties. However, it is safe to say that, in general, collective coordination of duties will often provide better and more effective rights protection and aid provision than individuals acting alone in a disorganised manner. Tangible and definite obligations have to be supported by institutions and cultures that embody coherent and effective allocations of obligations.[297] This is not to say that citizens of powerful developed countries cannot be found directly accountable for the production of poverty and health deficits for which the governments they elected

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[295] L.M. Fleck, *supra* note 71.
[296] T. Nagel, "Poverty and Food: Why Charity Is Not Enough" in P.G. Brown & H. Shue, eds., *Food Policy* (New-York: The Free Press, 1977) 54, at 57.
[297] O. O'Neill, "Public Health or Clinical Ethics: Thinking beyond Borders" (2002) 16:2 *Ethics & International Affairs* 35, at 39.

are often responsible as a result of their democratic self-interested choices in the fields of international politic and trade. As "participants" to injustice, we all have a responsibility to people affected by such injustice. This leads us to say that inequalities in health are unjust if they are the result of unjust (international) social arrangements. [298] Therefore, individuals, as participants of the existing global institutional system, could have the responsibility of not cooperating in the imposition of unjust institutional schemes and of instead promoting reforms and establishing just institutional arrangements. The institutions thereby created would be accountable for granting efficient protection to individuals' interests and human rights. As discussed in the first part of this chapter, as things stand now, states may well be the main agents for fulfilling duties regarding equality between individuals in the field of health and genetics. In fact, as we have seen, in the face of the actual institutional inability of the international structure to perform distributive justice duties, states are major representatives of political reality; as such, they can foster special bonds of sentiment, identity, and obligation. Such characteristics can be taken into account if the individualistic theoretical basis of justice is acknowledged and respected and the needs and interests of the others affected by those distributive mechanisms are also considered.[299] As clearly put by Pogge, we believe that: "[...] radical inequality can be avoided and economic human rights securely maintained within a global system of states."[300]

Many different actors are involved in the production and distribution of genetic knowledge, technology, and resources. Of course, not all states are in a position to fulfill obligations and duties generated by individuals' interests in better access to health for equality of opportunities. Charles Jones responds to this problem by suggesting that states with more than enough resources, wealth, and technology could

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[298] This affirmation is rooted in Rawlsian justice and based on the idea that, in justice as fairness, the society is formed by a *fair system of cooperation* between free and equal persons (at the national level). For a more detailed discussion of this notion: J. Rawls, *supra* note 61, at 311 et ss.; F. Peter and T. Evans, *supra* note 72, at 28; T.W. Pogge, "Cosmopolitanism and Sovereignty", *supra* note 84.

[299] C.R. Beitz, *supra* note 83. T. Christiano, "Democracy and Distributive Justice" (1995) 37 *Arizona Law Review* 65-72.

[300] T. W. Pogge, "Severe Poverty as a Violation of Negative Duties", *supra* note 278. at 59.

have a duty to redistribute such goods to more deprived states to help them meet basic and important needs with distributive justice.[301] This could be accomplished through the establishment of institutional arrangements integrating other non-state agents involved in genetics, like multinational companies, universities, and everyone who elects governments at the head of states, who are unlikely to self-regulate toward this end. Shue identifies those who have a primary duty to aid (*the affluent*) as the ones who spend a lot in the satisfaction of preferences as compared to rights fulfilment.[302] Nonetheless, exploring the details of the potential political actions for the assignment of duties to the affluent in this context would be outside the scope of this chapter.

The next two subsections introduce two types of obligation that have been suggested as normative grounds for a global distribution of benefits and resources.

2.2.2.3. Rawls' duty of assistance

As discussed above, Rawls' theory of justice as fairness establishes principles of distributive and egalitarian justice that apply only within individual states, which represents a circumscribed context of social cooperation from which rights and duties arise. Even though we already provided a critique of this aspect of Rawls' theory of justice earlier, it appears important to return to it here as one of the main proposition for distributive actions. Rawls' ideal of justice requires fair equality of professional opportunities between individuals with similar skills and talent and accepts inequalities as long as they are to the greatest advantage of the least well-off members of society. However, Rawls does not subscribe to the same standards of justice in the global context. Instead, he argues for a duty of assistance toward burdened societies, as stated in principle 8 of the *Law of People*: "peoples have a duty to assist other peoples living under unfavorable conditions that prevent their having a just or decent political and social regime."[303] This system of transfers and mutual aid aims at

[301] C. Jones, *supra* note 78, at 70.
[302] H. Shue, *Basc Rights*, *supra* note 245, at 119.
[303] J. Rawls, *supra* note 82, at 107, 115-119.

bringing those societies above a minimal threshold where it becomes possible for them to satisfy their people's needs with just and decent domestic institutions. It does not, however, impose any restriction on the distribution schemes that should govern the global structure of internally well-ordered societies. According to this view, global inequalities in distribution, poverty, and wealth are meant to be dealt with internally by each domestic structure, which leaves the global level unaddressed. Those who oppose endorsing a global distributive mechanism toward the least fortunate indicate that it would ask too much on the part of those countries that are more organised, careful, and productive and that behave and invest more responsibly and reasonably.[304] This is why they call for a well-circumscribed duty of assistance, with a clear objective and cut-off point instead of the establishment of international institutional mechanisms for distribution. The duty of assistance seems to derive from the importance of expanding the Society of People to include every society in the world; in so doing, Rawls completely avoids the notion of global distributive justice. Such duty of assistance does not entail the obligation to reduce inequalities among individuals living in societies with different endowments of natural or human resources, different histories, or different cultures.[305]

Rawls' duty of assistance is not sufficient and can be criticised on various grounds. This duty to aid is not qualified as a collective responsibility of well-off societies and there is no mention of a right of the less-advantaged to receive any benefits. Rawls does not provide much detail on the scope of this potential duty, making it seem more like a vague "duty of charity" than an obligation of justice as described earlier.[306] By not endorsing global distributive principles for the reason that it would result in some states bearing some costs that arise from decisions made by others,[307] it emphasises the negative aspects of the internal structure, culture, and tradition of less-advantaged countries. As discussed above, and bears repeating, the ability of a society to reach a higher stage of development and address internal inequities is not

[304] A. Buchanan, *supra* note 25; W. Hinsch, *supra* note 137.
[305] C.R. Beitz, *supra* note 83.
[306] A. Buchanan, *supra* note 25
[307] J Rawls, *supra* note 82, at 74-77 and 105.

only a result of voluntary economic and political choices at the domestic level, but is also a direct consequence of its natural resource endowments and situation in the international political economy.[308] Indeed, Rawls' duty of assistance does not protect poor societies from the international terms of cooperation imposed through negotiations that are greatly affected by the unbalanced bargaining power that marks the basic global structure. His account is misleading since it emphasises lack of assistance to the deprived rather than questioning the justness of the global order that is imposed by the most wealthy and powerful.[309] Rawls seems to recognise this issue as he mentions that the "unjustified distributive effects" of cooperative organisations need to be corrected, but he does not go further, instead endorsing a duty of assistance that does not allow such correction.[310] Rawls' fear over "open-ended" redistributive initiatives should not prevent any sort of distributive commitment, since limited egalitarian principles can be adopted to constrain inequalities in specific spheres of importance, such as health and basic needs.[311]

Furthermore, the cosmopolitan focus of this thesis demands that we consider each individual as a standard of moral concern, but Rawls' duty of assistance does not permit such consideration. It instead allows the major health and welfare gap between individuals living in different countries of the world to persist. By emphasising the responsibility of burdened societies as a rationale for a limited and simple duty of assistance, Rawls does not acknowledge that most individuals living in those societies have no power whatsoever over poor investments. In fact, the conduct of an irresponsible country is often dictated by a few elites who act alone, without their population's assent or participation. It is therefore difficult to conceive how previous, current, and future generations could be held responsible for those choices.[312] As we clearly cannot rely on Rawls' duty of assistance to support our moral framework of global distributive justice, some have instead proposed to extend Rawls's difference principle to the global context as a basis for obligations of justice.

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[308] A. Kuper, *supra* note 168.
[309] T.W. Pogge, "Cosmopolitanism and Sovereignty", *supra* note 84
[310] J. Rawls, *supra* note, 83, at 43 and 115.
[311] For example, refer to A. Buchanan, *supra* note 25.
[312] C.R. Beitz, *supra* note 87.

2.2.2.4. Rawls Difference principle applied globally

Some argue for a global application of Rawls' difference principle as a normative tool for a theory of global distributive justice. In his *Theory of Justice*, Rawls argues that rational individuals who would position themselves behind a "veil of ignorance"[313], after ensuring equal distribution of basic liberties, would choose two basic principles to govern distribution in their institutions: equality of opportunity (professional) in priority and the difference principle (difference in social primary goods such as wealth, power, income, and the social base of self-respect are to be justified only if they make everyone better off and are to the greatest advantage of the least well-off). This test aims at identifying principles that will promote the good of individuals as equal moral entities. Rawls uses this contractual test to develop our traditional notions of moral obligation, express the inherent moral standing of persons, and negate differences in bargaining power.[314]

Unlike a duty of assistance, the difference principle gives rise to a duty to eliminate existing inequalities in order to comply with an egalitarian principle of justice as opposed to satisfying claims of need to reach certain limits, beyond which limits no more equalisation would be required. The difference principle calls for transfers on purely egalitarian grounds. Endeavours of high importance and the realisation of special values and the meeting of basic needs are not taken into consideration by the application of the difference principle. Its aim is mainly to minimise unjustified inequalities.

Rawls developed the difference principle in the context of his theory of domestic justice as fairness and, in his opinion, it should only apply to the distribution of wealth and income within societies. However, as demonstrated at the beginning of

[313] A fictional position where they would know neither what type of society they would live in nor their place and position in this society
[314] W. Kimlicka, *supra* note 89.

this chapter, in the actual global structure, boundaries do not establish and limit the scope of social cooperation; they should therefore not restrict associated social obligations. We believe that the statist perspective of the world has lost its normative significance due to the rise of global economic interdependence. Consequently, some argue that the distributive responsibility of states should simply represent a continuation of our general duty of justice at the global level. According to this view, the difference principle adopted in the domestic context would also be selected as a standard of justice in the global context where, due to an extended veil of ignorance, issues of citizenship would not be taken into account.[315] As a result, a just global distribution of social primary goods that could be distributed by social institutions (like income, wealth, powers) would have to maximise the absolute position of the least privileged individuals and societies of the global order.

As discussed above, in Rawls' view, the less advantaged position is determined in terms of individuals' possession of primary social goods, as opposed to natural primary goods like health, opportunities, and natural talents. Health should therefore be regulated by the baseline principle of equality and equality of opportunity as discussed above. Some have suggested instead that inequalities in health that are influenced by wealth should also be justified by the difference principle; others endorse the premise that natural primary goods and endowments should also be taken into consideration in the definition of the least-privileged.[316] If we take those views and consider that health inequalities should not just be analysed with the principle of equality of opportunity but also pass the difference principle test, an application of Rawls' *maximin* difference principle to health concerns would therefore require the prioritisation of the least-favoured groups in society in terms of health conditions or the improvement, with social policies, of the health of the poorest members in society. To determine if a difference principle applying to natural goods would provide an appropriate solution to health inequalities created by the application and distribution of new genetic applications, we need to identify the *least well-off*. With

[315] C.R. Beitz, *supra* note 55; C. Jones, *supra* note 78; W. Hinsch, *supra* note 137.
[316] S. Marchand, Daniel Wilker & B. Landesman, *supra* note 210; W. Kimlicka, *supra* note 89.

Rawls' theory, health is not a criterion for determining the position of an individual, but wealth and income are. The application of this reasoning might lead to a desirable outcome in our process of aiming at a global distribution of the genetic-innovation benefits. If we take the criterion for the identification of the least privileged globally to be poor health due to class inequality, this group would likely comprise a majority of individuals from developing countries. It would thus mean that global inequalities in the distribution of the genetics-research benefits and the investment of research funds could be justified under the difference principle if they would improve, even very slightly, the situation of those living in developing countries. Is this really what we are aiming at? Would this kind of solution allow every individual's genetic needs to be met globally?

The scope of the underlying elements of the difference principle remains very unclear. It gives no precise indication of the conditions to meet in order to be part of the least-privileged group and does not detail what is required to attain the *greatest benefit for the least-advantaged group* threshold. Therefore, in the case under study, it appears that the application of the difference principle could allow leaving many sick individuals (for whom access to genetic innovations could make a difference) outside of the redistribution scheme depending on the interpretation of the difference principle. In fact, the reason transfers to the least privileged are required is not to enable them to realise specific values or to meet specific crucial needs, but to minimise unjust inequalities.[317] For example, individuals affected by health problems in a difficult socio-economic context, but not necessarily falling within the world's least privileged group (for example, people living in middle income countries), could be left out of the distribution process.[318] In fact, a *maximin* principle like the difference principle could justify giving priority only to the least privileged as opposed to a focus on all class inequalities in health.[319] Also, the "worse off group"

[317] W.Hinsch, *supra* note 137.
[318] T. Nagel, *Mortal Questions* (Cambridge: Cambridge University Press, 1979) at 122-130; A. D. Williams, "The Revisionist Difference Principle" (June 1995) 25:2 *Canadian Journal of Philosophy* 257, at 280.
[319] S. Marchand, D. Wilker & B. Landesman, *supra* note 210, at 461.

could be interpreted as those who have the most urgent and serious health conditions without any reference to socio-economic conditions. Such an interpretation could also leave many individuals in need of the benefits of genetic therapies outside of the realm of distribution.

The application of the difference principle could also allow major differences in access to genetic services and technology to persist. In fact, the standard of the difference principle does not require equality, but only an absolute improvement of the situation of the least well-off to justify inequalities. It does not ensure that the basic needs of the least well-off will be met and that they will be able to flourish as human beings. Therefore, major global inequalities in access to genetics could be tolerated given the observation of an absolute improvement of the situation of the globally less-privileged group. In fact, the application of the difference principle can result in the reward of productivity and wealth and the endorsement of a hierarchy between individuals and societies, provided only that the less-privileged agents also receive some benefits. For example, limited access to available genetic technologies by some very poor populations in need could be seen as sufficient improvement in the actual situation of the global least-privileged, which could consequently justify unequal distribution and access to genetic benefits more generally by the affluent. As Shue demonstrates, this aspect of Rawls' theory does not provide everyone the means to keep their heads above water; what it does is merely allow people to "continue to drown but with less and less water over their heads."[320] It is thus safe to say that the economic order created by Rawls' theory is characterised by free bargaining and the improvement of the wealthier societies' position. As such, it is open to criticism for the above mentioned reasons, even if it prevents the most disadvantaged from falling below a certain minimum threshold.

Since a number of global inequalities in health could be left unaddressed by the application of the distributive duties generated by the difference principle, it is not part of our ideal approach as it stands now. This takes us back to our concept of

[320] H. Shue, *Basic Rights supra* note 245, at 128.

justice in health and to the right to equality of opportunities. As argued above, the right to equality of opportunities and the corresponding duties of the affluent to give aid provide a better rationale for distribution as compared to a duty of assistance, charity, or beneficence. Moreover, Rawls gives priority to this notion before addressing acceptable inequalities with the difference principle. This means that ensuring individuals are brought to an appropriate level of normal functioning, to make sure they can profit from available opportunities, should not be compromised by inequalities permitted by the difference principle. In other words, attaining normal functioning to be in a position to benefit from equality of opportunities is a priority, and is therefore supposed to be protected against interferences from inequalities persisting with the application of the difference principle.

However, as mentioned earlier, since a just system involves many requirements in various areas and because of the reality of limited health resources for unlimited health needs, real and universal equality of opportunity remains out of reach (for now) at the non-ideal level. Although we focus on an ideal framework of justice, we can say that intermediate standards will be needed at first, to allocate scarce resources to our health justice ideals. As health can be influenced by social primary goods like wealth and income, an intermediate distributive standard could take the form of a modified difference principle with a special focus on basic needs, as proposed by Doyal: "Rawls's difference principle should be expanded to state that inequalities will only be tolerated to the extent that they benefit the least well-off through leading to the provision of those goods and services necessary for the optimisation of basic need-satisfaction."[321] Similarly, others have proposed, instead of focusing on the least well-off, that health-resource distribution should favour individuals who are below a threshold level of health. This system would not require achieving equality in health, something that appears impossible given the current high level of health in industrialised countries, but would require that no one remain below this acceptable minimum level of health. This global threshold

[321] L. Doyal & I Gough, *supra* note 92, at 132.

would be defined in light of existing medical technology.[322] These propositions avoid the troubling possibility of having to trace a line between the absolute worst-off and others who are not part of the least-healthy category but should nevertheless have their basic health needs taken into account when undertaking distribution of health and genetic resources. In referring to a basic need for health and a threshold level of health, these new versions of the difference principle would secure, in priority, a distribution of health and genetic resources for the people who need them to meet their basic needs.

As our basic claim is to argue for more equitable distribution of resources to vulnerable populations globally, taking need and normal functioning into account, these propositions are a good starting point to meet our goal. Ideally, however, we believe that just distribution should go one step further and consider needs and normal functioning in their broader context, as influencing the fair range of opportunities that should be available to every individual.

Conclusion

In this chapter, we provided an analysis of the specificity of health as the central part of our framework of distributive justice. We first emphasised the importance of health and genetics in normal functioning and then the role of normal functioning in allowing individuals to profit from equality of opportunity. After having established that fair distribution was required in this field, we addressed if and how it should be undertaken, analysing correlative rights and obligations. As a result, we were able to build a solid argument for the use of distributive justice mechanisms to solve avoidable health inequalities and foster equitable access to the benefits arising from genetics.

[322] A. K. Acharya, *supra* note 5; T. Nagel, *supra* note 318, at 125.

More generally, we dedicated the first part of this dissertation to the construction of a global distributive justice framework to serve as a basis for more equitable access to health and genetic care, benefits, and resources. In this ideal moral scheme, individual's health interests receive equal consideration for the pursuit of equal opportunities.

This ideal conception of justice could be criticised on the ground that it demands unrealistic health standards that cannot be incorporated into the current global order. This critique emerges from an institutional conception of justice that starts from the actual world structure, characterised by existing states, territorial boundaries, and strong power differences. It does not try to change or eliminate it, but instead aims to discover how we can continue to support it with a different focus, one that takes principles of justice into account.[323] To justify their focus on the national structure, proponents of this view argue that the institutional arrangements that can help develop the basis for cooperation, that can allow political coercion and initiate shifts in the distribution of wealth and power, are often provisional and insufficient at the international level. Some are even talking about democratic deficits and lack of accountability on the global scene, due, in part, to state differences and mostly to the growing presence of powerful non-state actors. The existing state system and international order, their capacity to integrate structural changes and interact together, and the main actors in charge of shaping and controlling them are important aspects of the actual political reality that need to be considered. Moreover, they believe that enforcement mechanisms for compliance with minimal international redistributive policies are lacking. For example, the United Nations has failed to convince the affluent to supply as little as 0.75% of their gross national products for international development initiatives.[324] For them, it is

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[323] Such view has been qualified as an institutional form of an ideal theory since it does not take non-ideal conditions for granted, but instead aims to find justifications for existing institutions, taking ideal circumstances into account. It is different from the ideal theory we argue for. In fact, our primary goal is not to justify the existing institutions, but to determine how best to meet our global distributive justice ideals in health, preferably but not necessarily within the actual institutional structure. M. Blake, *supra* note 121, at 262-264.

[324] C.R. Beitz, *supra* note 55; *Towards Accelerated Development--Proposals for the Second United Nations Development Decade* (United Nations Publication, E.70.II.A.2, 1970); UN Committee for

therefore important to understand that in order for the concept of ideal justice to have some practical application, it will inevitably be constrained by the institutional reality of the world.[325] Indeed, those who express scepticism about an ideal account of justice believe that it might be incompatible with reality, more specifically with the political account of how the present system of international economic inequality came into existence, whose interests it serves, and how it can effectively be adapted or changed to serve the interests of the poor and deprived.[326] As Onora O'Neill states, "knowing that some distribution (equal, maximin, or what-ever) of resources, or of health care, would be *ideally* just does not take us far toward knowing who should do what for whom in order to work toward that distribution."[327]

We believe in the relevance of an ideal theory of justice. As mentioned at the very beginning of this first part, we consider that it is of the utmost importance to get a sense of first, what we are setting aside when agreeing to non-ideal conditions and second, how we can envision social reforms. To this effect, Thomas Pogge states:

> Realism hardly requires that the principles of justice conform themselves to the prevailing sordid realities. We don't feel justified to give up our ideals of domestic justice or personal honesty just because we despair of achieving them fully. We cannot reasonably demand of moral principles that they vindicate the status quo. All we may ask is that a conception of justice provides a criterion for assessing our global order that allows us to choose from among the feasible [...] avenues of

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Development Policy, The role of the Committee for Development Planning (CDP) in the formulation of the United Nations International Development Strategies (for the 1970s, 1980s and 1990s) and a Summary of CDP's Main Recommendations for those Strategies, CDP/2000/PLEN/10, 20 March, 2000, online on the UN website: <http://www.un.org/esa/policy/devplan/cdp00p10.pdf> (accessed: May 17th, 2006).

[325] For example, the structure and functioning of TRIPS is a reality of the global order and could have negative impact on developing countries' welfare and development. We will be coming back to this specific system later in the dissertation, but for a discussion on this point refer to: J.H. Reichman, *Implications of the Draft TRIPS Agreement for Developing Countries as Competitors in an Integrated World Market*, UNCTAD Discussion Papers no. 73 (UNCTAD/OSG/DP/73, November 1993); A.S. Oddi, "TRIPS: Natural Rights and a Polite Form of Economic Imperialism" (May 1996) *Vanderbilt Journal of Transnational Law* 29

[326] C. Brown, *supra* note 61, at 180.

[327] O.O'neill, *supra* note 1.

> institutional change and thus specifies our moral task—gradually to improve the justice of this order.[328]

By focussing on establishing ideal principles of justice in health, we acknowledge that the existing order is not completely static and unalterable. Indeed, the global order paradigm is less than 60 years old, and this might mean that "changes can be achieved through human agency in response to changing times."[329] This is especially true in the sphere of health, where it has become quite clear that individual and isolated actions and initiatives for improving human health are not providing the sustainable changes required at the global level. As such, one of the biggest challenges is a shift in perspective from economic self-interest to growing solidarity and a shared spirit of mutual caring.[330] There is no reason to think that such changes of perspective would be impossible. Indeed, it is interesting to observe how much institutional change has been achieved over a relatively short period of time. Many of the most influential institutions in the world have appeared in the last 50 years. In fact, most trans-national corporations, international organisations, banks, and development agencies are new types of actors in the ever-changing global picture. However, the type of transformation we are aiming for is unlikely to take place automatically and voluntarily in a world mainly driven by market powers and self-interest.[331] This is one of the reasons why we do not argue for starting from scratch

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[328] T. Pogge, *Realising Rawls* (Ithaca: NY: Cornell University Press, 1989), at 260.

[329] M. MecGwire, "The paradigm that Lost its Way" (2001) 77:4 *International Affairs* 777, at 793; M. MccGwire, "Shifting the paradigm" (2001) 77:1 *International Affairs* 1.

[330] R Rorty, *Contingency, Irony and Solidarity* (Cambridge: Cambridge University Press, 1989); S.R. Benatar, A.S. Daar & P. Singer, *supra* note 182, at 122.

[331] Many have proposed practical initiatives to reunite the ideal theory with the non-ideal reality. We will come back to some of them in the thesis conclusion, to set the basis for further discussion. For example, some have proposed a very egalitarian solution to the issue of access to health care resources and genetic services and technologies, arguing that their use should be banned unless they can be made available to everyone who needs them. This argument is based on the fundamental equality of persons that should entail equal opportunity, respect and treatment. Such position has been endorsed by the Council on Ethical and Judicial Opinions of the American Medical Association with regard to the availability of genetic enhancement of foetuses and embryos. A. Gutmann, *For and Against Equal Access to Health Care, in Securing Access to Health Care, ed. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research* (Washington, D.C: U.S Government Printing Office, 1983) at. 53; American Medical Association, Council on Ethical and Judicial Affairs, "Ethical Issues Related to Prenatal Genetic Testing" (1994) 3 *Archives of Family Medicine* 633, at 640-641; S. R. Benatar, A. S. Daar & P. Singer, *ibid* at 119. Others suggest a multilayered institutional scheme in which government authority, instead of being concentrated at the state institutional level, would be dispersed among different political units, and not necessarily

and ignoring the existing institutional order, agreeing instead to work with some of the institutions already in place when major changes can be undertaken to reflect the health equity concerns that constitute our argument.

The purpose of the second part of this dissertation is to present two existing international normative systems and to determine whether their structure and functioning adequately account for, and balance, the many values of the global distributive justice framework in facilitating a future redistribution of potential benefits in the field of genetics. If need be, distributive justice will guide the critique of the actual framework and the reconstitution of the ground rules that should regulate property, cooperation and exchange, as well as conditions of production and distribution.[332]

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constrained by existing historical borders. Therefore, spreading authority over different units could reduce the incidence of poverty and oppression, factors that to often shape the actual state of the world order. In a sense, the adoption of political agencies that properly control different spheres of human action, not all territorially-based, is an alternative to both a world state and a state-dominated system. T.W. Pogge, "Cosmopolitanism and Sovereignty", *supra* note 84; A. Kupler, *supra* note 83. Thomas Pogge also proposes a transfer of one percent of the affluent class' gross domestic product to worse-off states, as well as a global resource tax—two options that have been criticised and which in any case would be interesting to investigate further. T.Pogge, "Eradication Systematic Poverty: Brief for a Global Resources Dividend" (2001) 2 *Journal of Human Development* 59; T.Pogge, "A Global Resources Dividend" in D.A. Crocker & T. Linden, eds., *Ethics of Consumption: The Good Life, Justice, and Global Stewardship* (Lanham, Md.: Rowman and Littlefield, 1997); G. Screenivasan, "International Justice and Health: A Proposal" (2002) 16:2 *Ethics and International Affairs* 81.

[332] T.W. Pogge, *supra* note 84, at 97.

PART II: SOME NORMATIVE TOOLS FOR DISTRIBUTION IN HEALTH

How does our normative theory of distribution translate into positive law now? The cases of intellectual property and international human rights law

The first part of this dissertation established clear normative landmarks to assess how equitably the world distributes health and genetic benefits. It set out an approach that gives equal consideration to everyone's basic health needs, adopting a cosmopolitan approach where individuals are treated with the same consideration regardless of their citizenship or geographical location. We then reflected on the universal importance of health, its vital role in normal functioning and in the pursuit of equal opportunity for all. This analysis led us to establish a global distributive justice framework in health which supports our argument for equitable access to the benefits arising from genetic advances, taking basic health needs and opportunities into account. This framework represents the theoretical basis that was needed to justify our interest in every individual's basic health needs and our focus on equality of opportunity for all.

Now that we have built those foundations, we can begin discussing how this normative approach to distribution translates (or not) into positive law. To this end, we will identify and analyse the main obstacles to legal compliance with global distributive justice in health and genetic research. This will be the main goal of the second part of this dissertation.

Although many spheres of law can be applicable and useful when dealing with the different issues emerging from the development of genetic science, we decided to concentrate on the two that appeared most relevant and important to addressing distributive justice issues in health: intellectual property law and human rights law. Not only are these two legal systems discussed extensively in the literature, they are also very important in the global normative picture in their own different ways—especially in terms of access and equity issues. Therefore, the next two chapters will

aim to present and analyse the international intellectual property and human rights systems, assessing their underlying philosophy, construction, and application with the precise benchmarks of justice established in our theoretical framework. In other words, we will assess whether these legal systems help or hinder access to health and resulting equality of opportunities using different lenses of analysis, such as the global aspect of access and different units of measure, like availability and affordability.

This analysis will help us identify important weaknesses of these legal frameworks and to realise that, although of very different nature, they are both greatly influenced by powerful agents and market factors which undermine their focus on justice and equity issues. Following the analysis of the conceptual links existing between the two legal systems and real access to health, the third and last chapter of this second part will introduce practical examples to better understand how the systems interact, how they perform together and how the conceptual weaknesses identified in the two previous chapters translate into real-life situations.

Chapter III: International Intellectual Property Law: A First Tool?

Introduction

In the last section, we set the theoretical basis of our argument in constructing a global distributive justice framework that can serve as a foundation for equitable access to health and genetic research benefits and resources. In this context, we argued for the equal consideration of everyone's health needs for the purpose of securing equal opportunity for all on the global scene.

The aim of this chapter is to determine whether the foundation, structure, and purpose of the existing intellectual property law system, and especially patent law, assists or hinders the realisation of global distributive justice in health and genetics. More specifically, an analysis of the IP system will be provided in order to determine whether it adequately considers and accounts for the moral principles underlined by our global distributive justice framework.

We will commence with a brief introduction to intellectual property rights, in particular, patent law and its application to genetics. The second part of this chapter aims to present and provide a succinct analysis of some of the main theoretical foundations brought forward for justifying property rights on intellectual inventions. The third section assesses the patent system in referring to considerations of distribution, equality, and justice. An evaluation of the patent system by reference to the standard of access (global access to resources, availability and affordability of products and services) shall be provided in order to establish whether the international patent system can serve the purpose of global distributive justice.

Introduction to Intellectual Property

Property rights are used as legal and political tools to help ensure social order, structure, and harmony in communities. They translate the connection between property holders and non-holders into enforceable legal rights. Through this system, objects of property can be viewed as articles that can be traded in the market, providing property owners with some degree of economic power.[333] In this sense, *property institutions fundamentally shape a society.*[334] Property rights can be associated both with tangible and intangible and intellectual objects. These are referred to as intellectual property rights (IPRs), and can be defined as rights in original ideas included in tangible products of cognitive effort, which give IP holders a legal right to exclude people from making use of their property in exchange for a public disclosure of the object of their right.[335]

Intellectual property has increasingly become a prevalent form of ownership and signifies a very valuable asset for many IP holders worldwide. In fact, the economic significance of IP in the global market represents hundreds of billions of dollars and is constantly growing.[336]

Although intellectual property refers to different forms of legal protection (patents, copyrights, trade secrets, trademarks, etc.), some general features are common to all forms of IP. For example, the object of intellectual property is intangible, and is therefore non-exclusive; that is, it does not disappear after it has been used or shared. In other words, the possession or use of any intellectual object by one person does not

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[333] C. May, "Unacceptable Costs: The Consequences of Making Knowledge Property in a Global Society" (2002) 16:2 *Global Society* 123; A. McEvoy, "Market and Ethics in United States Property Law" in H.M. Jacobs, ed., *Who Owns America? Social Conflict Over Property Rights* (Madison : University of Wisconsin Press, 1998) 94, at 99.

[334] E.C. Hettinger, "Justifying Intellectual Property", in A.D. Moore, ed., *Intellectual Property: Moral, Legal, and International Dilemmas* (Maryland: Rowman & Littlefield, Lanham, 1997) 17, at 27; J. Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (Cambridge and London: Harvard University Press, 1996).

[335] J. Hugues, "The Philosophy of Intellectual Property" (1988) 77:13 *Geo. L. J.* 287, at 294-296.

[336] J. Boyle, *supra* note 334, at 121; L. G Thurow, "Needed: A New System of Intellectual Property Rights" (Sept-Oct 1997) *Harv. Bus. Rev.* 95, at 96-97.

prevent others using or possessing it concurrently. Hence, in order to enhance the dissemination of ideas (copyrights and patents) or to encourage the creation of proprietary information (trade secrets), IP artificially creates scarcity. In fact, it allows holders to exclude people from using their intellectual objects even if simultaneous uses by a multitude of individuals would be possible without additional cost or risk of overexploitation.[337] Another particularity of intellectual property that differentiates it from material property is the temporal limits associated with the rights awarded. In most cases, IPRs are granted by states for a fixed period, after which the objects of IP become freely available to the community as part of the public domain.

The protection awarded to intellectual property in the field of human genetics is mainly established in patent, trade secrets, and copyright systems. Before addressing patent issues, which will be the focus of this chapter, it is necessary to briefly discuss the application of copyright and trade secrets to genetics.

A copyright is a right granted to the author of some original work (literature, films, songs, etc.) on the expression of his ideas (and not the ideas per se). A copyright allows its owner to reproduce the work, distribute copies of it, display it, and inhibit others from copying it in whole or in part for a limited period of time, which varies between 50-70 years following the death of the author. Copyrights arise automatically without registration procedure or fees. There is considerable copyrightable material involved in the field of genetics. Indeed, since the outcomes of DNA sequencing are often used as an information storage base for future breakthroughs, and require substantial and lengthy further analysis, it is safe to say that there is a great informational potential and value in some unique collection of DNA sequences. Copyright law can be used to protect the value of some original compilations of results arising from genetic research including and not limited to a gene sequences database, a list of single

[337] E.C. Hettinger, "Justifying Intellectual Property" in P. Drahos, ed., *Intellectual Property* (England: Darmouth Publishing, 1999) 117.

nucleotide polymorphisms (SNPs), a diagram of the order of the fragments on some molecules, etc.[338] Since most genetic research data is collected in databases of different forms, many genetic and genomic compilations qualify for copyright protection and can therefore be subject to access and subscription fees.[339] However, as numerous other aspects of genetic research do not give rise to copyrightable material, we must turn to other IP protection regimes.

A trade secret is used to protect the confidentiality of important and valuable business information. Trade secrets should not be known within the industry, since the exclusivity of the information is what provides considerable advantage to the secret holder over competitors. Moreover, trade secrets encourage the production of proprietary information by offering protection against its misappropriation.[340] The same subject matter protected by trade secrets could instead be patented or copyrighted; the choice of one protection regime over another is a matter of business strategy. Trade secrets do not have to be publicly disclosed (they must remain secret), and they can last as long as they stay confidential. One problem with trade secrets, however, is that once the object of the secret is revealed, disclosed, or figured out, anyone can use, reproduce and sell the invention or process without any restrictions from the trade-secret holder. For example, if a computer hacker deciphers how to access the secret and then steals it; or if there is a leak from inside and the secret is revealed; or if someone invents, discovers, or creates the equivalent of the secret's subject matter independently, the system of trade secrets could be invoked to claim reparation from the thief for breach of security, or the employee for breach of trust and confidentiality. Nothing, however, could prevent the public from freely making use of the revealed secret.[341] This is probably one of the reasons why the use of trade secrets is not widespread in the

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[338] H. Haker, R. Hearn & K. Steigleder, *Ethics of the Human Genome Analysis* (Germany: Attempto Verlag Tubingen, 1993) at 112.
[339] R. S. Eisenberg, "Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences" (2000) 49 *Emory L. J.* 783.
[340] T. A. Lipinski & J. Britz, "Rethinking the Ownership of Information in the 21st century: Ethical Implications" (2000) 2:1 *Ethics and Information Technology* 49.
[341] R. Merlin-Bennett, *Knowledge Power, Intellectual Property, Information and Privacy* (London: Lynn Riender Publishers, 2004).

field of biotechnology and genetics, where keeping secrets can prove quite difficult. Since a great deal of genetic research involves the use of similar technologies, and aim to isolate and identify the same biological functions of the same genetic elements, chances are that different research teams could, at a certain point, independently and accidentally produce identical results. Unless the object of the secret is completely novel and original in the sense that it has no equivalent in the natural world, researchers will often be capable, over time, of finding out the subject matter of a trade secret by replicating it from material existing in nature.[342] Therefore, given that genetic research and innovation often involve huge investments in terms of time and capital, it is unlikely that the majority of inventors and authors would risk protecting their ideas through the trade secret regime.

This leads us to a third system of IP protection: patents. In the field of genetics, this is certainly the preferred legal system for protecting genetic inventions, investments, and benefits, due to the broad scope of application and the important financial returns associated with patents. The following section will present the patent system as applied to the field of genetic development, addressing some ethical debates raised by gene patents and discussing the national and international aspects of the patent system.

3.1 The Patent System

Genetic research and development is a field giving rise to substantial ethical and legal debates, among which patents are one of the most litigious issues.[343] A patent is a third form of IP right granted to an inventor over his invention, which qualifies as patentable under certain conditions. The patent gives him the right to exclude other people from using, making, importing, or selling his inventions for the duration of the

[342] D. B. Resnik, *Owning the Genome: a Moral analysis of DNA Patenting* (Albany: State University of New York Press, 2003).
[343] A. Finlay, "Gene Patenting: Seeking Benefits for All" (2003) 82 *Reform* 52. at 53; J. P. Hinojosa, "The Human Genome, Property of All: Opportunities Under the ALRC Inquiry into Gene Patenting and Human Health" (2004) 26 *Sydney Law Review* 447.

patent, in exchange for wide disclosure and publication of a detailed description of his invention. In this sense, patent rights reveal a natural tension between dual roles: protection and dissemination. [344] To be patentable, an invention (products or processes) must be new (not previously patented or published), involve an inventive step (non-obvious improvement of what already exists), and be capable of industrial application (useful).

The main purpose of awarding exclusionary rights to someone for an eligible invention is to allow the patent-holder to recoup the time and funds invested in developing the invention and, subsequently, to encourage more innovation.[345] Patents raise the issue of monopoly power, as they allow patent owners to have some control over prices and productivity.[346] Patent rights thus create an exception to the principle of free enterprise, competition, and availability of information on the basis that they are meant to promote further technological progress and innovation.[347] In addition, they could prevent significant profit losses by restricting imitation.[348] In other words, some believe that the patent system, by imposing temporary restrictions on widespread use and access to knowledge, information, and ideas, has an important role to play in boosting the production of crucial knowledge and innovation in biotechnology, genetics, and health.[349] In the field of genetics, translating scientific

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[344] J. Boyle, "A Theory of Law and Information: Copyright, Spleens, Blackmail, and Insider Trading" (1992) 80 *California Law Review* 1415, at 1440.

[345] The amount of money invested in the development of an invention can be very high in certain fields of activity. These funds can be used to cover the costs of R&D, make up for ineffective trials, and get the necessary regulatory approvals. The exact amount invested varies depending on the sector and the companies, and can be as high as several hundred million dollars to develop and market a single drug. For more on R&D investments refer to: M. Mowzoon, *supra* note 18; J. C. McGlynn & G. Heidrich, "Biotech Financing Remains a Tough Row to Hoe" (1995) 13 *BIO/TECH* 638; G. Carr, "A Survey of the Pharmaceutical Industry: The Alchemists" (Feb. 21, 1998) The *Economist* 4; F. S. Kieff "IP Transactions: On The Theory & Practice of Commercializing Innovation" (2005) 42:3 *Houston Law Review* 727.

[346] M. Trebilcock & R. Howse, *The Regulation of International Trade* (New York: Routledge, 1995) at 249.

[347] E. R. Gold, "Finding Common Cause in the Patent Debate" (2000) 18 *Nature Biotechnology* 1217; M. Mowzoon, *supra* note 18; M. Trebilcock & R. Howse. *The Regulation of International Trade* (New York: Routledge, 1995), at 249.

[348] H. Grabowski, "Patent, Innovation and Access to New Pharmaceuticals" (2002) *J. of Int'l. Eco L.* 849, at 850; M. Trebilcock & R. Howse, *supra* note 346, at 250.

[349] For proponents of this position, the benefits of patents vis-à-vis innovation and development prevail over the cost of exclusivity for society. To illustrate this point, one author refers to the example of granting patent rights over the cure of cancer, arguing that while it may sound outrageous that a

discoveries into useful therapeutic products and services can be a long, complex, and expensive process. Additionally, the economic value of patents awarded in this field can be very high.[350] Thus, many acknowledge the potential advantages of granting patent protection in this field to stimulate investment and encourage further developments in an area with tremendous promise for global health.[351] One reason given to justify the importance of patents in genetics and biotechnology is the major difference between the costs of innovation and of imitation in these specific fields of scientific activity.[352] It is important to mention, however, that others still consider there to be very little empirical evidence sustaining this incentive theory, which furthermore refers only to a small subset of the whole of innovation.[353] We will return to this specific point throughout this chapter.

Even after more than 20 years of existence, patents on genetic material are still at the center of a number of social policy dilemmas, particularly on the very nature of genes and their capacity to qualify as patentable material in relation to the basic patenting rules. Nevertheless, the current international legal consensus is that isolated human genetic material is patentable. In fact, claiming strong proprietary rights in genetic material has been a widespread practice since the early 1980s[354] and, in the majority of countries, none of the ethical and social concerns voiced by various stakeholders have changed this permissive approach. Instead, we have witnessed an explosion of human genetic patent applications in terms of quantity and diversity in the major

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company could gain exclusive rights over such a crucial matter for 20 years, without a patent inducement, it could take hundreds of years longer to find the same treatment for cancer. D. L. Burk & M. A. Lemley, "Policy Levers in Patent Law" (2003) 89 *Vanderbilt Law Review* 1575, at 1581; M. Mowzoon, *supra* note 18.

[350] For example, the value of the patent right awarded on the gene involved in producing a hormone used in kidney disease treatment (erythropoietin) is about $1.5 billion a year. L. B. Andrews, "The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs" (2002) 2 *Hous. J. Health & Pol'Y* 65

[351] UNESCO International Committee on Bioethics, *Report of the IBC on Ethics, Intellectual Property and Genomics*, 10 January 2002, SHS-503/01/CIB-8/2 Rev.

[352] R. M. Cook-Deegan & S. J. McCormack, "Patent Secrecy and DNA" (2001) 293 *Science* 217, at 217; B. A. Caulfield, "Why we Hate Gene Patents" (January 2003) *American Lawyer* 51.

[353] E.R.Gold et al., *supra* note 122; S. Macdonald, "Exploring the Hidden Costs of Patents" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 13.

[354] D. B. Resnik, "The Human Genome: Common Resource but not Common Heritage" in *Proceedings from a Frontis Workshop on Ethics In the Life Sciences*, Wageningen University, 2004, c. 13, 197, at 203.

industrialised countries.[355] As of September 2004, over three million genome-related patent applications had been filed worldwide.[356]

Awarding patents in human genetics and especially gene patenting have nevertheless given rise to numerous ethical debates.[357] The main ethical issues generated by patents in genetics will be analysed and re-examined at more length and detail throughout this chapter. For the moment, we can say that many ethical issues arise from the very dichotomy of patent rights that are meant to promote a balance between appropriation/protection (the inventor's rights) and dissemination (the community's rights). Some important issues arising from genetic patents relate to human dignity; access to research, products, and services;[358] and to the suitability of granting exclusive property rights over material embodying essential information for building our common knowledge of human genetics and genomics.[359] Therefore, granting exclusive property rights over genetic material is, for some, equivalent to allowing

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[355] Indeed, in the field of human genetics, it is possible to patent processes like methods for isolating, purifying, cloning, multiplying, changing, examining, and manufacturing DNA. In addition, genetics patents can also be granted on resources e.g. DNA sequences, genes and their end point markers, expressed sequence tags (ESTs) isolated and purified, spliced into recombinant vectors, or introduced into recombinant cells under laboratory conditions. Since DNA sequences are both molecules and information, it is important to determine what is actually covered by exclusive patent rights. Patent rights over genetic composition of matter should give the patent-holder temporary exclusive rights over the material substance of the molecule. However, the very nature of the patent bargain imposes, in exchange for this exclusive right, the disclosure of the invention itself and of information about the nature, functioning, and properties of the invention. The patent system thus allows the public to get access to, use, and analyse this genetic information, with the correlated obligation to respect the inventor's conditions, which can sometimes be very restrictive, onerous, and demanding. For more details, refer to D.B. Resnik, "DNA patents and human dignity" (2001) 29:2 *The Journal of Law, Medicine, and Ethics* 152; W. Cornish, *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (Oxford: Oxford University Press, 2004); B.A. Caulfield, *supra* note 352; J. P. Hinojosa, "The Human Genome, Property of All: Opportunities Under the ALRC Inquiry into Gene Patenting and Human Health" (2004) 26 *Sydney Law Review* 447; R. S. Eisenberg, "Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences", *supra* note 339.

[356] Human Genome Project Information, online HGPI: <http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml> (date accessed: 20 April 2006) "Genetics and patenting, what are patents, and how do they work?"

[357] T. Caulfield, E. R. Gold & M. K. Cho, "Patenting Human Genetic Material: Refocussing the Debate" (2000) 1 *Nature Reviews Genetics* 227; B. M. Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey" (1999) 22 *Nature Genetics* 23.

[358] M. A. Heller & R. S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698; M. R. Henry et al., "DNA Patenting and Licensing" (2003) 297 *Science* 1279; J. P. Walsh, A. Arora & W. M. Cohen, "Working through the Patent Problem" (2003) 299 *Science* 1021; UNESCO International Committee on Bioethics, *supra* note 351.

[359] S. Sell & C. May, "Moments in Law: Contestation and Settlement in the History of Intellectual Property" (Autumn 2001) 8:3 *Review of International Political Economy* 467, at 474.

the commodification and gradual drain of some common asset of humanity and keeping it out of access for subsequent basic research and important screening and therapeutic purposes.[360] Consequently, endorsing private exclusionary rights in such material for a few select, wealthy corporations and countries can lead to substantial health inequalities based on economic considerations. Others defend the view that temporary appropriation of such material is essential to foster subsequent scientific innovation, and that preventing genetic patents would be equivalent to promoting unreasonable use of those resources.[361] Let us examine a few of the major ethical debates arising from patents in genetics.

Human Genetic Material: Patentable Substance?

Gene patents can be awarded in the fields of agriculture, plant breeding, and animal research, as well as human genetics. As previously mentioned, however, our discussion will be limited to patents concerning human genes, genetic sequences, and related genetic material, in addition to patents on technology, tests, and processes relating to human genetics and health. We have stated that, to qualify as patentable, an invention must be new, non-obvious, and useful. There has been an ongoing debate as to whether genetic material should qualify more as discovery or invention.[362] Today, patents are generally conferred on some isolated and purified

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[360] D. Butler, "Drive for Patent-Free Innovation Gathers Pace" (July 10, 2003) 18 *Nature* 424; B.A.Caulfield, *supra* note 352.

[361] .German National Ethics Council, *Opinion on the Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin,* October 2004, Berlin. The dual function of patent law and its effect on distribution and justice in health will be discussed in section 3.3 of this chapter.

[362] Initially, the main issue in gene patenting was whether genetic material that had been manipulated or isolated from its natural environment and purified would be considered patentable material or a product of nature. Some opponents to gene patenting believe that no amount of manipulation is enough to label such material with the title of invention. For example, see: UNESCO International Committee on Bioethics, *Report of the IBC on Ethics, Intellectual Property and Genomics*, 10 January 2002, SHS-503/01/CIB-8/2 Rev; German National Ethics Council, *Ibid.* However, since the US Supreme Court case of *Diamond* v. *Chakrabarry* 447 U.S. 303, 100 S. Ct. 2204 (1980) which decided that a genetically-engineered bacterium was patentable because it was human-made and that "anything under the sun that was made by man" was patentable, very little has not been considered patentable subject matter in the field of biotechnology and genetics. It is now settled as a matter of positive law. For more on this point, see: M. Mowzoon, *supra* note 18, at 1082; T. Caulfield, "Sustainability and the Balancing of the Health",*supra* note 23. Care and Innovation Agendas: The Commercialization of

genetic material, on the basis that human intervention was required to take it from its natural stage and bring it to its new stage. The rule for novelty and non-obviousness in genetic patenting is thus quite broad. Something can be characterised as new and non-obvious when it constitutes a real advancement and its existence was not previously documented in terms of constitution, structure (provided by genetic sequencing), process by which it is obtained, or other relevant criteria.[363]

The main contentious patenting criterion in genetics is nevertheless usefulness or utility. There is an important distinction to make between simple isolation and sequencing of genetic material and going a step further, identifying its practical application and functions. In the fast-growing field of biotechnology and genetics, scientists and institutions are racing to be the first to identify and secure exclusive (and valuable) patent rights over genetic material of interest. Since the human genome is composed of only about 30 000 genes governing millions of other biological substances and proteins, it is likely that most of these genes and gene sequences have multiple functions and interactions that will, with time and effort, gradually be discovered.[364] When exclusive rights are granted over a whole genetic substance in exchange for some limited and incomplete information on its roles, functions, and applications, the patent-holder achieves substantial control over this material at a minor cost. In this sense, broad and vague genetic patents do not fully meet the utility criteria, lead to overcompensation and possible obstruction of research, and can therefore create some inequitable bargain between society and patent-holders. This is why things have changed gradually. We went from a trend of

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Genetic Research" (2003) 66 Sask. L. Rev. 629, at 636; F. S. Kieff, "Property Rights and Property Rules for Commercializing Inventions" (2001) 85 *Minn L. Rev.* 697.

[363] O. Liivak, "The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents" (2005) 85:4 *Journal of Patent and Trademark Office Society* 261; R. S. Crespi, "Patenting and Ethics-A Dubious Connection" (January 2003) *85 Journal of Patent and Trademark Office Society* 31, at 36.

[364] For example, in 2002, scientists announced that they had decoded the genetic sequence of the one-celled parasite that causes most human malaria. The scientists discovered that malaria could involve interactions among 500 of the 5 300 genes identified in the parasite. M. J. Gardner et al., "Genome sequence of the human malaria parasite *Plasmodium Falciparum*" (2002) 419 *Nature* 498; B. A. Caulfield, *supra* note 352.

early patent application on genetic material of very vague and incomplete present and future implications to much more narrow and precise patent claims.[365]

Following this general presentation of the patent system and of the various ethical and legal issues triggered by its application to genetics, it is essential to conclude this section with a few words on the territorial reach of patents, particularly on the international IP system.

National and international patent rights

Patents are territorial rights in the sense that they give the patent-holder a proprietary right over his invention within a given country where he can exclude people from using, selling, and importing his invention. Every country can set up its own patent norms, subject to other conflicting national norms and international rules. Patents are widely enforced in industrialised countries and used more and more in developing nations under constant pressure to develop stronger IP standards. However, this is to some extent a new reality. Most of today's industrialised countries strongly resisted providing and respecting patent rights at the beginning of their economic development. Indeed, over the last century, most were focussed on copying patented

[365] This clearly appears from the United States Patent and Trade Office (USPTO) 2001 guidelines stipulating that any viable genetic patent claim should disclose specific, substantial, and credible utility. USPTO Utility Examination Guidelines Federal Register vol. 66 No 4 January 5, 2001 online on the USPTO website: <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf> (accessed: May 30th, 2006). These criteria have also been applied by the European Patent Office and some developing countries' patent offices; see also M. Enserink, "Patent Office May Raise the Bar on Gene Claims" (2000) 287 *Science* 1196. Moreover, in September 2005, the US Court of Appeals for the Federal Circuit applied those guidelines in an important case on the patentability of expressed sequence tags (ESTs). In this case, the majority decided that, although the claimed ESTs were contributing to biotechnology research, they did not meet the appropriate utility requirement because the claimant did not identify the "function for the underlying protein-encoding genes". In *re Dane K. Fisher and Raghynath* v. *Lalgudi,* United States Court of Appeals for the Federal Circuit, 04-1465 (Serial No. 09/619,643), September 7th, 2005. Judge Rader, however, enounced a dissenting opinion to the effect that the ESTs should be patentable as research tools, because they are useful for isolating and studying other molecules. There is still an ongoing debate about patents on ESTs found in a gene to determine whether they can block the use of the full patentable gene, For more on this debate, see A. K. Rai, "Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff" (2001) 95:2 *Northwestern University Law Review* 707. (F. S. Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai & Eisenberg" (2001) 95:2 *Northwestern University Law Review* 691; J. Doll, "The Patenting of DNA" (1998) 280 *Science* 689.

inventions without paying IP owners.[366] This practice ended very recently, in the 1980s, when the new industrialised countries reached a satisfactory level of social and economic growth, which put them in a position to enforce IP rights nationally. Modern developing countries have not had the same options. Even if they are far behind in terms of development, and if most believe that strong patent rights are not the best solution for their particular economic and social circumstances,[367] both developing and developed countries have to comply with the same standards according to the agreement on Trade Related Aspects of Intellectual Property (TRIPS).[368]

Traditionally, patents were exclusively a matter of national law resulting in substantial differences between countries in terms of level of protection and enforcement processes. In the course of the 1980s, newly industrialised countries began to protest against the weak IP protection system prevailing in developing countries, and to push for increased protection with the creation of a uniform international IP system. Consequently, in 1995 the World Trade Organisation (WTO) was created to strengthen the international trade regime. TRIPS was adopted as part of the multilateral trade agreements signed as the final act of the Uruguay Round of Multilateral Negotiations within the framework of the General Agreement on Tariffs

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[366] On this topic see G. Dutfield, "Turning Knowledge into Power: Intellectual Property and the World Trade System" (2005) 59:4 *Australian Journal of International Affairs* 533, at 544-545; G. Dutfield & U. Suthersanen, "Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History" (2005) 23:2 *Prometheus* 131; C. May, *A Global Political Economy of Intellectual Property Rights, The New Enclosures?* (London: Routhledge, 2000) at 22-44 and K. Maskus, *Intellectual Property Rights in the Global Economy* (Washington, DC: Institute for International Economics, 2000) at 143. More specifically, for an example of what happened in Japan, refer to C. Chien, "Cheap Drugs at What Price to Innovation? Does Compulsory Licensing of Pharmaceuticals Hurt Innovation?" (2003) 18 *Berkeley Tech. L. J.* 853, at 863-864.

[367] A large part of most of developing countries' economies is based on imitation, something that patent law does not allow: K. A. Czub, "Argentina's Emerging Standard of Intellectual Property Protection: A Case Study of Underlying Conflicts Between Developing Countries, TRIPS standards and the United States" (2001) 33 *Case W. Res. J. Int'l. L.* 191, at 191; K. Maskus, *Intellectual Property Rights in the Global Economy* (Washington, DC: Institute for International Economics, 2000) at 148.

[368] *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments–Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994); W. Pretorius, "TRIPS and Developing Countries: How Level is the Playing Field?" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 183.

and Trade (GATT).[369] While one role of the WTO is to deal with TRIPS implementation, enforcement, and related dispute settlement, there is another specialised international organisation established in 1970, the World Intellectual Property Organisation (WIPO), that focuses on administering other existing normative intellectual property documents and on providing technical and legal assistance to countries that need it.

TRIPS' main purpose is to create an international legal structure supporting a set of minimum standards for the protection of intellectual property. All WTO member states have to comply with these legally binding principles as part of the general institutional framework set up under the WTO. This is meant to reinforce the global nature of this single intellectual property system. With its mandatory ratification and its strong and effective enforcement and compliance system, TRIPS creates a unique framework at the international level.

TRIPS supplements the 1883 *Paris Convention for the Protection of Industrial Property* and the 1886 *Berne Convention for the Protection of Literary and Artistic Works,* creating new minimum requirements relating to subject matter, scope, and enforcement of IP by all WTO states.[370] In fact, TRIPS requires all WTO member states to protect patent rights in all fields of technology for a period of twenty years from the application. This does not mean that TRIPS creates one static uniform law for everyone. Instead, TRIPS is meant to establish general minimum principles while leaving flexibility for national differentiated application, depending on specific needs and levels of development.[371] However, the effective

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[369] T. Kongolo, "Morocco's Patent System and its International Connection" (2002) 42 *IDEA: The Journal of Law and Technology* 181; S. K. Sell, *Private Power, Public Law: Globalisation of Intellectual* Property (Cambridge: Cambridge University Press, 2003) at 150-163; C. May, *supra* note 366, at 33.

[370] D.G Richards, *Intellectual Property Rights and Global Capitalism,supra* note 32, at 123-126.

[371] To this effect, par. 6 of TRIPS' preamble mentions *that Member State recognise:* "*the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.*" Examples of such freedom can be found under sections 7 and 8 of TRIPS, which provide member states with a clear legal basis for taking measures that may diverge from generally accepted applications of the agreement by promoting *social and economic welfare, public health, nutrition, and public interest in sectors of vital importance* with the important restriction that those

ability of countries to take advantage (or not) of this freedom depends on various factors including external economic and political pressure, internal politics, local capacities, and limitations in terms of science and technology development, expertise, and infrastructures.[372] Following TRIPS' entry into force in 1995, there have been growing concerns and scepticism from many developing countries that it was not at all adapted to their needs and does not allow them enough latitude to pursue crucial public health goals.

It is in this context that the *Doha Declaration on the TRIPS Agreement and Public Health* (Doha Declaration) was proposed by a group of eighty countries led by the Africa Group, Brazil, and India. It raised considerable opposition from more affluent states but was finally adopted in November 2001.[373] The main purpose of this document is to clarify that TRIPS' dispositions should be applied in a way that allows public heath protection and encourage global access to health, especially access to affordable generic medicines for all. It also recognises that, even if intellectual property may have a positive impact on health innovation, countries need flexibility to address of their domestic health needs.[374] Some believe that the Doha Declaration represents a first step in looking at TRIPS with a public interest perspective.[375] However, despite the special attention awarded to public health in the Doha Declaration, TRIPS remains an international agreement applied mainly to foster the interests of intellectual property owners and promote international trade. In fact, there

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measures be consistent with the provisions of TRIPS itself. Moreover, art. 27 (2) stipulates that states may exclude inventions from patentability in order to protect *ordre public* or morality, including to protect human, animal, or plant life or health, or avoid serious prejudice to the environment. WTO members may also exclude diagnostic, therapeutic, and surgical methods for the treatment of humans or animals (27 (3) a)) and award compulsory licences (authorising a third party to work the patent without the authorisation of the patent-holder) in limited cases and if they meet very strict criteria (art 31).

[372] K. Balasubramaniam, "Access to Medicine: Patents, Price and Public Policy- Consumer Perspective" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 87.

[373] Doha WTO Ministerial Declaration, November 14, 2001, WT/MIN(01)/DEC/1.

[374] This Declaration addresses issues of compulsory licenses in situations of health emergency, exhaustion of rights, real and applicable differentiation in patent rules to protect public health, technology transfer, extension of the grace period for integrating TRIPS' standards for the least developed countries, etc.

[375] C. M. Correa, *Implications on the Doha Declaration on the TRIPS Agreement and Public Health*, WHO Health Economics and Drugs, EDM Series no. 12, June 2002.

is growing evidence of socio-economic problems originating from TRIPS enforcement in many developing countries.[376]

In order to measure the importance of the different interests at stake in the application of IP and, more specifically, patent rights, the next section of this chapter will study the theoretical foundations of patent protection.

3.2 Some Theoretical Justification for the Institution of Patents

What purpose this system (as it exists today) is designed to achieve?

In the previous chapter, this dissertation set out a theoretical framework to help us address issues of access and distribution in genetics and health. After presenting the basics of IP and patents, and briefly assessing their importance and the issues they raise in genetics, this section aims to review and analyse the main theoretical arguments put forward to justify the existence of patents.[377] This is an important step

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[376] For example, in Brazil, the enactment of a new TRIPS-compliant patent act in 1996 has had detrimental effects on availability and affordability of medicines. In fact, new patent applications have almost all been filed by non-Brazilians, medicine imports have greatly increased without similar growth in exports, and the price of drugs has increased considerably because of the lack of satisfactory anti-trust regulatory authorities. Also, in India, since TRIPS has put a stop to reverse engineering (coming up with a new process to create the same chemical entity), the domestic pharmaceutical industry has been experiencing major difficulties and has failed to secure access to important drugs for the Indian population. Moreover, price increases of 5 to 67 per cent for patented drugs have been observed, and the associated welfare loss is being transferred to foreign stakeholders who recently recorded profits ranging between US$10 to 839 million. For more on the effects that TRIPS have had on the Brazilian and Indian economies, refer to: T. E. DeMasi & J.D. Garretson, "PERSPECTIVE: Willful Patent Infringement Law Needs Reform" (July 28, 2003) 230 *New York Law Journal* 5 (col.1); J.A.Z. Bermudez, R. Epsztein, M.A. Oliveira & L. Hasenclever, *The WTO Trips Agreement and Patent Protection in Brazil: Recent Changes and implications for local production and access to medicines.* WHO/PAHO Collaborating Center for Pharmaceutical Policies, Rio de Janeiro, 2002; K. Balasubramaniam, *supra* note 372; D.G. Richards, *supra* note 370; J. Watal, "Pharmaceutical patents, prices and welfare losses: Policy options for India under the WTO TRIPS agreement" (May 2000) 23:5 *World Economy* 733; R. Gerster, "How WTO/TRIPS Threatens the Indian Pharmaceutical Industry" Third World Network, 2000, online on the TWN website: <www.twnside.org.sg/title/twr120h.htm> (accessed June 3rd, 2006).

[377] We do not aim to present an exhaustive overview of patent theory. We simply briefly introduce some of the main arguments of the major patent theories. For a deeper analysis, we encourage the reader to consult the literature on the topic, namely: J. Hughes, "The Philosophy of Intellectual Property" (1988) 77 *Geo. L. J.* 287; B. Sherman & L. Bently, *The Making of Modern Intellectual Property Law* (Cambridge: Cambridge University Press, 1999); E. Hettinger, "Justifying Intellectual

in understanding the reasons put forward to justify relying on such system. Indeed, it will help us identify some of the primary objectives of the patent system, for the purpose of our further assessment.

Let us begin this subsection with a troubling quote from Edith Penrose from 1951: "[i]f national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them".[378] This highlights what many have described as the lack of clear grounds and agreed upon explanation for awarding legal protection to intellectual objects, and the "formidable task" of justifying IP.[379] For some, intellectual property is not something that can be theoretically justified because it is dependant on constantly evolving historical and cultural variables and does not have solid foundations.[380] For others, since patentable inventions are non-exclusive (they can be used by many people concurrently) and impose limits on the circulation of ideas, the burden of presenting theoretical foundations for patents falls to those who favour them.[381]

IP justification often refers to property more generally.[382] There are two main ways of rationalising institutions like property in moral philosophy: deontological and consequentialist. Deontological rationalisation refers to rights-based theories aiming at protecting what people are entitled to. It demands that decision be made balancing the duties of some and the rights of others, determined in relation to principles that do

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Property" (1989) 18 *Philosophy & Public Affairs* 32; D. Vaver, "Intellectual Property Today: Of Myths and Paradoxes" (1990) 69 *La Revue du Barreau Canadien* 98.

[378] E. Penrose, *The Economics of the International Patent System* (Baltimore, MD: Johns Hopkins Press, 1951) at. 40 quoted in D. Vaver, "Intellectual Property Today: Of Myths and Paradoxes" in P. Drahos, ed., *Intellectual Property* (England: Darmouth Publishing, 1999) 485, at 495.

[379] For example, see E. Hettinger, *supra* note 377, at 52; R. L. Ostergard, Jr., "Intellectual Property: A Universal Human Right?" (1999) 21:1 *Human Rights Quarterly* 156.

[380] Drahos refers to this position as post-modernist scepticism in his book: P. Drahos, *A Philosophy of Intellectual Property* (Adelshot: Darmouth Publishing Company, 1996), c. 9, at 200.

[381] B. Martin, "Against Intellectual Property" in P. Drahos, ed., *Intellectual Property* (England: Darmouth Publishing, 1999) 517.

[382] L. Becker, *Property Rights: Philosophic Foundations* (London: Routledge and K. Paul, 1977); J. Waldron, *The Right to Private Property, supra* note 259; S.Munzer, *A Theory of Property* (Cambridge: Cambridge University Press, 1990).

not change according to a change in circumstances.[383] Consequentialist justification refers to the resulting positive consequences (like incentive, for example), without worrying about their underlying morality.[384] According to Nance, these two analytical tools should be used simultaneously, since "[o]ur trust in institutions like property should depend upon the existence and convergence of coherent deontological and consequentialist theories that support the rights in question and cohere with our respective views toward tangible private property and government supported private monopolies"[385].

While the philosophical foundations for awarding patents are uncertain, it remains that theorists of different views have identified some moral and economic grounds to justify awarding exclusive protection to inventions. These can generally be categorised as follows: 1) respect for the inventions arising from the work of the inventor (Locke's labour theory); 2) importance of the ownership of intellectual objects in an inventor's personal development (Hegel's theory of the self); 3) significance of awarding exclusive proprietary rights on inventions in promoting inventive endeavours and innovation, their diffusion and commercialisation (utilitarian incentive theory); and 4) importance of patents in serving an established economic system driven by powerful agents aiming to achieve specific social and economic outcomes (Drahos' economic power theory). Each of these four general categories is addressed in the next subsections, with a special focus on the two more relevant for our analysis: the consequentialist utilitarian theory and power theory.

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[383] Wikipedia, the Free Encyclopedia, online: <http://en.wikipedia.org/wiki/Deontological> (accessed May 19th, 2006).

[384] H. M Spector, "An outline of a Theory Justifying Intellectual and Industrial Property Rights" in P. Drahos, ed., *Intellectual Property* (England: Darmouth Publishing, 1999) 535, at 536; J. Raz, *The Morality of Freedom* (Oxford: Clarendon Press, 1986) c. 1; G. Davies, *Copyright and the Public Interest, Studies in Industrial Property and Copyright Law* (New York: John Wiley & Sons, 1994) at 13.

[385] D.A. Nance, "Foreword: Owning Ideas" (1990) 13 *Harvard Journal of Law & Public Policy* 757, at 767.

3.2.1 Locke's labour theory

With his labour theory of proprietary rights, John Locke elaborated one of the most famous deontological justifications of the institution of private property more than 300 years ago. Locke's first principle is that everyone has property over his own person (what one decides to do with himself) and is consequently entitled to property rights over the products of his labour.[386] Hence, what is generated with the help of a person's efforts, aptitudes, and talents should be his, even if his or her labour was mixed with resources already existing in the commons.[387] Another reason for justifying property through labour is that property plays an important role in society by encouraging people to work, something people would otherwise naturally wish to avoid.[388] Therefore, when one's labour results in valuable goods and in a society's prosperity, he should be compensated.[389] Locke also limits the possible acquisition of proprietary rights over the product of one's labour with two provisos. The first condition is that property rights can only be awarded if there is "enough and as good left in common for others,"[390] while the second condition is that one must not get property rights on more than what he or she can use before it spoils.[391]

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[386] J. Locke, *Two Treatises of Government* (Cambridge: Laslett, 1988) (1690).

[387] J. Locke, *Second Treatise of Government* (Cambridge: Laslett, 1988) c. 5. It is important to highlight the difference between two labour theories: one based on natural rights to property (where property rights are owed, such as with Locke's version) and the other based on desert to property (where property rights are deserved).[387] Under the desert labour theory, the efforts invested in labour, the risk assumed, and ethical concerns are evaluated to determine if they justify awarding property rights.[387] This version excludes luck, intelligence and natural talents from the equation, as they are clearly not appropriate variables to assess desert.[387] This distinction is not possible with a natural rights property theory like Locke's. For a discussion of this point, see J. Feinberg, *supra* note 250, at 16; L.C. Becker, *Property Rights: Philosophic Foundations* (Boston: Routledge, 1977) at. *46;* E. Hettinger, *supra* note 377, at 42.

[388] L. Becker, "The Labour Theory of Property Acquisition" (1976) *Journal of Philosophy* 653; C. May, "Unacceptable Costs: The Consequences of Making Knowledge Property in a Global Society" (2002) 16:2 *Global Society* 123; J. Bentham, "The Theory of Legislation" in C.B. Macpherson, ed., *Property, Mainstream and Critical Positions* (Toronto: University of Toronto Press, 1978) at 53.

[389] Locke's theory is derived somewhat from natural law in that he suggests that property exists naturally in the principle of self-ownership and does not require the intervention of the law, state, or institutions to be created. However, it can be seen as a weak version of natural law, since governments have nonetheless the authority to regulate it with positive law. D. G Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32, at 26-33; P. Drahos, *supra* note 380, at 54.

[390] This means that exclusive property rights can be awarded as long as no one is made worse off. For a discussion on that specific clause, see R. L. Ostergard, Jr., "Intellectual Property: A Universal Human Right?" *supra* note 379.

[391] J. Locke, *supra* note 387, c. 5, sect. 27 and 31.

Although Locke was actually sceptical of the application of his theory to intellectual property, many have argued for its application to IP and patents.[392] Indeed, the production of inventions through creative effort and ideas is a type of labour that should be encouraged and patents can be essential to reward efforts and investment in research, innovation, and development. [393] However, many critiques can be formulated of Locke's theory as a philosophical foundation of patents. First, it is not always clear whether the compensation awarded by patents is proportional and justified by the efforts of the patent-holder. For example, in genetics, the fruits of one's labour will often be the result of a mix of work, highly specialised computerised research tools (e.g., for sequencing and decrypting human genetic material), and a fair amount of luck. In science, moreover, it is not uncommon for several scientists to come up with the same invention almost simultaneously and totally independently.[394] It is thus hard to justify why, with the application of Locke's theory of labour, the fastest and luckiest inventors should receive all of the benefit when so many others have laboured and probably invested as much time, effort, and money in the same research endeavours.

Moreover, Locke allows property rights over anything with which one mixes his labour, suggesting that the actual labour is responsible for the quasi-total value of the fruits of labour.[395] This cumulative inventive process can create serious problems, especially in genetic research, where inventors have to build on existing knowledge and ideas, and on previous valuable inventions created and constructed over the years by many different agents within a broad social process.[396] Once the research team identifies some new, non-obvious and useful subject matter, Locke's theory allows them to obtain exclusive property rights over it and its entire market value, as if it had been developed in a social vacuum, in isolation from the broader social context.[397] In

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[392] For example, see B. G. Damstedt, "Limiting Locke: A Natural Law Justification for the Fair Use Doctrine" (Feb. 2003) 112:5 *Yale Law Journal* 1179; J. Hughes, *supra* 378, at 320.
[393] C. May, *supra* note 366.
[394] D. Vaver, *supra* note 377.
[395] Locke believes that things have very little importance until they are being worked on. He even proposes that 99% of objects' value is created by labour. J. Locke, *supra* note 387, par. 5, sec. 40.
[396] B. Martin, *supra* note 381.
[397] D.G Richards, *supra* note 380, c.2, at 25-52.

this case, awarding exclusive proprietary rights over an invention and its market value can be unfair to society and to other stakeholders, and does not demonstrate an appreciation of the importance of the numerous independent variables involved in the establishment of the actual market value of goods.[398]

Also, in aiming to reward labour, Locke seems to assume that the inventor and the patent-holder will necessarily always be the same person. This is not compatible with the patent system structure, which rewards the patent-holder with exclusive proprietary rights over some invention without worrying about the identity of the actual inventor.[399] In the fields of genetics and biotechnology, though most inventions originate from the work of some individual researchers or groups of scientists, most patents are awarded to multinational corporations and private and public research labs that employ those inventors.

Our last critique of Locke relates to his emphasis on the importance of one's ability to accomplish labour work. Locke does not talk about property redistribution, and his theory does not allow taking individuals' natural capacity differences into account. His libertarian vision brings him to focus only on capacity to generate property rights and not on compensating the less fortunate for their lack of capacity in terms of labour productivity.

Overall, Locke's vision is consistent with a libertarian theory of justice that we chose to set aside at the beginning of this dissertation to focus on a liberal theory of distributive justice. Indeed, for us, the main concern is not the compensation for labour, but more the protection and access to health. Allowing redistribution towards this end is therefore crucial to giving people more control over their lives and to target a goal of equality of opportunities. We will come back to this point in greater detail in section 3.3.2.2 of this chapter.

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[398] For Hettinger, a product's market value is influenced by the productivity of competitors, the demand for the product, and the type of property institutions prevailing in a given country—all things over which the labourer does not have influence: E.C. Hettinger, *supra* note 337, at 227-230.
[399] C. May, *supra* note 366, c. 4, at 115-117.

3.2.2 Hegel's theory of the self

A second important deontological theory of property comes from Hegel, who says that "property is the embodiment of personality."[400] Basically, Hegel's argument is based on the idea that property, both in material and intellectual objects, plays a crucial role in assuring individuals' social and biological survival, as well as in the construction of their personality. For Hegel, property is not a natural entitlement arising from labour work and it can be transgressed and ignored only in situations of extreme need, as when, for example, someone could be denied life and freedom of will as a result of property rights' enforcement.[401] Property rights are important to secure individual freedom from intrusion and interference by society and other individuals. According to Hegel, people can only be free if they have property over what characterises and supports the development of their personalities and their most important needs.[402] In that sense, the very principle of individual freedom justifies property rights.[403]

In his discussion on property in knowledge and ideas, Hegel recognises the incentive role of property protection in innovation, and at the same time, emphasises the importance of creating, improving, and maintaining a society's knowledge platform. This is why, in allowing intellectual property rights over such crucial information, a state also ought to ensure that the normative structure simultaneously allows the protection of the knowledge commons.

Although Hegel does not believe that the state should be in charge of creating property privileges, he nevertheless recognises the role of the legal system in institutionalising the protection of citizens' property rights. Hegel admits that

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[400] G.W. Hegel, *Philosophy of Right, trans.* T. M. Knox (Oxford: Clarendon Press, 1952, lst ed., 1967 reprint) at 51.
[401] P. Drahos, *supra* note 380, at 252-253.
[402] C. May, *supra* note 366, at 100.
[403] D.G Richards, *supra* note 370, at 33.

property systems can produce poverty by assigning exclusive rights in necessary elements of people's development, and in awarding property rights through contracts often characterised by unequal bargaining power.[404] In this sense, property rights influence opportunities. Hegel does not propose any solutions to this problem, but believes that government should have a role to play in controlling some market forces to provide the minimal necessities to those without property.

One problem with Hegel's theory is that even though he argues for the protection of the knowledge commons, he does not present an analysis of the connection between the institution of property and the protection of the commons. He focusses on the influence of property on the personal development of individuals and, in so doing, neglects the broader role of property institutions for knowledge diffusion.[405] Another problem with Hegel's theory of the self is the strong link it makes between property and personality, and the fact that it presupposes that the object of property has to remain within the control of the property owner in order to influence the construction of his own personality. When applied to IP, Hegel's self-development theory does not seem compatible with the way the actual international intellectual property system operates, characterised by a strong trade component which requires total alienability of both IP rights and intellectual objects affected by IPRs.[406]

Additionally, in aiming to link property with personality and self, Hegel, like Locke, presumes that the property holder will have a personal and intimate interest in the object of his property. This does not translate well in the field of patent law where the personality of the inventor is not at all considered and only the patent owner, regardless of who it is, gets the benefits.[407] In genetics and biotechnology, most inventors do not turn out to be patent owners, and this title almost always falls under

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[404] *C.* May, "Cosmopolitan Legalism Meets Thin Community: Problems in the Global Governance of IP" (2004) *Government and Opposition* 393, at 396 et ss; D. G Richards, *supra* note 380, c.2; J. Hughes, *supra* note 335.
[405] P. Drahos, *supra* note 380, at 250-275.
[406] C. May, *supra* note 366, c. 4, at 98-103.
[407] *Ibid,* c. 4, at 115-117.

the control of wealthy and powerful multinational corporations and private and public research labs.

Moreover, by drawing a direct connection between property and the expression of the self, Hegel's property theory accepts that inequalities between individuals will persist. Even if he proposes that governments should help those without much property meet their basic needs for survival, Hegel still believes that owning property rights is an absolutely requirement to achieve personality. This leaves those who cannot afford property rights out of the definition of personality. Furthermore, in making a direct association between inequalities in wealth and inequalities in positive personal characteristics, Hegel does not propose anything to improve the situation of those who have been less fortunate in terms of abilities, talents, wealth, health, etc. He simply notices those differences, associates them with personality and property, and seems to accept that different people will continue to have different opportunities.[408] This clearly sanctions the very principle of self-ownership that has been rejected by Rawls on the basis that disadvantaged people who suffer from undeserved conditions should have a right to compensation for those inequalities.[409] Applying a simplified version of Hegel's theory of the self to property in genetics could mean, for example, that sick people of different countries who would need to access genetic products and services for meeting some of their important health needs would necessarily have to acquire property rights over them.[410] This would allow those who can afford it to go one step further in developing their personality toward practical freedom while leaving those who cannot out of the process.[411] This result is clearly contrary to the principles of distributive justice in health developed in our theoretical framework, something we will address at greater length when we assess the IP system in the next section of this chapter.

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[408] D.G Richards, *supra* note 380, c. 2, at 30-40.
[409] This directly refers to the application of Rawls' difference principle analysed in length in the last chapter.
[410] This could be by paying for them or having some kind of private or public mechanisms in place that would allow property transfer.
[411] For the purposes of this example, we are assuming that the genetic products and services are not absolutely necessary for one's survival and freedom of will. Therefore, one cannot transgress property rights over them even if they can play an important role in improving one's health condition.

This brief overview of Hegel's theory allows us to conclude that it is also inconsistent with the liberal theory of distributive justice we adopt in this dissertation.

3.2.3. The utilitarian justification of property

The most common and popular justification of property is the utilitarian argument arising from the consequentialist tradition. Property theory begins with the idea that knowledge should remain freely available and unappropriated unless there is a good reason to allow its appropriation.[412]

Basically, the idea underlying this argument is that inventions are good for maximising societal benefits and that intellectual property protection is required to encourage innovative activities, production and dissemination of valuable knowledge, scientific and technological progress, and fair competition in the creation of new intellectual objects.[413] Another aspect of the utilitarian scheme is that the scarcity of ideas promotes innovation and encourages the production of more knowledge.[414] This ideology is anchored in a Western tradition that endorses a positive role for private property in economic development and does not consider inventions differently than other types of production.[415] For utilitarians, the positive effects of patents are measured in terms of their consequences on human preferences satisfaction, without taking the nature of these preferences into consideration.[416] Thus, the effects of patents on progress are positive when they play a role in improving economic

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[412] E.C. Hettinger, "Justifying Intellectual Property", *supra* note 377, at 35-36 cited in E. R. Gold & T. Caulfield *Patents and Human Rights*, paper prepared for Justice Canada, April 2003, online on the CIPP website: <http://www.cipp.mcgill.ca/data/publications/00000006.pdf> (access April 20th, 2006), at 46.

[413] In fact, as previously explained, the amount of money that needs to be invested in the development of an invention can be very high, particularly in some specialised fields of activities like biotechnology and genetics. This is one reason why many argue that incentives in the form of patents are needed to foster innovation. D.B. Resnik, "DNA patents and scientific discovery and innovation: assessing benefits and risks" (2001) 7:1 *Science and Engineering Ethics* 29; J. Hughes, *supra* note 378; M. Mowzoon, *supra* note 18. D.G Richards, *supra* note 380, c. 6, at. 147-151.

[414] C. May, *supra* note 333, at. 127.

[415] R. L. Ostergard, Jr., *supra* note 379, at 165, D.G Richards, *supra* note 380, chap. 2, at. 30-35

[416] D. Nance, *supra* note 385 at. 764-767.

development and in contributing to progress in medicine, health, agriculture, biotechnology, etc. The utilitarian justification of patents is also intended to balance their dual role, which is meant to encourage the dissemination of knowledge for long-term advancement and further development of ideas, and concurrently reward inventors with temporary exclusive proprietary rights.

There are different types of utilitarian justifications for IP relating mainly to on the one hand, its role as an incentive for innovation, dissemination, and development, and on the other hand, its role in commercialisation of inventions. We will say few words on each of these paradigms.

IP and innovation, dissemination, and development

The most popular utilitarian justification is to argue that IP protection creates the artificial scarcities necessary to ensure that potential inventors have sufficient financial incentive to invest in a given sector and disseminate their results.[417] As we know, when an inventor is granted a patent over an invention, he can use this right to prevent others from using the invention, recover the amount invested in developing it, disclose it to the public, and fund other research projects.[418] Proponents of this view argue that, without intellectual property rights, progress toward prevention, treatment, and cures for important health issues could be compromised or delayed.[419] Innovation and dissemination are viewed as a way to increase social welfare and inventors' reward as a mechanism to attain this goal.[420] The positive impact of patents on

[417] F-K Beier & J. Straus, "The Patent System and its Informational Function--Yesterday and Today" (1977) 8 *Int'l Rev. Int. Prop. & C'right L.* 387; K. Arrow, "The Economics of Information: An Exposition'" (1996) 23:2 *Empirica* 125.
[418] S. A. Singham, "Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry" (2000) 26 *Brook. J. Int'l L.* 363, at 367-372.
[419] M. F. Grady & J. I. Alexander, "Patent Law and Rent Dissipation" (1992) 78 *Vanderbilt Law Review* 305; A.S. Oddi, "Un-Unified Economic Theories of Patents – the Not- Quite-Holy Grail" (1996) 71 *Notre Dame L. Rev.* 267
[420] E. R. Gold, "The Reach of Patent Law and Institutional Competence" (2003-2004) 1 *UOLTJ* 263; D. L. Burk & M. A. Lemley, "Policy Levers in Patent Law", *supra* note 349; *Apotex Inc.* v. *Wellcome Foundation Ltd.* 2002 SCC 77 (December 5, 2002), Justice Binnie, at par. 37.

innovation was established in the economic literature a while ago[421] and is enshrined in the western judicial interpretation of patents' positive implications. [422] In biotechnology and genetics, this argument is said to be especially relevant because of the high costs of Research & Development (R&D) and the often lengthy process of market approval.[423] Increased dissemination is meant to happen as patents are granted in exchange for the disclosure, in the patent application, of the information necessary to use and manufacture the invention. This is meant to encourage inventors to disclose what they would otherwise keep confidential.[424] However, depending on the strategy adopted by patent-holders, patents will not always play an important role in knowledge dissemination.[425]

Another argument in favour of this utilitarian justification of patent protection relates to its role as a mechanism to foster development. Indeed, in addition to increasing R&D and innovation, it is argued that patents are necessary to insure industry growth and national development through improved foreign direct investment and technology transfers.[426]

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[421] These studies determined that patents were responsible for 15 to 25% of all innovation. For more details and reference to those studies refer to E.R. Gold et al., *supra* note 353, at 303.

[422] For some examples on how the Courts have interpreted and justified IP, see *Fogerty* v. *Fantasy Inc.,* 510 U.S. 517(1994) and *Graham* v. *John Deere Co.,* 383 U.S. 1 (1966) cited in A. K. Rai, "Regulating Scientific Research: Rights and the Norms of Science in Biotechnology Research" (1999) 94 *Northwestern University Law Review* 77.

[423] This argument is incomplete, as clearly explained in E. R. Gold & T. Caulfield, *supra* note 412.

[424] However, secrecy does not protect from independent innovations and might not always be an efficient means to protect inventions. R. S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 *U. Chi. L. Rev.* 1017.

[425] For example, patent-holders could decide to disaggregate their invention into different components and claim patent rights on each of them. For more on this point, see: E.R. Gold et al, *supra* note 353, at 303; on the disclosure role of patents, see also J. Hughes, *supra* note 378; *Cadbury Schweppes Inc. v. FBI Foods Ltd.* 1999, 1 S.C.R. 142; F. Machlup, An Economic Review of the Patent System, Subcomm. on Patents, Trademarks, and Copyrights of The Senate Comm. on The Judiciary, Study No. 15, 85th Cong., 2d Sess. (GPO, 1958) at 21.

[426] J.P Walsh, C. Cho & W.M. Cohen, "Science and Law; View from the Bench: Patents and Material Transfers" (2005) 309:5743 *Science* 2002; E. Mansfield, "Intellectual Property Protection, Direct Investment and Technology Transfer" (*International Finance Corporation Discussion Paper No. 27*, 1995, at 11; S. Crespi, "Models of Intellectual Property" (2002) 20 Trends in Biotechnology 451; J. Reichman, "Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement" (1996) 29 *Int'l L.* 345; UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights in Development Policy,* London, September 2002, online on the website of CIPR, <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf> (date accessed: 11 May 2005), at 18 & 22-26 (already cited in introduction); K. Maskus, *Intellectual Property Rights in the*

Another important aspect of the utilitarian theory of IP relates to its role in welfare maximisation. Utilitarianism requires the allocation of objects of property to those who value them the most in economic terms for the maximisation of societal benefits. In other words, utilitarianism requires the maximisation of overall welfare rather than equality in its distribution, on the basis that patents create incentives to encourage innovation. Because innovation is deemed to be good for society, allocation of patent rights should be encouraged in a utilitarian solution. Following this reasoning, property will preferably be allocated to those who can make the most productive and efficient use of it in a competitive context, allowing society to recover a maximum of benefits from those rights.[427]

IP and Commercialisation

A second important utilitarian justification for IP has to do with its role in commercialisation in terms of contribution to the manufacturing and distribution of innovations. In other words, some argue that patents are necessary for encouraging investment and coordination of the "complex, costly and risky" commercialisation process required for taking interesting ideas and promising inventions and transforming them into useful products available in a given market.[428] This theory emphasises the importance of commercialising inventions as rapidly and efficiently as possible for the benefit of different stakeholders. For this purpose, many things must be accomplished, such as fundraising, setting up facilities to produce and manufacture the invention, establishing distribution networks, and raising public

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Global Economy (Washington DC: Institute for National Economy, 2000); S. A. Singham, *supra* note 418, at 375-385.

[427] C. May, *supra* note 366, c. 4, at. 122-123.

[428] Kieff articulates the commercialisation theory in F. S. Kieff, "Property Rights and Property Rules for Commercializing Inventions" (2001) 85 *Minn. L. Rev.* 101; S.F. Kieff, "Perusing Property Rights in DNA" in S.F. Kieff, ed., *Perspectives on Properties of the Human Genome Project* (California: Elsevier, 2003) c.7, 125; for more on the commercialisation theory of patent see also G. S. Rich, "The Relation Between Patent Practices and the Anti- Monopoly Laws" (1942) 24 *J. Pat.Off. Soc'Y* 85; D. S. Chisum et al., *Principles of Patent Law: Cases and Material*, (New York: Foundation Press, 2004).

awareness about the patented product.[429] These steps come with a price, and patents are meant to exclude those who have not shared in the costs from the benefit of commercialisation. In this sense, patents can represent an important tool for securing further investment, fostering countries' competitiveness in certain areas of research, and making useful inventions available to communities.[430] Publicly recorded patents play a crucial role in helping different users of the inventions (such as developers, manufacturers, labourers, managers, investors, advertisers, and marketers) get in contact with one another and coordinate their activities around a specific invention to bring it to a stage where it can be useful to people and profitable for the patent-holder.[431] This theory is particularly adapted to the biotechnology and genetic sectors, where commercialisation costs and risks of failure are very high.[432]

Critique

There are problems with the way different aspects of the utilitarian justification for patents work today. In fact, they justify temporarily restricting access to the object of patents on the basis that this will encourage more production and better access to inventions in the future. This reasoning finds its origins in the idea that patents should balance both the interest of inventors in the protection of their invention, and that of society in the diffusion of new inventions. However, such balance is not easy to reach. Indeed, as Hettinger states: "IP laws have been used more recently not as part of a social contract between creators and society, but as a tool for securing market share in an increasingly competitive global economy."[433] For now, dissemination is constrained by the willingness and capacity to pay for accessing patented inventions.

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[429] F. S. Kieff, *supra* note 346

[430] R. Adler, "Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization" (1992) 257 *Science* 908.

[431] H. Demsetz, *Toward a Theory of Property Rights II: The Competition Between Private and Collective Ownership* (2002) 31 *J.Legal Stud.* S.653; F. S. Kieff, "The Case for Registering Patents and the Law and Economicsof Present Patent-Obtaining Rules" (2003) 45 *B.C. L. Rev.* 55

[432] For a enlightening and well referenced discussion on this point, refer to F. S. Kieff, "IP Transactions: On The Theory & Practice of Commercializing Innovation" (2005) 42:3 *Houston Law Review* 727.

[433] E.C. Hettinger, *supra* note 377, at. 50.

Consequently, the importance of the free flow of ideas and knowledge for societal development finds itself diluted by the application of a too strong and often unbalanced utilitarian justification of IP.

One critique of the utilitarian vision of patents arises from the fact that the encouragement of innovation is often compromised by the growing importance of patents in stimulating legal monopolies. As we will explain in more depth with examples in the last chapter of this thesis, some suggest that biotechnology and genetic patents often do not act as incentives for socially valuable research and innovation, especially in developing countries—but more as tools used by large corporations to advance their economic agendas, gain access to more markets, and prevent other firms from penetrating specific fields of activity.[434] Indeed, the system is at the origin of inefficient "races" between potential patent-holders who want to secure their patents first. Because only one patent ends up being granted for a single invention, this creates unnecessary duplication of research and investment in very specific, potentially profitable spheres of research.[435] Therefore, the positive impact of patent on innovation first established with economic studies is now being questioned. Recent comparative economic studies looking at different countries' patent systems and empirical research in the specific area of genetic testing suggest that there might not always be a positive link between patent rights and innovation

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[434] F. Machlup, *Production and Distribution of Knowledge in the United-States* (Princeton: Princeton University Press, 1962) at. 164-175; J-C St-Onge, L'envers de la Pillule (Montréal: Ecosociété, 2004 (on the massive production of non-innovative, "me-too" drugs); S. Joseph, "Pharmaceutical Corporations and Access to Drugs: The Fourth Wave of Corporate Human Rights Scrutiny" (2003) 25 *Human Rights Quarterly* 425 (on concerns about the type of innovation that patents foster); D. Noble, *America by Design* (New York: Knopf, 1982) c.6; R. L. Ostergard, Jr., *supra* note 379, at 165-166; E. R. Gold, *supra* note 420; M. Sakakibara & L. Branstetter, "Do Stronger Patents Induce More Innovation? Evidence From the 1988 Japanese Patent Law Reforms" (2001) 32 *RAND Journal of Economics* 77; P. J. Smith, "Patent Rights and Trade: Analysis of Biological Products, Medicinals and Botanicals, and Pharmaceuticals" (2002) 84 *Amer. J. Agr. Econ.* 495; P. J. Smith, "Are Weak Patent Rights a Barrier to U.S. Exports?" (1999) 48 *Journal of International Economics* 151; R. S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research" (1996) 82 *Vanderbilt Law Review* 1663.

[435] P. David, "Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History" in M. B. Wallerstein, M. E. Mogee & R.A. Schoen, eds., *National Research Council, Global Dimensions of Intellectual Property Rights In Science and Technology* (New York: National Academy Press, 1993) 19; K.W. Dam, "The Economic Underpinnings of Patent Law" (1994) 23 *J. Legal Stud.* 247.

development and access.[436] To this day, however, there is insufficient evidence to extend this conclusion to other sectors of research.[437]

Moreover, concerning the effect of IP on development, it is not clear yet from the literature, if we can establish or not a clear relationship between strong IPRs on the one hand, and foreign direct investment, foreign and local research into developing countries' diseases and technology transfer on the other hand. In other words, more empirical evidences are needed to determine if strong IPRs are, in themselves, sufficient incentive or not to attract massive foreign investment to developing countries, or to encourage technology transfer and investment in research.[438] Most

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[436] E. R. Gold et al., "Needed: Models of Biotechnology Intellectual Property" (August 2002) 20:8 *Trends in Biotechnology* 327; R.K. Burch, P.J.D. Smith & W.P. Wheatley, "Divergent Incentives to Protect Intellectual Property: A Political Economy Analysis of North-South Welfare" (2000) 3 *Journal of World Intellectual Property* 169; A. J. Glass, "Costly R&D and Intellectual Property Rights Protection" (2000) 19 *International Journal of Technology Management* 179; E.R. Gold et al., *supra* note 122. Specifically on the effect of patents on genetic testing: J. F. Merz et al., "Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Haemochromatosis" (2002) 415 *Nature* 577; J.F. Merz & M.K. Cho, "What are Gene Patents and Why are People Worried about Them?" (2005) 8:4 *Community Genetics* 203; M. K. Cho et al., "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services" (2003) 5:1 *Journal of Molecular Diagnostics* 3.

[437] Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD, Paris: 2002), online on the website of OECD, <http://www.oecd.org/dataoecd/42/21/2491084.pdf> (accessed May 20th, 2006), at 18 and 68.

[438] Those who argue that IPRs are not determinant in development often refer to the example of the flourishing pharmaceutical industry in India, Brazil, and Argentina—nations with very weak IP norms. Most development issues must be resolved principally with the help other international normative, economic, and political mechanisms, and many other factors need to be taken into consideration, including nations' education level, natural resources, cost of domestic labour, etc. Others, to the contrary, believe that there is a clear link between IPRs and FDI, research and technology transfer. As these issues are not the focus of this chapter, we encourage the reader to refer to the following references for a more detailed analysis of the link between intellectual property rights and countries' level of development: K. Balasubramaniam,*supra* note 372; P. Drahos, "The Rights to Food and Health and Intellectual Property in the Era of "Biogopolies" in S. Bottomley & D. Kinley, eds., *Commercial Law and Human Rights* (Ashgate Dartmouth: Aldershot, 2002) 227; Commission on Macroeconomics and Health, *supra* note 201 at 56; H. E. Kettler & C. Collins, "Using Innovative Action to Meet Global Health Needs through Existing Intellectual Property Regimes", UK Commission on Intellectual Property Rights, *Study Paper 2b*, London, 2002; Gold et al., *supra* note 122; C. Primo Braga & C. Fink, "The Relationship Between Intellectual Property Rights and Foreign Direct Investment" (1998-1999) 9 *Duke J. Comp. & Int'l L.* 163, at 163; C. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (London: Zed Books, 2000); S. A. Singham, "Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry" (2000) 26 *Brook. J. Int'l L.* 363.; D.G. Richards, *Intellectual Property Rights and Global Capitalism,supra* note 32; Arguing for a strong link between IP and development: UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights in Development Policy,supra* note 426 at 22-26; K. Maskus, *Intellectual Property Rights in the Global Economy* (Washington DC: Institute for National Economy, 2000); B. M.

development issues have to be resolved principally with the help of other international normative, economic, and political mechanisms, and many other factors need to be taken into consideration (including nations' education levels, natural resources, and cost of domestic labour).[439] This only reveals that, before we can use this type of utilitarian argument as a reliable foundation for patent law, more empirical evidence will be needed as to the incentive function of patents when compared to other economic factors, and as to the proportionality between the means used in granting exclusive proprietary rights and the end of promoting innovative activities in genetic research.[440] As Gold and Caulfield note, the lack of economic evidence of the role of patent is symptomatic of a larger problem in patent policy: "its reliance on *faith* and anecdotal evidence rather than on careful study and data."[441]

In reaction to the commercialisation theory of patents, some argue that patents can interfere with commercialisation, especially in the area of fundamental research, where the patent-holders can decide to enforce their rights restrictively, potentially reducing creative activities.[442] Such an attitude toward patents can generate additional transaction costs and limit the transfer of patented products and services to the public through commercial channels. This is what has been called the *tragedy of the anti-commons,* which occurs when too many people have the right to exclude others from

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Hoekman, K. E. Maskus & K.Saggi, *Technology Transfer to Developing Countries: Unilateral and Multilateral Policy Options* (World Bank Policy Research Working Paper 3332, 2004); E. Mansfield, *Intellectual Property Protection, Direct Investment and Technology Transfer*, International Finance Corporation Discussion Paper No. 27, 1995; H. Grabowski, "Patent, Innovation and Access to New Pharmaceuticals" (2002) *J. of Int'l. Eco L.* 849, at 850.

[439] As those issues are not the focus of this chapter, we encourage the reader to consult the following for a more detailed analysis of the link between IPRs and nations' levels of development: K. Balasubramaniam, *supra* note 372. Commission on Macroeconomics and Health, *supra* note 201 at 56; H. E. Kettler & C. Collins, *ibid.* "; Gold et al., *supra* note 122, at 301-309; C. Primo Braga & C. Fink, *ibid,* at 163; C. Correa, *ibid.*; D.G. Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32.

[440] D. Vaver, *supra* note 377; E. Mackaay, "Economic Incentives in Markets for Information and Innovation" (1990) 13 *Harvard Journal of Law & Public Policy* 867.

[441] E. R. Gold & T. Caulfield, *supra* note 412, at 27; see also, S. Crespi, *supra* note 426.

[442] M. A. Holman & S. R. Munzer, "Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags" (2000) 85 *Iowa L. Rev.* 735; A. K. Rai, *supra* note 422; R. S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use", *supra* note 424; A. K. Rai, "Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff", *supra* note 365.

using resources from the commons, giving rise to their underutilisation.[443] Even if we are not in a position to conclude, one way or another with regards to the general effect of patent on preventive research at present, we can conclude that in some very specific fields -such as clinical genetics- patents appear to restrict research.[444] This is why some argue that commercialisation should not occur through complete privatisation, but should also leave some space for the public domain.[445]

Most importantly, the utilitarian arguments presented in favour of IP mainly relate to the positive effects that IP can have on the competitiveness of states and companies, and on the commercialisation and availability of products in a given market. Although individuals could, in theory, benefit from IP in the long term if its incentive role were to be confirmed, the most important question this thesis examines is whether products emerging from innovation are truly accessible to the people who need them. The economic incentive aspect of the utilitarian theory focusses on a limited set of stakeholders, on those who value patented products the most in economic terms rather than considering the needs of all agents, including the less powerful. In fact, the only need that seems important is the need for efficiency,

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[443] We will come back on the practical application of this concept when we discuss availability issues under sub-section 3.3.2.1. M. A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) *11 Harv. L. Rev.* 621, at 624; M. A. Heller & R. S Eisenberg, *supra* 358; G. Hardin, "The Tragedy of the Commons" (1968) 162 *Science* 1243.

[444] In fact, it is argued that innovation in drug discovery has not been seriously affected by patents on research tools, except in the area of genetic diagnostics, where some negative effects have been observed on research. Some like Keiff, sceptical about the negative effect of research tools' patents on further innovations, suggests that more empirical research should be undertaken to obtain evidence about the process of exchange failure in specific area of research. S.F. Kieff, "Perusing Property Rights in DNA" in S.F. Kieff, ed., *Perspectives on Properties of the Human Genome Project* (California: Elsevier, 2003) c.7, 125; J.P. Walsh, A. Arora & W.M. Cohen, "Effects of Research Tool Patents and Licensing on Biomedical Innovation" in W.M. Cohen & A. Merrill, eds, *Patents in the Knowledge-Based Economy* (Washington, DC: The National Academies Press, 2003) 285, at 297-305, online on the NAP website:
<http://books.nap.edu/books/0309086361/html/297.html#pagetop> (accessed: May 26th, 2006); On the negative effect of patents on genetic diagnostic tools, see J.F. Merz et al., *supra* note 436; J.F. Merz & M.K. Cho, *supra* note 436; B. Martin, *supra* note 381: Organisation for Economic Development and Cooperation (OECD), *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies,* Paris, 2002, at 50.

[445] A. K. Rai, *supra* note 422. .

while the link between IP and other social needs remains unaddressed.[446] Both the incentive and the commercialisation utilitarian justifications allow us to ignore members of a community or entire nations when they do not fit into the welfare maximisation calculus. For example, utilitarianism can accept health differences between poor and wealthy individuals if the latter value some health-related products the most economically, as long as such allocation does not make some people worse off[447] and results in a positive impact on the overall population's health.[448] In other words, utilitarianism in health can result in awarding access and control of genetic knowledge, products and services to those who can invest in their development and commercialisation and who can pay for them, on the grounds that their activities will likely result in overall maximisation of benefits for society (in terms of further innovation, for example).[449] However, as bluntly put by May:

> By individualising creation, by disembedding it from the social milieu from which all knowledge is drawn, IPRs deny the importance of the public realm, and by doing so reward only a small group of rights holders rather than the carriers of social knowledge, and, more importantly, ignoring the social welfare benefits of those excluded from use, not by ignorance or lack of interest, but by their poverty.[450]

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[446] C. May, *supra* note 333; P. Steidlmeier, "The Moral Legitimacy of Intellectual Property Claims: American Business and Developing Country Perspectives" (1993) 12:3 *Journal of Business Ethics* 162.

[447] Again, the evaluation of the notion of being worse off is problematic. As we mentioned previously, we agree with the view that being worse off can be interpreted in a relative sense, for example when something that could improve one's condition exists and this person cannot have access to it because of strong patent rights. To this effect, see: R. L. Ostergard, Jr., *supra* note 379, at. 169. On the opposite view, refer to A.D. Moore "Toward a Lockean Theory of Intellectual Property" in A. D Moore, *Intellectual Property: Moral, Legal, and International Dilemmas* (Maryland: Rowman & Littlefield, Lanham, 1997) 81, at. 85 and 98; J. W. Child, "The Moral Foundations of Intangible Property" in A. D Moore, *Intellectual Property: Moral, Legal, and International Dilemmas* (Maryland: Rowman & Littlefield, Lanham, 1997) 57.

[448] F. Peter & T. Evans, "Ethical Dimensions of Health Equity" in T. Evans *et al.*, eds., *Challenging Inequities in Health, from Ethics to Action* (Oxford: Oxford University Press, 2001) 25, at 28.

[449] This explains why, for example, only a very small fraction of all new chemicals developed between 1975 and 1996 were for the treatment of tropical diseases. For more on the effect of IP on innovation for the poor, refer to P. Cullet, "Patent and medicines: the Relationship Between TRIPS and the Human Right to Health", (2003) 79:1 *International Affairs* 139l; J. H. Barton, "Intellectual Property Rights and Innovation" in N. Imparato, ed., *Capital for Our Time: the Economic, Legal, and Management Challenges of Intellectual Capital* (Stanford: Hoover Institution Press, 1999) 123; UK Commission on Intellectual Property Rights, *supra* note 47, at 33.

[450] C. May, *supra* note 388, at 139.

Therefore, in allowing health and wealth differences, utilitarianism appears insensitive to issues of equality and distributive justice,[451] two critical concerns for equitable access to global health.

This brief overview of the utilitarian justification of IP brings us to conclude that, once again, we are not in the presence of a balanced, reliable, and complete theoretical foundation for IP. Although we are not contesting the efficiency of the IP system for serving economic and commercial purposes, it does not allow us to address our equity, access, and need issues. As it stands now, the main focus of the incentive and the commercialisation utilitarian theories remains economics, and it is imperative to balance it with other important social goals if we wish to ensure that IP can be justified in terms of distributive justice.[452]

After presenting three of the most commonly-used normative justifications of IP, we are forced to admit that none satisfactorily meets the requirements of a liberal cosmopolitan theory of distributive justice. Some arguments are either not adapted to the context of IP, or are based on unconfirmed assumptions about a hypothetical strong link between IP and innovation. Most importantly, none of the justifications considers the potential negative effects IP can have on those who are not in a position to own such rights.

Facing this apparent lack of a single and strong normative justification of IP, Nance proposes combining components of different theories to get a general explanation of the widespread use of, and reliance on, IP rights in today's world.[453] However, it is doubtful that any of the theories presented in the last section, taken together or separately, supply a complete justification of IP that balances deontological and consequentialist arguments in the interest of both inventors and society. To quote Nance, one should be "sceptical of a justification of intellectual property in its

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[451] B. Williams, "A Critique of Utilitarianism" in J.J.C. Smart. ed., *Utilitarianism: For and Against* (Cambridge: Cambridge University Press, 1973) 75.
[452] E.C. Hettinger, *supra* note 335, at 134-137.
[453] D. A. Nance, *supra* note 385, at 766 & 772.

present forms under any of the theories that present themselves as obvious candidates, and more sceptical of a convergence of those theories in support of intellectual property."[454]

This leads us to the analysis of a fourth and last approach in our exercise of establishing some theoretical foundations for IP protection.

3.2.4. Drahos' economic power theory of IP

Drahos' philosophy essentially rests on guarding society against the excess and normative risks associated with the dynamic nature and changing boundaries of IP. In an ideal world, Drahos believes in an instrumentalist approach to intellectual property rights where property is considered as a tool rather than a right. The peculiarity of Drahos' vision is that, unlike other proponents of instrumentalism, he believes that we should not focus on using IP as a tool for meeting economic ends, but instead for serving already existing moral values and distributive goals. However, Drahos' evaluation of the current IP system highlights important divergences between his ideal philosophy of IP and what he describes as an *inescapable political power theory of IP*.

In studying the development and evolution of IP law, Drahos focusses on the real importance of proprietarianism, a concept he uses to explain how IP holders are always awarded special treatment. Because property rights permit excluding and preventing others from using, selling, and producing the object of property, they allow increased private property over intellectual objects and concentration of power and sovereignty over key assets of global dependence. The effect of property rights on scarcity in knowledge essentially serves the interests of specific groups. Since IPRs are valuable assets upon which people and companies can build more possibilities, they can be defined as a form of capital, and capital is among the most important sources of power. In a way, we can say that intellectual property governs

[454] *Ibid.*, at 772.

the relationship between various stakeholders, and has a direct effect on the distribution of goods and relations of dependency between IP owners and non-owners. Following this reasoning, Drahos argues that IPRs have a precarious inner logic since they are more likely to be awarded to powerful stakeholders.[455]

For Drahos, knowledge is power, and power is created by law and spread among intellectual property holders. When the law allows broadening the scope of what can be patented, society can expect that *threat power* arising from dependency relationships will end up under the control of a few. As Gold states, "[t]he purposeful omission of broader social considerations, coupled with a blind acceptance of the desirability of patents, belies a hidden libertarian agenda that favours existing distributions of wealth."[456] In fact, obtaining ownership over intellectual objects, especially in specialised fields of activity, often requires prior scientific competence and monetary investment from patent-holders. In return, when the patent is awarded, it can generate more capital for this group of powerful agents through licensing agreements and strict control on access. For example, when lawmakers decide to extend patent protection to genes and gene-related products and services, it creates more opportunity for small elites of powerful stakeholders, who already work or may be capable and interested in investing in genetics and biotechnology.

In this particular field of activity, we deal with universally important resources such as health knowledge and scientific progress. According to the logic of collective action, powerful agents are likely to team up in small groups to foster their common and well-defined economic interests by working on maintaining a rationalisation for the IP system.[457] In fact, the gains made by one member of the team will often benefit the rest of the group, who also share common values and interests. On the other hand, this logic does not apply in the same way to larger groups who might have a common interest in protecting the intellectual commons, such as, for example, African AIDS

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[455] P. Drahos, *supra* note 380, c. 7, at 145-169.
[456] E. R. Gold, *supra* note 420, at par. 40.
[457] M. Oslon, *The Logic of Collective Action* (Cambridge: Cambridge University Press, 1965); C. May, *supra* note 366, at. 22-44.

patients in need of cheap drugs, but for which putting up a structure and organisation to support collective action might be too much of a burden in terms of dissuasive costs. These obstacles directly influence the type of knowledge created and how it is produced and distributed.

Drahos also refers to a Rawlsian theory of justice to argue for the distribution of information instead of the excessive accumulation to which IP can give rise. Property should be treated not as the foundation of justice, but more as an instrument for achieving well-established principles of justice; it is not a right with a fixed status, but a privilege subject to specific duties.[458] For example, in our analytical context, property in genetic therapeutic products and services is a very powerful instrument, as it can affect other people in critical aspects of their lives. Following Drahos' distributive ideals, IPRs should therefore be used responsibly, so as to allow better access to genetics for global health improvement. Rights and property, however, form a dominant alliance in the actual IP system, and IP owners' obligations are not specified, and are often non-existent.[459] Intellectual property rights foster the interests of rights-holders without considering the associated social costs, the inequalities they can create, and the effects they can have on individuals and democratic institutions.[460] Drahos' ideal vision of IP would require the replacement of the proprietarianist view by an instrumentalist attitude supporting a different social role for IP. In fact, as Drahos mentions,

> [i]nstrumentalism would require strongly articulated conception of the public purpose and role of intellectual property. Under instrumentalism IP would be located in the context of some broader moral theory and set of values. Property rights would be morality's servants and not its drivers.[461]

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[458] P. Drahos, *supra* note 380, at 195.
[459] M. Tushnet, "An Essay on Rights" (1984) 62 *Texas Law Review* 1363.
[460] P. Drahos, *supra* note 360, at 197-198.
[461] P. Drahos, *supra* note 380, at 224.

One criticism of Drahos' vision is that it overemphasises the instrumental aspect of IP and treats knowledge and information as pre-existing collections from which individuals and companies *steal* for their personal benefit. Some argue that Drahos does not consider that patent-holders do not only draw from a pre-existing and static commons, but also participate in enriching it by adding to it through innovative and creative activities. This utilitarian critique of Drahos also suggests that the temporary restriction awarded by IP rights is probably the best solution to increase the bulk of information and knowledge through innovation.[462]

Drahos responds by arguing that a proprietarianist approach to IP does not necessarily encourage valuable innovation able to enrich the commons for the benefit of society as a whole. It instead contributes to creating powerful elites of property holders who participate in maintaining distributive inequalities among individuals. In fact, the IP system in its current state is often used to prevent competition and help the system's winners increase their control over more and more innovation.[463] The same legal construction that was supposed to promote the diffusion of information as a common good for society is being used to restrict knowledge access by focussing almost exclusively on its economic value.[464] Because the market of ideas and knowledge is characterised by major social and economic inequalities, and since it inspires an artificial construction established to foster the interests of the more powerful property owners, the assumed utilitarian incentive theory of intellectual property seems unfounded.[465] Drahos therefore describes IPRs as special and invasive privileges that encourage power and wealth concentration in the hands of small elites, something that creates clear socio-economic and ethical struggle for the most vulnerable. Moreover, since IPRs' inner logic does not require any form of redistribution to the less powerful, Drahos argues for limited scope of IPRs without suggesting a total abolition of inventors' rewards.

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[462] W. Van Caenegem, Book Review of *A Philosophy of Intellectual Property* by P. Drahos (1996) 8 *Bond L. R.* 217.
[463] M. Goldhaber, *Reinventing Technology* (New York: Routledge and Kegan Paul, 1986) c. 10
[464] T. A. Lipinski & J. Britz, *supra* note 338.
[465] In fact, the financial incentive for innovation is supposed to come from the market, which is flawed by major economic inequalities. B. Martin, *supra* note 381.

The overview of the different theoretical approaches to IP presented in this section was not meant to be a comprehensive discussion of all of the different theories of property. However, it clearly demonstrates how challenging it is to try to justify property and IP. In this section, we have covered different and contradictory positions, somehow representative of the inherent contradictions present in the IP system, namely between its dual purpose of diffusion and protection.[466] Indeed, some economists in favour of maintaining an IP system (but simultaneously disturbed by some of its inbuilt and functional inconsistencies) have acknowledged that "[i]t is almost impossible to conceive of any existing social institution so faulty in so many ways. It survives only because there seems to be nothing better."[467]

It thus appears difficult to justify patent protection with the traditional theories, particularly in the context of genetic development. For example, it is not rare in genetics to see strong public governmental participation in basic research with no strong commercial motivation; patent-holders are often private corporations and public institutions rather than actual inventors. Also, inventors are often motivated by non-commercial incentives to innovate; passion, recognition by peers, and contribution to science.[468] Moreover, human genetic resources appear to be of very special nature, and should be considered a crucial part of the commons to be distributed following justice, need and equity considerations. In this context, Drahos' critique offers a very relevant and adapted perspective on the flaws of the existing IP system as it functions and is justified today. He addresses crucial questions regarding power imbalances created by IP and its insufficient focus on distributive justice issues.

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[466] T. A. Lipinski & J. Britz, *supra* note 338 at. 58.
[467] J. Jewkes, D. Sawers & R. Stillerman, *The Sources of Invention*, 2d ed. (New York: W. W. Norton, 1969) at 187-188.
[468] J. Walsh, C. Cho & W.M. Cohen, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research* (Final Report to the National Academy of Sciences' Committee [on] Intellectual Property Rights in Genomic and Protein-Related Research Inventions), September 20, 2005, online on the website of the University of Illinois, <http://tigger.uic.edu/~jwalsh/WalshChoCohenFinal050922.pdf> (accessed May 6th, 2006).

These issues lay the foundation for our next section, where we will assess the IP system by highlighting the main values and principles underlined by this normative system and measure its compatibility with the theory of global distributive justice in health developed in the first part.

3.3 Global Distribution, Justice, and the Patent System: an Assessment

This section aims to assess the patent system with precise benchmarks of justice. In fact, its purpose is to identify, through the lens of a global distributive justice theoretical framework, the ideal relationship that should prevail between property, genetic information, and knowledge, and assess the compatibility of the results with reality.

In the first part of this dissertation, we established principles of global distributive justice to guide us toward our goal of global distribution of genetic research benefits. As explained in previous sections, IPRs are of considerable commercial value, and are often held by private corporations both in developed and developing countries. Although they allow patent-holders to temporarily exclude others from using, selling, or producing the object of their property right, IPRs also encourage public disclosure of new knowledge and information in exchange for exclusive rights over it. Despite the theoretical dual role of the patent system, only one seems to prevail; it thus appears important to determine whether the system truly accomplishes its societal goal of knowledge disclosure for the common good.[469] The extensive use of patents can give rise to important dilemmas in terms of equitable access to the object of patents, particularly when they are useful for meeting basic human needs. Indeed, although the inner logic of patents calls both for innovation protection and knowledge diffusion, it does not necessarily call for fostering equality among individuals. To examine these issues, it is relevant to test the IP system against the analytical tools developed in our theoretical framework. Our benchmark for assessing the IP system

[469] T. A. Lipinski & J. Britz, *supra* note 338, at 55-56.

is access to genetic technologies to support health, in order to further the goal of equality of opportunities. Access is a broad concept that we will analyse through different lenses. We will begin with the evaluation of the relationship between IPRs and global access to genetic resources. We will then address the existing link between IPRs and access, in terms of availability and affordability of genetic products and services.

3.3.1. Global access to genetic resources and international intellectual property rights

With a global and international focus, we will first examine the compatibility of the IP system with the notion of *public good* often associated with the human genome. Following that, we will assess whether appropriation of health resources from the commons and global distributive justice in health are consistent. Finally, we will look at the possibility of equal consideration of every human being in the international IP system.

3.3.1.1. Genetic common heritage vs. private appropriation of human genetic resources

The interest for genetics arises mainly from the value of emerging knowledge, which is often considered a public good. Knowledge arising from genetics and genomics can be viewed as global public goods [470] because their invention, production, and utilisation are not limited by territorial considerations (they can be used by everyone concurrently without losing value for subsequent use), and because research funding and publication in these fields are, in large part, undertaken by the public sector.[471] As things currently stand, however, the public-good nature of genetic knowledge can

[470] Which are defined as "goods with benefits that extend to all countries, people and generations" in I. Kaul, *Providing Global Public Goods: Managing Globalization* (New York: Oxford University Press, 2003) at 23.

[471] H. Thorsteinsdottir et al., *supra* note 30, at 892; P.P. Kayhan & E.A. Egan, "Patent: The Public Interest Versus the Private Privilege" (2005) 2:3 *American Journal of Bioethics* 45; J.M. Mueller, "Public Access Versus Proprietary Rights in Genemic Information What is the Proper Role of IP Rights" (2003) 6:2 *Journal of Health Care Law and Policy* 222.

only benefit countries who have technology and resources to transform, apply, and use it for products development, further research, and therapeutic purposes.

The principles emerging from article 1 of the *Universal Declaration on the Human Genome and Human Rights* are a good starting point for our reflection on global access to genetics and IPRs:

> The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.[472]

While this later expression has been used and supported by many,[473] its scope and practical application remain unclear. As briefly mentioned earlier, even if in fact, patenting of genetic material is possible and accepted under positive law, some people remain completely opposed to any appropriation of parts of the genome with patent rights.[474] To support their position, they argue that genetic material is very special, that it was not created by human beings, and that since we all possess copies of the human genome, it should not be possible for one to acquire exclusive property rights over what we all carry.[475] Others, on the contrary, reject the notion of common

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[472] UNESCO, *Universal Declaration on Human Rights and the Human Genome*, Paris, 1997, art. 1.

[473] For example, refer to the Council of Europe Parliamentary Assembly, *Recommendation No 1425: Biotechnology and Intellectual Property,* September 23, 1999, rec. 10; HUGO, *Statement On The Principled Conduct of Genetics Research,* March 21, 1996, online: <http://www.gene.ucl.ac.uk/hugo/conduct.htm> (accessed May 28th, 2006); Nuffield Council on Bioethics, *The Ethics of Patenting DNA: a Discussion Paper* (Nuffield Council on Bioethics: London), 2002, online on the website of the Nuffield Council: <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf> (accessed May 30th, 2006), at 22-23.

[474] German National Ethics Council, *supra* note 361; C Lawson, "Patenting Genetic Diversity, Old Rules May be Restricting the Exploration of a New Technology" (1999) 6 *Journal of Law and Medicine* 373, at 391; B. Looney, "Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement" (1994) 26 *Law and Policy in International Business* 231; M.L. Sturges, "Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Mankind" (1997) 13:1 *American University International Law Review* 219.

[475] J. Sulston, "IP and the Human Genome" in P. Drahos and R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 61; C. Joyner, "Legal Implications of the Concept of the Common Heritage of Mankind" (January 1986) 35:1 *International and Comparative Law Quarterly* 190; see also UNESCO, *International Consultation on the outline of the Universal Declaration on the Human Genome, Summary of the response to the questionnaire*, Paris, 1997; S. Paquerot, supra note 58.

heritage and believe that property rights over the human genome are acceptable because they encourage the production of additional health and economic benefits for society.[476] A third group of thinkers rejects the concept of *heritage of humanity* for its difficult practical application, instead proposing the notion of *common resource,* which supports a form of transfer of benefits to humankind.[477] This last vision does not prevent patents over parts of the human genome if moral duties of justice and stewardship to the genome are respected.[478] In other words, the ethics and legitimacy of patents on human genetics depends on their effects on the human gene pool and on current and future generations, who all share an interest in protecting the human genome.[479] The value of the human genome for humankind is enormous. In most cases, this value is evaluated only in terms of the benefits that can be derived from resources, products, and services arising from genetic research. One fundamental challenge is thus to ensure that emerging knowledge about the human genome will benefit the entire human community.

The current IP system does not necessarily always prioritise the public domain. As previously mentioned, there was, until very recently, a strong tendency to apply very broad patentability criteria in the fields of biotechnology and genetics but things are changing gradually. [480] However, it remains that, as Drahos taught us, proprietarianism has had a crucial role in the development and evolution of IP law by increasing the scope of private property in intellectual objects. Our actual IP system thus represents a tacit acceptance of a negative community where nobody owns the elements of the public domain, and where all states and stakeholders are free to

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[476] J. P. Hinojosa, *supra* note 341; .M. Spectar, "The Fruit of The Human Genome Tree: Cautionary Tales about Technology, Investment, and the Heritage of Mankind" (2001) 23:1 *Loyola of Los Angeles International and Comparative Law Review* 1.

[477] J. P. Hinojosa, *supra* note 343; M. Kirby, "Genomics and Democracy, A Global Challenge" (February 2003) 31:1 *UWA Law Review* 1 at 18; D. B. Resnik, *supra* note 354; E.T. Juengst, "Should we Treat the Human Germ-line as a Global Human Resource?" in E. Agius & S. Busuttil, eds., *Germ-line Intervention and our Responsibilities to Future Generations* (Dordrecht: Kluwer Academic Press, 1998) 85.

[478] These notions have been borrowed from the field of environmental protection. H. Rolston, *Conserving natural value* (New York: Columbia University Press, 1994); D. B. Resnik, *supra* note 354, at 198.

[479] D. B. Resnik, *ibid.* at 201-202.

[480] Refer to footnote 365 for a discussion and references on this point.

appropriate those resources (depending on their actual economic and innovative capacities), in opposition to a positive community, where every agent automatically has joint ownership over the same elements of the commons,[481] which often results in over-consumption of the resources of the commons.[482] Those notions are directly applicable to the extensive privatisation of the human genome, made possible through the preservation of a negative community where no one opposes the privatisation of the commons, and where governments do not seem to intervene to prevent it because of its reported positive effects on innovation and related commercialisation.

In fact, even if one goal of IPRs is more knowledge diffusion for the benefit of society, the whole structure of the system of intellectual property tends to underestimate the value of the commons by "failing to make actors and society as a whole internalise the losses caused by the extension and exercise of intellectual property rights."[483] Those who critique the functioning of the current system believe in improved access to the human genome as a common resource. This could lead to a new egalitarian way forward in thinking about the global knowledge commons, for example, by limiting monopoly rights to encourage increased knowledge diffusion in furtherance of our goal of global distribution of genetic technologies.[484] However, some important obstacles remain, especially with regard to the growing importance, value, and protection of property rights in society, with the concomitant power relationships to which property rights often give rise, and the technical incapacity of developing countries to exploit genomics knowledge for their particular needs.[485]

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[481] P. Drahos, *supra* note 380, at 48-49.
[482] G. Hardin, "The Tragedy of the Commons" (1968) 162 *Science* 1243.
[483] J. Boyle, "A Politics if Intellectual Property: Environmentalism for the Net?" (1997-1998) 47 *Duke L. J.* 87, at 111.
[484] K. Aoki, "Neo-colonialism, Anticommons Property and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection" (1998) 6 *Ind. J. Global Leg. Stud.* 11, at 29-35; S. Picciotto, "Defending the Public Interest in TRIPS and WTO" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 224; C. May, *supra* note 333.
[485] C. May, *ibid.* at 134-137; C. Wellman, *The Proliferation of Rights: Moral Progress or Empty Rhetoric* (Boulder: Westview Press, 1999).

The reduction of the knowledge commons for the benefit of individual appropriation is more and more pronounced[486] and, as explained by Lange, it has to do with courts' and legislators' perception of the public domain as "an unexplored abstraction instead of a field of individual rights fully as important as any of the new property rights."[487]

3.3.1.2. Universal importance of health vs. private appropriation of human genetic resources

As we saw earlier with Drahos, certain fields of activity, like genetics, have given rise to a serious concentration of power in the hands of those who have scientific and economic resources to obtain patent rights over resources upon which there is universal reliance. For example, disease-gene patenting can grant patent-holders considerable control over resources that could otherwise play an important role in improving people's health. Patentees are free to exercise their exclusive rights as they see fit for the duration of the patent,[488] without the burden of any distributive justice obligation. Therefore, even if the existence of patents is not unfair per se, the fact that property rights often take precedence over other competing rights, entitlements, and interests requires care and vigilance in their application.

Exclusive IPRs simultaneously grant economic advantage to those who have economic, knowledge, and innovative power, and often increase access costs for non-IP owners.[489] Distribution of the costs and benefits arising from IPRs is not driven by distributive justice principles, but more by power relationships exacerbated by exclusive property rights of small elites.[490] These effects can be observed within countries, but are often more serious between countries. In fact, most people from

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[486] And that, even though some steps have been taken in terms of free accessibility, for example, to the human genome draft sequence and the SNPs database. These initiatives remain the exception.
[487] D. Lange, "Recognising the Public Domain" (1981) 44:4 *Law and Contemporary Problems* 147, at 178; C. May, *supra* note 333.
[488] subject to existing legislation.
[489] This will be discussed later in this chapter
[490] J. W. Singer, *Entitlement: The Paradoxes of Property* (New Haven: Yale University Press, 2000), at 68.

developing nations are being left out of the IPRs system in innovative fields like genetics, as they often do not have the necessary scientific and technical power to get involved, innovate, and apply for IP protection. With TRIPS, however, they must still bear the costs associated with compulsory protection of intellectual objects mostly coming from abroad. In this sense, the international system of IPRs does not ensure that people from developing countries have their health needs satisfied; in some cases, it even contributes to engendering health gaps within and between nations. We will come back to this specific topic with examples in the last chapter of the dissertation.

The principles established in the first part for global equitable distribution of genetic benefits recognise the universal importance of health for every human being, no matter where they live. Our theoretical analysis led us to conclude that since health is a crucial human need, securing it is necessary to avoid serious harm and to develop a normal range of opportunities. This is what inspired our argument in favour of genetic-benefit distribution in an effort to compensate for global health inequalities and deviations from normal functioning, two important elements for equality of opportunity. This global distributive justice framework for equitable access to health should encourage the establishment of international principles and institutions. However, these values are not TRIPS' primary focus.

3.3.1.3 Universal consideration of every human being in the international IP system

In the last two subsections, we briefly discussed the compatibility of the values underlined by the global IP system with obligations of distributive justice in health. We also have to address another important aspect of our theoretical framework in relation to IP: the cosmopolitan focus of our approach to justice. To this end, we will assess the global structure supporting the international IP system to determine whether it conforms to the principle of universal consideration of every human being required by moral cosmopolitanism. To aid us in this task, we will determine whether

the international IP system can qualify as a just global basic structure and whether it responds to shared human interests in equality of opportunity.

Does the international IP system correspond to a just global basic structure?

Some who are opposed to a global application of principles of distributive justice argue that the existence of a coercive network of law is absolutely essential to engage in redistribution, and that this type of network does not exist on the global scene.[491] This argument does not stand, especially when applied to the international IP system, which easily qualifies as a coercive legal network.[492]

In our theoretical framework, we supported a distribution of benefits arising from the commercialisation of a common resource (the human genome) extended to the global scene, arguing that boundaries and citizenship should not limit the scope of social cooperation, loyalty, and obligations. We therefore adopted a cosmopolitan focus referring to each individual as a unit of moral concern, and concluded that everyone affected by institutional distributive arrangements should be given the chance to secure a normal range of opportunities for himself, in order to have access to a *decent* life.[493] We also adopted the cosmopolitan idea that the state should not be given absolute priority when discussing issues of distributive justice in areas of crucial importance for every human being. We addressed the limits of boundaries in arguing that states were not necessarily the best actors to protect justice within and outside their territories, but we did not reject the existence and relevance of states all together. In fact, national regulatory interventions can be important in biotechnology and genetics, by providing the agency required to perform distribution of the private

[491] For example, refer to M. Blake, *supra* note 121, at 291-292.
[492] Indeed, every WTO member state is required to adhere to and comply with TRIPS, which is complemented by a unique and effective enforcement mechanism.
[493] We refer the reader to the theory chapter for a comprehensive discussion on cosmopolitanism.

gains arising from these fields. All that cosmopolitanism requires is a vision of sovereignty that does not constitute an arbitrary limit on the scope of justice.[494]

Indeed, principles of distributive justice can continue to impose obligations for the satisfaction of individual rights both on states (which, for now, remain the primary agents of distributive justice), and on other institutional actors (who may also be viewed as potential agents of international justice obligations). A significant challenge is to find a balance between the order supported by sovereignty and the pursuit of justice through moral universalism. Some propose that state and non-state agents should work toward an agreement on general ethical principles, values, and duties that international society should internalise and promote as a group. It would extend the frontiers of communities, despite the different cultural and community allegiances.[495] In fact, these principles would serve as a basis for the establishment of a broad political community outside the boundaries of states. It is relevant to mention that we can actually observe a proliferation of transnational advocacy networks driven by common values and aiming to reconstruct the scope and limits of state sovereignty on the international scene by denouncing inequities.[496]

Therefore, even if there is, to this day, an institutional inability to implement principles of distributive justice at the international level, these principles have an important role to play in identifying future courses of action to develop institutional capacity and governance in an emerging global society.[497] This could result in the expansion of democracy beyond the state structure and help challenge the

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[494] O. O'Neill, "Justice and Boundaries" in C. Brown, ed., *Political Restructuring in Europe: Ethical Perspectives* (NewYork: Routledge, 1994) at 69.

[495] A. Linklater, *Transformation of Political Community* (London: Polity Press, 1998) at 167; R. A. Payne & N. H. Samhat, *Democratizing Global Politics, Discourse Norms, International Regimes and Political Community* (New York: State University of New York Press, 2004); J. Thompson, "Community, Identity and World Citizenship", in D. Archibugi, D. Held & M. Kbhler, *Re-imagining Political Community: Studies in Cosmopolitan Democracy* (Stanford, CA: Stanford University Press, 1998) 179, at 191.

[496] M.E. Keck & K. Sikkink, *Activists Beyond Borders: Advocacy Networks in International Politics* (Ithaca: Cornell University Press, 1998) c. 6.

[497] C.R. Beitz, *supra* note 55 at 271; B. Barry, "International Society from a Cosmopolitan Perspective" in D. Maple & T. Nardin, eds., *International Society: Diverse Ethical Perspectives* (Princeton University Press: Princeton, 1998) 146; T. Christiano, "Democracy and Distributive Justice" (1995) 37 *Arizona Law Review* 65; A. Buchanan, *supra* note 25, c. 4, at 191-230.

mechanisms of non-democratic globalisation from above which are supported by the International Monetary Fund, the World Bank, and the World Trade Organisation.[498]

This brings us to the notion of global basic structure, a concept referring to the existing, well-established global scheme, characterised by international legal systems mostly controlled by private property and trade regimes.[499] Some, like Beitz and Barry, argue that this global basic structure creates a *pattern of global interdependence* between participating states, and that this system implies mutual cooperation required by global distributive justice.[500] Drahos is more sceptical; he does not automatically link states' economic interdependency and their involvement in a scheme of mutual cooperation. He believes that the global structure is very heterogeneous in terms of group beliefs, moral codes, and cultural practices, and that it is therefore difficult to identify global principles of justice for mutual cooperation. He does not rule out global distributive justice theory, but decides not to pursue it because of the problems he anticipates with its application.[501]

Whatever qualification we apply to the existing global structure, whether we believe it is a site of interdependence or of mutual cooperation, there is no reason why it should not also be a subject of justice.[502] Unfortunately, justice, as we envision it, does not seem to direct the existing global structure. Indeed, for some, the global community emerging from this structure mirrors the economic inequalities and gives rise to the same concentration of power observed at state levels. This makes this

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[498] R. Falk, *On Humane Governance: Toward a New Global Politics* (University Park, PA: Pennsylvania State University Press, 1995) at 125; R. A. Payne & N. H. Samhat, *supra* note 495.

[499] The basic global structure is composed of regional and international economic agreements like NAFTA and TRIPS, international monetary schemes like The World Bank and the International Monetary Fund, and international human rights standards.

[500] C.R. Beitz, *Political Theory and International Relations*, *supra* note 64 at 145; B. Barry, *The Liberal Theory of Justice: Critical Examination of the Principal Doctrines In A Theory of Justice by John Rawls* (Oxford: Clarendon Press , 1975) at 129.

[501] P. Drahos, *supra* note 380, c. 8, at 170-198. We have already analysed similar critiques of global distributive justice in the theory chapter, basing our argument on the special character and universality of health as something that transcends countries' cultural differences, special beliefs, and moral codes. For that reason, we decided to reject a communitarianist approach to justice. We refer to reader to section xxx of the previous chapter for a more complete discussion on the topic.

[502] A. Buchanan, *supra* note 25, c.2, at 73-74.

international structure unsuitable to further global community interests.[503] Other scholars, including Cox and Richards, believe that it is not a few states which dominate the world order, but more a dominant ideology with a central mode of production and distribution infiltrating every state.[504] This new elite occupies a privileged space on the international scene, without representing individual interests and without being democratically accountable. As explained by Hymer, the power of multinational corporations as principal agents of globalisation is replacing the traditional authority of the state: "[w]hen a corporation invests abroad it not only sends capital and management out but also establishes a system for drawing foreign capital and labor into an integrated world network."[505]

One issue that is not debated is that the shared global order currently in place is established by the most fortunate and imposed on the worst-off. As it represents an important part of the global order, we here subject the international IP system to assessment from a global distributive justice perspective. It should contain mechanisms to ensure that everyone has access to a certain level of health (influenced by access to genetic knowledge and products), in order to be able to secure a normal range of opportunities. This duty of justice in health originates from different theoretical sources already discussed in the first part of the thesis.[506] Regardless of

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[503] C. May, "Cosmopolitan Legalism Meets Thin Community: Problems in the Global Governance of IP", *supra* note 404, at 410.

[504] R. Cox, *Approaches to World Order* (Cambridge: Cambridge University Press, 1996); D.G Richards, *supra* note 380.

[505] S. Hymer, *The Multinational Corporation: a Radical Approach* (Cambridge: Cambridge University Press, 1979) at 76; D.G Richards, *supra* note 380, c. 4, at 79-111.

[506] Here is a brief reminder of what we studied in the last chapter with regards to duties of justice. The first one is the general moral duty to avoid causing harm to others, an obligation that can be met by avoiding participation in an unjust global structure. Our ideal, just global structure requires that we denounce the actual IP structure and adhere to global distributive mechanisms to avoid such harm. However, the actual international intellectual property system does not appear to work this way. T. W. Pogge, *World Poverty and Human Rights*, *supra* note 284; T.W. Pogge, "Symposium on World Poverty and Human Rights", *supra* note 284. A second foundation for global distributive mechanisms in health does not relate to responsibility for harm, but instead to the urgency and seriousness of the problems of the less affluent. Basically, this argument requires that the most affluent take action to improve global health if it is of substantial significance for the recipient and it does not impose too much of a burden on the donors. As we know, TRIPS has been established by the most affluent, mostly multinational pharmaceutical and software companies, in order to further their particular interests. As a result, exclusive property rights are granted on many health-related products, technology, and services that can play a major role in saving lives and providing therapeutic solutions for serious and life-threatening diseases. In this context, one could argue that patent-holders could renounce their exclusive

which theoretical reason we choose to justify justice obligations (we argued for a duty to avoid harm in our theoretical framework), the economic disparity between different countries and regions of the world makes it impossible to address issues of distributive justice and property rights over the human genome without polarising the world into two large groups: developed and developing countries.[507] In fact, even if we all share our genetic background with everybody else on the planet, the technology for unlocking the value of these human genetic resources is patented mostly in developed countries and sometimes in developing countries, for the most part by stakeholders from the developed world. This factor, among many others, can influence access to genetic benefits by individuals of different regions of the world.[508]

This dichotomy is illustrated in the application of TRIPS, which was created primarily to secure benefits for the IP owners, encourage international trade, and establish a system that fosters minimal standards of IP for every WTO member state. In fact, the global scheme broadens patentability criteria for a minimum 20-year period and has a general negative effect on developing countries, and people from those countries, in terms of access to health and genetics. The basic mission of the

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rights in the most serious and urgent cases without serious economic consequences. H. Shue, *Basic Rights*, *supra* note 245, at 159-180; J. Arthur, "Rights and the Duty to Bring Aid" in W. Aiken & H. LaFolette, *World Hunger and Morality,* 2nd ed, (New York: Prentice-Hall, 1996) 39, at 49. A third justification for global distributive mechanisms is Buchanan's duty of justice, which requires the creation of mechanisms to provide everyone with access to just institutions. This idea is based on a cosmopolitan vision that treats all human beings with equal consideration by respecting and protecting their basic rights. Because the international intellectual property system mainly prioritises trade and affluent countries' patent-holders, it does not correspond to a just institution and should be regulated and reformed for the sake of justice. A. Buchanan, *supra* note 25, c. 2, at 73-117; Drahos provides a fourth perspective in referring to Rawls' law of people to justify obligations of justice, and what parties in the original position would choose as just property mechanisms. As we know, Rawls argued that people under the veil of ignorance would choose to comply with equality of opportunity and with the difference principles. Following Rawls, Drahos believes that since property plays a big role in trade, parties who do not know what states they represent would choose to award a minimal level of protection. They would surely reject protectionist mechanisms such as rigid, long, extensive, and broad IP rights, because they would be incompatible with principles of equity and justice, and would tolerate huge differences in people's socio-economic status and access to genetics. As we know, this is not what is happening with TRIPS, as extensive protectionist patenting measures equally apply to both less affluent and developed states.

[507] P. Kameri-Mbote, *Property Rights and Biodiversity Management in Kenya* (Act Press: Kenya, 2002).

[508] For statistics on this point, refer to World Bank, World Development Indicators 2005, Geneva, 2005, online on the website of the WB, <http://devdata.worldbank.org/wdi2005/index2.htm> (accessed May 2nd, 2006), table 5.12.

WTO is to foster a uniform system of liberalised trade at the global level.[509] In this sense, TRIPS is a tool to encourage international capitalism and strengthen existing global inequalities. This obviously creates tensions between exporters and importers of IP goods. Some scholars and numerous reports argue that, in prioritising protection instead of diffusion, this system mainly targets the needs of wealthy inventors and IP owners, and results in shrinking the bulk of public knowledge. They also believe that the global standardisation and proliferation of IP norms fostered by TRIPS does not encourage more and better knowledge diffusion and dissemination as a single patent application in one country only is sufficient to ensure diffusion.[510] TRIPS can thus harm poorer producers and the public at large by not taking egalitarian grounds into consideration and not fostering public welfare goals.[511] The proponents of this position highlight that IP globalisation can be very costly for poor countries and have disastrous effects on global welfare with very little benefit for the majority in return.[512] However, as we know, others argue instead that increasing IP protection globally can result in positive welfare effects for developing countries by encouraging innovation, foreign direct investment, and technology transfer.[513] We will come back to those opposing views in the last chapter of this dissertation, when we discuss the effect of gene patents on access to health in developing countries.

Regardless of the view we adopt on the practical short- and long-term effects of patents on innovation in developed and developing countries—something to be discussed later in this chapter—the fact that TRIPS emerged from negotiations

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[509] As very well explained by D. Moellendorf, "The World Trade Organization and Egalitarian Justice" (January 2005) 36:1/2 *Methaphilosophy* 145, at 150-152.

[510] P. McCalman, "Reaping What You Sow: An Empirical Analysis of International Patent Harmonization" (2001) 55 *Journal of International Economics* 161.

[511] And that, even though some dispositions aim to find some balance between innovation and diffusion with exceptions to patent protection. This will be discussed further in the last section of this chapter.

[512] For example, refer to: UNCTAD, *The TRIPS Agreement and Developing Countries,* UNCTAD, Geneva, 1996; UNDP, *Human Development Report 2001*, Geneva, 2001; UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights in Development Policy,supra* note 426, at 5; D.G Richards, *supra* note 380; K. Maskus, "Normative Concerns in the International Protection of Intellectual Property Rights" (1991) 14 *World Economy* 403; J. Ordover, "A Patent System for both Diffusion and Exclusion" (Winter 1991) 5:1 *Journal of Economic Perspectives* 43.

[513] For example, refer to E.Su, "The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries" (2000) 23 *Hous. J. Int'l L.* 169; Gold *et al., supra* note 353, at 328.

undertaken under the auspices of the WTO explains most of its effects on global access and distribution of health and genetics. Some argue that since the *Uruguay Round Agreements* (including the *Multilateral Agreements on Trade in Goods*, the *General Agreement on Trade in Services*, and TRIPS) were voluntarily signed by various countries—both from the developed and the developing world—it must have been satisfactory and beneficial to everyone.[514] This reasoning implies that those agreements leave everybody in a better position and that consent is sufficient to infer legitimacy. However, what the proponents of this view seem to ignore is that TRIPS' negotiations occurred within a global scheme and under an international organisation characterised by numerous power inequalities.[515] As explained by Buchanan, "unless the background institutions of the basic structure are just, injustices may be perpetuated by voluntary agreements."[516] In this case, developing countries were made to realise that they did not really have any other choice but to accept TRIPS' conditions negotiated in a context of economic oppression and power imbalance.

Consequently, in reply to the question of whether the international IP system qualifies as a just global basic structure, we can say that TRIPS is part of a global scheme imposed by the most affluent on the less fortunate, a structure that does not qualify as just when assessed from our global distributive justice perspective. Indeed, global distribution of health benefits is a crucial element of our ideal theory of justice, and it does not seem to be central to TRIPS, which was designed by a few stakeholders to further their own private interests in a global structure they run. Undeniably, the international political system and, more specifically, TRIPS, as they work now, give rise to power struggles that almost always take our attention away from the universal principles and values standing at the basis of a cosmopolitan vision of humanity.

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[514] Following a complex process of negotiations, developing countries agreed to TRIPS in exchange for concessions in others trade related sectors like agriculture and textile. *Marrakesh Agreement Establishing the World Trade Organization,* Annexes 1A, B and C, 33 I.L.R. 1197 (1993)

[515] For an enlightening discussion on this point, refer to K. Raustiala, "Compliance and effectiveness in international regulatory cooperation" (Summer 2000) 32:3 *Case Western Reserve Journal of International Law* 387; P. Gerhart, "Reflections: beyond compliance theory - TRIPS as a substantive issue" (Summer 2000) 32:3 *Case Western Reserve Journal of International Law* 357, at 371.

[516] A. Buchanan, "Rawls's law of peoples: Rules for a vanished Westphalian World" *supra* note 56, at 705.

Does the international IP system offer a response to shared human interests in equality of opportunities?

Our normative cosmopolitan principles require that individuals be considered the "normative epicentre of a system of functionally plural sovereignty."[517] Some could argue that since the international IP system was established in an agreement between sovereign states for minimum standards of protection for both inventors and the public, it is therefore compatible with a cosmopolitan ideal, since it considers everyone. An analysis of the historical and political context of TRIPS' adoption, however, leads us to conclude that its creation, adoption, and enforcement have not been driven by shared morality but by the interests of the more powerful.[518] Overall, in increasing the scope and reach of intellectual property at the international level, TRIPS strengthened the property power of the most affluent stakeholders of the world. [519] As May describes, "the legal rules encapsulated within the TRIPS represent the triumph of the knowledge structure's agenda of the metaphorical links between knowledge and property".[520]

This clearly demonstrates that TRIPS did not result from negotiations undertaken in conditions of voluntary mutual assistance. Each state that had a minimum amount of power took care of advancing its own interests and advantages as much as it could.[521] Moreover, the WTO is an organisation which has no democratic features and is subject to the same economic inequalities we find at the state level, something which greatly limits democracy at the international level because of the lack of central

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[517] A Kupler, *supra* note 83

[518] For a detailed analysis of TRIPS' context of adoption and operation, we suggest that the reader refer to: S. K. Sell, *supra* note 369. The author even questions the legitimacy of the agreement because of its coercive negotiation context and absence of mutual benefits. See also D. Dufield & U. Suthersanen, *supra* note 366.

[519] C. Arup, "Competition over Competition Policy for International Trade and Intellectual Property" (1998) 16:3 *Prometheus* 367, at 376.

[520] C. May, *supra* note 366, at 34.

[521] For Buchanan, "the state is nothing more than a discretionary association for the mutual advantage of its citizens" A. Buchanan, "The Internal Legitimacy of Humanitarian Intervention" (1999) 7 *Journal of Political Philosophy* 71.

authority.[522] In a way, it is "extra-governmental" and beyond the direct reach of the electorate.

In response to this situation, some argue for increased decentralisation and prioritisation of national interests, both on the international and the national scenes, instead of trying to agree on global shared interests. One argument to support this view is that different cultures call for different actions, and attempts by some states to establish international moral standards could lead to moral imperialism.[523] There are a few problems with this national interest view. One is that, in reality, the national interest is often the expression of the interests of small number of elites who have enough power to neutralise the interests of other groups. This is clearly illustrated by the outcome of TRIPS' negotiations. The strong multinational lobby of the pharmaceutical industry, represented in different industrialised countries, vigorously promoted its own interest in a universal minimal coverage of patent protection.[524] In so doing, these multinational corporations had a large impact on the adoption of the TRIPS agreement as it now stands.[525] They were very efficient in convincing state policymakers to promote their interests. By letting the pharmaceutical lobby implicitly lead the negotiations and further their economic agenda in the name of whole nations, developed countries like the US and Japan, as well as the EU, agreed to translate private interests into matters of public interest. This concurrently left out the concerns of other national interest groups like patient groups, NGOs, and citizens.[526]

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[522] J. S. Dryzek, "Transnational Democracy" (March 1999) 7:1 *Journal of Political Philosophy* 30, at 33.

[523] H.J. Morgenthau, *Politics Among Nations: The Struggle for Power and Peace*, 6th ed. (New York: Alfred A. Knopf, 1985); C. Rice, "Campaign 2000, Promoting the National Interest" (Jan-Feb 2000) 79 *Foreign Affairs* 45

[524] In fact, large pharmaceutical companies believe that patent protection is the most important tool to uphold their investment in R&D and innovation, in addition to furthering their corporate strategies as explained in F.M. Scherer, "Le Système de Brevet et l'Innovation dans le Secteur Pharmaceutique/ The Patent System and Innovation in Pharmaceuticals" (2000) 1 *Revue Internationale de Droit Economique* 110, at 112.

[525] M. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Washington DC, Brookings Institution, 1998) at. 67-72; S.K. Sell, *supra* note 369, at 23-25.

[526] Many interest groups who stand on diametrically opposed grounds to pharmas exist everywhere in the world. There is, for example, Oxfam, Greepeace, Médecins sans Frontières, Canadian HIV-AIDS Legal Network, the Consumer Project on Technology, etc. Refer to the following document for an

Another difficulty arising from a focus on national interest is that it assumes that state officials will necessarily act to promote their populations' interests. It thereby ignores the fact that many poor countries are very poorly governed. In fact, many of them are run by corrupt officials, not always democratically elected and often more concerned about advancing their own interests than those of their populations. It is thus fair to say that individuals forming the populations of such unstable states cannot count on their governments to represent them adequately, and would therefore derive great advantage from the application of global principles of shared morality. Moreover, we cannot ignore the global institutional context's role in maintaining some of these corrupt, undemocratic, and unstable governments. As long as affluent states recognise the effective political and trade power of unstable governments and will design global normative instruments like the international intellectual property scheme hand-in-hand with them, global inequities and poverty will persist.[527]

The liberal cosmopolitan distributive justice theory adopted in this thesis calls for a shared morality between all societies and humans to meet basic and universal needs and values. Stuart Hampshire defines basic ethical principles as "those that if followed, help avert the worst harms to which all human beings are vulnerable, those principles to which adherence is necessary for people being able to lead decent human lives."[528] It is important to identify spheres of common and universal interest that can forge a sense of global identity necessary to find a consensus on common ethical principles relating to universal concerns for the well-being of every individual. Such an exercise has been successfully completed in the field of research ethics, where a broad agreement on common ethical principles has been reached for a minimal protection of human

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example of joint action in opposition to the economic agenda of big pharmas: The Interagency Coalition on AIDS and Development, Canadian Council for International Cooperation, and Canadian Treatment Action Council, *An Open Letter to All Members of Parliament*, October 25th, 2001, online on the website of MSF:
<www.msf.ca/access/pics/msf_letter_par_e.pdf> (accessed: May 30th, 2006).

[527] T. W. Pogge (2005), *supra* note 506, at 7.

[528] S. Hampshire, *Innocence and Experience* (Cambridge, MA: Harvard University Press, 1989) at 90; see also A. Linklater, *supra* note 495, at 167-170.

research participants at the international level by medical researchers under the auspices of the *World Medical Association* (WMA)[529] and by regulators and representatives of pharmaceutical companies in the field of clinical trials with the *Guidelines for Good Clinical Practice* (GCP) adopted through the *International Conference on Harmonisation* (ICH).[530] Global health improvement is another one of those fields that should be of common and universal concern, for reasons already analysed earlier.

In the broad area of international law, this shared morality should be served by integrating distributive justice standards in trade relations, labour and environmental law, and in the global intellectual property rights scheme for a more equitable international allocation of the health benefits arising from biotechnology and genetics. For now, however, the social utility function of IP is interpreted quite narrowly as we witness the acquisition of property rights on products which make use of elements of the public commons by a small group of corporate stakeholders. Unfortunately, the international IP system can be viewed as a foil designed to benefit the owners and managers of multinational capital invested in funding, creating, and supplying the knowledge-based inventions in different markets worldwide.[531] TRIPS has the status of public international law and functions mostly without having to take health and welfare needs of the world's poor majorities into great consideration. TRIPS contains some exceptions and flexibility, but as it will be discussed in more detail in the next section, these are often given minimum consideration in practice. In this sense, TRIPS is compatible with the neo-liberal ideology that supports a fundamental civil right of *freedom of trade* for every

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[529] This international exercise has been fruitful, as most states now act in accordance with a common set of moral principles when conducting biomedical research. For an overview of this globally shared morality in the ethics of biomedical research, refer to: World Medical Association, *Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects* (5th rev), Edinburgh, Scotland, 2000, online on the website of the WMA: <http://www.wma.net/e/policy/b3.htm> (accessed: May 30th, 2006).

[530] International Conference on Harmonisation, *Good Clinical Practice : Consolidated Guideline,* E6-R1, June 10, 1996, Online on the ICH website: <http://www.ich.org/LOB/media/MEDIA482.pdf> (accessed May 2nd, 2006).

[531] R. A. Payne & N. H. Samhat, *supra* note 495 c. 5, at 135-140.

individual.[532] In awarding precedence to property rights and freedom of trade, this view concurrently legitimises inequalities in health and differences in opportunities.

This tendency needs to be corrected at the normative level if we want to hope for global distributive justice and social welfare. Actions have already been taken in this direction, with NGO campaigns denouncing the effects of TRIPS on access to essential drugs, yet much more needs to be done for the global IP system to mirror a shared human interest in health and to promote equality of opportunity through distributive justice mechanisms.

This section aimed at assessing one aspect of IP: the globalised perspective implanted in the system of international IPRs with a standard of global access. To do so, we used the cosmopolitan focus adopted in our theoretical framework and refered to the global nature of our distributive justice obligation in health and genetics. Our analysis highlights various challenging issues related to the political economy, philosophy, and functioning of the international IP system. First, in relation to the protection of the public domain, we realised that the current IP system does not prioritise the protection of the commons, but instead encourages patent claims on a broad range of resources and products. This is particularly relevant in the area of genetics, where we detect increasing and extensive privatisation of the human genome, contributing to the erosion of the commons. This can be detrimental to genetic research and innovation. Second, we observed that the system of international IPRs does not work to allow for a recognition of the universal importance of health for every human being. In fact, although it has clear legislative potential to this end, TRIPS, as it works, does not do much about the fact that most people from developing countries are being left out of the system's application, especially in innovative fields like genetics, as they often

[532] E.-U. Petersmann, "National Constitutions and International Economic Law" in M. Hilf & E.-U. Petersmann, eds., *National Constitutions and International Economic Law* (Deventer: Kluwer. 1993) 3; E-U. Petersmann, "The WTO Constitution and Human Rights" (2000) 3:1 *Journal of International Economic Law* 19, at 21-23.

do not have the necessary scientific and technical power to get involved. This can have a negative impact on health, as we will see in more detail in the next part of this chapter. A third problem with the international IPR system is that it does not ensure universal consideration of every human being. This is due in part to its protectionist nature, the interests it prioritises, and the economic gap it fosters between countries that innovate and those that cannot.

Having assessed the international dimension of the IPR system with different aspects of global access to genetic resources, we will now evaluate the compatibility of IPRs with other facets of access: availability and affordability of genetic research tools, products, and services as mechanisms to further equality of opportunities.

3.3.2. Patents and access in terms of availability and affordability

The philosophy of article 19 of the *Universal Declaration on the Human Genome and Human Rights* is a good starting point for our reflection on access to genetics in terms of availability and affordability:

> a) In the framework of international co-operation with developing countries, States should seek to encourage measures enabling:
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> i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;
>
> ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;
>
> iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;
>
> iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

> b) Relevant international organizations should support and promote the initiatives taken by States for the above mentioned purposes.

The main goal of this section is to determine how the need for access to genetics is realised in relation to availability and affordability, and whether the actual IP scheme is designed to meet and prioritise this need. After a brief presentation of different spheres of access affected by patents, we will assess the compatibility of IP rights with securing equality of opportunities and distributive justice in relation to genetic knowledge and related innovations.

3.3.2.1. Spheres of genetic access affected by patents

One particularity of genetics is that access to what has already been discovered is necessary to push the science further and discover alternative applications. As Sulston notes, "it is not possible to reinvent a human gene,"[533] and since the most important gene applications are often discovered following many years of cumulative research, access to prior work is of critical importance for the scientific survival of the whole field. Property rights in intellectual objects can have an impact on different spheres of genetic access. For example, patents can influence availability of research tools in placing a temporary embargo on crucial elements necessary for the advancement of genetic research. Patents can also affect the availability of genetic tests and services in vulnerable communities and populations as they can influence affordability of products and services.

[533] J. Sulston, *supra* note 475, at 86.

Availability of research tools

In genetics, research tools are the input needed to develop, discover, or invent innovative heath-related products. For example, these tools include DNA, genes, sequencing techniques, genetic bio banks, stem cells, cell lines, single nucleotide polymorphisms (SNPs), genetic knowledge, etc.[534] In the course of their research projects, investigators will often need to access, analyse, and duplicate many research tools. When they are patented, their use will increase the cost of research if, for example, patent-holders impose high licensing fees, or if the use of many patented tools is needed for the same project and some patent holders are reluctant to license their rights. This latter concern is especially relevant in genetic research, where it is not uncommon to see multiple (patented) genes and gene sequences involved in the expression of one single disease. As discussed earlier, this has been referred to as the *tragedy of the anti-commons*, occurring when too many holders of property rights are in positions to exclude others from using resources from the commons.[535] Some, like Kieff, respond to such concern arguing that patents on research tools will instead encourage their commercialisation and accessibility and that many patent-holders will naturally be inclined to widely license their right in useful research tools in order to become more famous and receive academic recognition from their peers.[536] As briefly mentioned earlier, there is not enough data for now to conclude that patents are at the origin of a *tragedy of the anti-commons*, but there are some indications that patents, at least in certain cases, can negatively impact the conduct of genetic research and inhibit science.[537] This is

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[534] WHO, *Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries*, *supra* note 19, at 39; J.P. Walsh, A. Arora & W.M. Cohen, *supra* note 444.

[535] This can happen with the ongoing race taking place in genetics and genomics. Various companies have taken out patents on multiple DNA sequences in a race to control entire genes, and they could use their rights in these sequences to prevent other scientists from using or studying them. Indeed, they could refuse to license their rights or charge high prices for their use. For example, M. A. Heller, *supra* note 443, at 624; M.A. Heller & R.S. Eisenberg, *supra* note 358; D. G. Richards, *supra* note 370, c. 2, at 36-38.

[536] For more on this argument, see: F. S. Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science- A response to Rai and Eisenberg", *supra* note 365; J. Walsh, C. Cho & W.M. Cohen, *supra* note 426; J. Walsh, C. Cho & W.M. Cohen, "View from the Bench: Patents and Material Transfers" (Sept. 23, 2005) 309:5743 *Science* 2002.

[537] Organisation for Economic Development and Cooperation (OECD), *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies,* Paris, 2002, at 50; J.P.

especially true for research undertaken by research bodies operating with limited capital and interested in areas of research that are likely to be less profitable. Because of high license costs, some might not be able to use patented, expensive tools to progress in their research and to further their efforts towards commercialisation, in contrast to those who are able to afford these instruments to further their own research and commercialisation agendas, mostly in profitable research areas. As bluntly put by Drahos and Mayne, "[i]f the poor want more patent based R&D for malaria they will have to hope that is overtakes obesity and impotence as a problem in western societies."[538] In the same vein, some even go as far as to argue that market forces and property rights contribute to establish new standards of health, normality, and disease.[539]

Availability of genetics products and services

Another availability issue concerns the development and distribution of genetic tests and services to people living in countries representing non-lucrative markets. As just mentioned, patents on research tools can, in some cases, slow progress in areas of special relevance to developing countries, which therefore have to rely on what is being produced and patented in more affluent countries. [540] Patent protection might not always encourage availability of products and services in either developed and developing countries. In fact, as already mentioned, there is an ongoing debate as to whether patents encourage innovation or not, and there is a lack of empirical evidence to support any position. One exception to this might be the field of diagnostic genetic tests,

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Walsh, A. Arora & W.M. Cohen, *supra* note 444, at. 297-305; J.F. Merz et al., "Diagnostic Testing Fails the Test", *supra* note 436; B. Martin, *supra* note 381.

[538] P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) Introduction, at 7.

[539] For a detailed explanation of this theoretical view, we refer the reader to: M. Martone "The Ethics of the Economics of Patenting the Human Genome" (1998) 17 J. *Bus. Ethics* 1679, at 1679 and T. Caulfield, *supra* note 362.

[540] Developing countries are also often technologically unable to develop tests, products, and services, as we will see in the last section of this chapter.

where the prospect of patent rights has not been an incentive to development.[541] In fact, there is evidence that patents have encouraged early release of genetic products that might not have been of the best quality and reliability. [542] Moreover, depending on the scope of the patent granted, patent-holders can control how the product will be used in clinical and research settings, its cost, and the mode of analysis to use with the product.[543] This could greatly influence availability of health related products, especially to the most vulnerable populations and individuals. In response to such important concerns, in February 2006, members of the OECD adopted guidelines for governing the licensing of genetic inventions used in health care settings. Those guidelines are meant to encourage both innovation in genetics and fair economic returns, rapid dissemination, and access to diagnostic and therapeutic products and services.[544] It will be interesting to follow how those non binding guidelines will changes licensing behaviours in OECD countries.

Another factor influencing availability, and which is not patent-related, is the lack of infrastructure within developing nations. Genetic compounds, products, and services will usually not be patented in developing countries because of the absence of a market and the lack of possible financial return and profits. Theoretically, this would mean that those countries could use the technology, products, and services without restriction. However, in these cases, availability of genetic services is not influenced by patent rights, but instead by a country's research, medical, and manufacturing infrastructure, and by its lack of trained professionals. As we will briefly explain in the next section, it is important to realise that although

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[541] In fact, the following article reports evidence that the development and the use of many genetic tests were undertaken by laboratories other than those planning to apply for patent protection: J.F. Merz et al., "Diagnostic Testing Fails", *supra* note 437; J.F. Merz et al., "Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Haemochromatosis", *supra* note 436.

[542] T.A. Caulfield & E.R. Gold, "Genetic Testing, Ethical Concerns, and the Role of Patent Law" (2000) 57 *Clinical Genetics* 370; E.R. Gold, "From Theory to Practice: Health Care and the Patent System" (Sept. 2003) *Health Law Journal*, Special Edition 2003: Precedent & Innovation: Health Law in the 21st Century.

[543] Subject to market forces, competition and existing legal norms.

[544] OECD Council, *Recommendation on the Licensing of Genetic Inventions*, February 23rd 2006. C (2005)149/Rev1, online on the OECD website: <http://www.oecd.org/dataoecd/39/38/36198812.pdf> (accessed May 2nd, 2006).

patents might have a role to play in availability issues in developing countries, it is only one issue to consider and must not be blamed for everything. It is thus crucial to highlight the importance of developing appropriate infrastructures and training programs for availability of genetics in these countries.

Affordability of genetics products and services

Affordability of products and services is another important sphere of access in genetics. Patents awarded in developed countries can have a direct effect on the price of genetic products and services both in developed and developing nations. In fact, since most developing countries do not have the necessary infrastructure to develop and manufacture health-related products, they have to rely on more affluent countries for the supplies they need.[545] Thus, the effect of patents on the cost of genetic technology and services will also be transferred to importing, developing countries. We know that awarding patent rights over intellectual objects allows patent-holders to license their rights under conditions they set or sell patented objects at a price they unilaterally fix.[546] This is meant to help patent-holders recoup the capital invested in research and development, but also often implies that these fees are transferred to the licensees and to genetic products and technology users. This temporary monopoly over the cost of products can generate access barriers for those who are unable to pay. Needs which are not voiced by purchasing power on the market are not taken into consideration by the patent system. Therefore, the capacity to pay (or not) can contribute to generate health gaps within and between countries.[547]

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[545] Of course, some developing countries have manufacturing capacity and can produce goods domestically. However, with the universal standards established in TRIPS, those countries have to comply and award national protection to patent-holders, often to the detriment of their national generic industry. We will come back to the effect of patents on those countries in the last chapter.

[546] Again, patent-holders' actions are obviously constrained by market forces, competition, and trade legislation.

[547] This ability will depend on various factors. For example, some countries, like Canada, provide universal health insurance for certain products and services; many countries do not. Depending on whether the patented product is covered by an insurance program or not, it can be each individual's business to assume their personal health care costs. D.G Richards, *supra* note 380, c. 2, at 25-38.

These last paragraphs briefly presented us with indications on how patents can influence availability and affordability in the field of genetics. We will now discuss if and how this is compatible with our principles of equality of opportunities and distributive justice in health.

3.3.2.2. Patents and distributive justice in health for equality of opportunities

We have seen that intellectual property rights allow holders to exclude others from using, selling, and producing the object of their right for 20 years. In other words, in granting IP rights, a government creates artificial scarcity in non-exclusive intellectual objects and institutes a system where the public has to pay for accessing and using information and knowledge assets. IPRs also have other roles including one in diffusion of knowledge and innovation and one in commercialisation in terms of contribution to the manufacturing and distribution of innovations. As we saw with the actual system, however, dissemination is often constrained by the willingness and capacity to pay for access and improved commercialisation of invention does not guarantee equitable access. This limitation on diffusion, access and utilisation of ideas can impact individuals' self-realisation and the progress of scientific innovation. Moreover, another problem with the way the actual system works is that the public is seen as a vague entity rather than a group of individuals who may have legitimate claims on patented knowledge and intellectual objects.[548]

Our global distributive justice theory demands that we do not harm global health; that institutional protection, relief, and aid development be provided against harm; and that genetic resources be redistributed to this end. These values and duties are not especially taken into consideration in the IP system, which allows retention of property rights and control over inventions that, if otherwise accessible, could be

[548] C. May, *supra* note 333.

crucial in meeting individuals' basic health needs. As Palmer notes, "intellectual property rights, however, do not arise from scarcity, but are its cause."[549]

In fact, property owners have the right to control access and decide how the object of their right will be used, produced, and exploited.[550] This necessarily influences the distribution of intellectual goods, but this alone does not say much about the quality of the distribution or its consequences for justice. We thus need to go one step further in enquiring about the compatibility of IPRs with global distributive justice. We already made our point on why we reject distribution undertaken by the free market or any *efficient* distribution that maximises the total amount of knowledge when it does not care about how this knowledge is distributed among individuals.[551] We instead argue for a mechanism that assesses distribution from a social welfare angle and grants direct help to individuals in need of health-related resources, technology, and services in order to bring them to a level where they can benefit from equality of opportunities. To this end, isolated charitable actions like temporary suspension of one company's drug patent in a particular country or drug donations in a few countries, are not sufficient to address the most vulnerable health needs. In fact, obligations of distributive justice demand rethinking IPRs and global institutions from a theoretical point of view, and require constant action and commitment from the agents in charge of establishing and enforcing IPRs both at the national and the global levels. Distributive justice also demands rejecting the protectionist scheme of IP and avoiding artificial shortage in intellectual objects that does not allow prioritising the neediest.[552] We have seen that Rawls' view on distributive justice suggests that inequality in distribution can be justified if it advantages the least well-off. We critiqued this justification because it still allows major disparities in access to genetic services and technology and is not concerned with equality, but with absolute improvement of the situation of the least well-off, even if it can be consistent with an

[549] T.G. Palmer, "Are patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects" (1990) 13 *Harvard Journal of Law & Public Policy* 860, at 861.
[550] H.T. Engelhardt Jr., *The Foundations of Bioethics* (New York: Oxford University Press, 1986) at 342-343.
[551] These views represent the libertarian and utilitarian perspectives on knowledge distribution, two philosophies discussed and critiqued in the theory chapter.
[552] P. Drahos, *supra* note 380, at 194-198.

important health divide.[553] Therefore, we instead focussed on justifying distribution in terms of its effect on existing health needs and equality of opportunities.

Equality of opportunities in genetics implies that everyone should have access to a certain level of health in order to be in a position to take advantage of different opportunities available in crucial spheres of life, and therefore be capable of achieving their full potential. As discussed in the first part, health is something of very special importance and universal significance for individuals of the world. We argued that, because of this, access to health requires particular standards of egalitarianism. In other words, as health is a vital element for every individual's personal development, the actual level of inequality in this area contributes to the preservation of a degrading and unfair level of inequality. This led us to conclude that inequalities in health should be repaired without taking individuals' personal financial situations into consideration. Hence, genetic knowledge, products, and services should be available and affordable to individuals in order to allow them to benefit from the different opportunities available. As more and more knowledge is produced, the amount of what is needed to be comfortable and capable of seizing opportunities increases as well. As discussed in the first part, even if the nature of opportunities is likely to vary between countries, the types of opportunities, such as the opportunity to pursue life and career undertakings, should be the same for everyone regardless of their nation, state, or ethnic group.[554] Taking this into account, property rights should be used as tools to maximise access to health and genetic-related knowledge, products, and services to ensure true equality in opportunities.[555]

However, this is not necessarily how the IPR system operates. In fact, patents can be awarded on genes, DNA sequences, tools, sequencing techniques, and

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[553] D. Fallis, *Social Epistemology and the Digital Divide*, presented at the Computing and Philosophy Conference, Canberra, 2004, online on the website of the CRPIT: <http://crpit.com/confpapers/CRPITV37Fallis.pdf> (accessed: May 20th, 2006); H. Shue, *Basic Rights supra* note 245, at 128.
[554] H Shue, *Basic Rights*, *supra* note 245, at 59-60 & 159 et ss.
[555] P. Drahos, *supra* note 380, at 178.

many other important resources for moving genetic science ahead. Nevertheless, multiple overlapping patents can oblige researchers to pay high prices for several licenses just to be allowed to conduct research projects, without any guarantee that they will result in positive outcomes. This is called "royalty stacking" and it can influence availability in discouraging the use of patented genetic knowledge in further research and innovation. As discussed earlier, this is particularly true in areas of specific interest for people living in less profitable markets because of excessive research costs and small possibility of financial returns. Furthermore, patent-holders are free to charge licensing fees and high prices to licensees and users of genetics technology and products, mostly because of their need to earn back the capital invested in developing those products, and also to engage in further innovation endeavours. This means that people's capacity to afford *available* patented products and services determines access to genetic advances. Thus, IPRs awarded in genetics are especially important because they can have direct influence on individual health by creating or worsening differences in people's health within and among nations. Therefore, in influencing individuals' health status and constraints, IPRs play an important role in shaping the opportunity package from which individuals can choose.

Because health is an important prerequisite for taking advantage of available opportunities, property rights in genetics can play a large role in shaping the actual access to opportunities available to individuals. The intellectual property system leaves much latitude to private IP owners who can control how and by whom patented products and services will be used and, consequently, whose health level will improve the most. In the genetic sector, strong enforcement of IPRs can delay the availability of crucial health-related products and services, which can be evaluated though the death and diseases of the less affluent.[556] Hence, IP owners have some power over health status, and this influence can be positive or negative, depending on the philosophy and the licensing strategy they

[556] C. May, *supra* note 366, c. 4.

choose to adopt. In other words, the actual system gives IP owners the freedom either to help individuals around the world meet their health needs (by contributing to developing affordable innovative technology) or making it more difficult (or impossible) for the less affluent to access the technology they develop. With this perspective in mind, it can be hard to justify IP when some people are made *worse off* by not getting the same chances to improve their health. Indeed, when they cannot access patented products, people are not made worse off in the absolute sense, as nothing really changes: they did not have access to those products before they were invented and they still do not get access to them after. They are however worse off in a relative sense, since something that could improve their condition exists and they cannot access it because of strong patent rights. They are thus worse than they could actually be.[557]

Even if the IPR scheme generally tends to treat all intellectual goods the same without taking their role and importance in meeting basic needs into account, there are some broad flexibilities and health equity safeguards built into the international IP system, both in TRIPS and in the Doha Declaration.[558] A few examples: art. 7 of TRIPS mentions that IP protection should promote a balance between technological innovation and transfer and dissemination of technology for social welfare. Art. 8 stipulates that states can 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 technological development, **but only** if they are not contrary to the stipulations of the rest of TRIPS. Member states also have the freedom to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from patentability (art. 27 (3) a) of TRIPS) and to award compulsory licences in

[557] For a more detailed discussion on this point, see R. L. Ostergard, Jr., *supra* note 379, at 169.
[558] J.H. Reichman, "From Free-Riders to Fair Followers: Global Competition under the TRIPs Agreement", (1997) 29 *N. Y.U.L.J. Int'l. & Pol.* 11; C. Correa, "Pro-Competitive Measures under TRIPS to Promote Technology Diffusion in Developing Countries" in P. Drahos & R. Mayne, *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002); C. Correa, *Intellectual Property Rights, the WTO and Developing Countries, supra* note 438.

limited cases (art. 31 of TRIPS).[559] Moreover, the Doha Declaration is meant to enable developing countries to pursue certain public health objectives, and states that countries can interpret TRIPS so it does not work against their health policies. It also allows states to grant compulsory licenses, especially to promote universal access to medicines, if they have sufficient manufacturing capacity in the pharmaceutical sector (art.4); for those who do not, they can look for it in other countries.[560] Moreover, art. 5 d) of the Doha Declaration, in combination with art. 6 of TRIPS, allows member states to decide how they wish to enforce the principle of exhaustion of rights within their territory.[561]

Applying these types of measures could reduce the market price of health-related products and have a general positive effect on research and availability of genetic innovation. In reality, however, these dispositions are given the absolute minimum consideration by the community of people who interprets them. Developed countries are putting strong pressure on developing countries wanting to use TRIPS' flexibility and, above all, are negotiating bilateral and regional free-trade agreements (FTAs) to

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[559] Compulsory licenses enable a government to license a company, government agency, or other party the right to use a patent without the title holder's consent under strict conditions.

[560] This has been made possible with the WTO August 30th, 2003 decision to lift TRIPS restrictions on compulsory licensing and allow exportation of generic medicines to countries that are not in a position to manufacture them themselves. *WTO General Council, Decision on the Implementation of par.6 of the Doha Declaration on TRIPS Agreement and Public Health*, August 30th 2003, online on the WTO website: <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> (accessed: May 20th, 2006).

[561] This means that countries can choose between national, regional, and international exhaustion of rights. An international exhaustion of patent rights means that once a patent owner or some authorised licensee has sold their patented product on a market, their rights in this product are exhausted on every market and they cannot prevent subsequent resale domestically or abroad. This can have important consequences on health access, as the application of an international exhaustion of rights can allow countries to import patented products at lower prices than they have to pay at home when the products have already been placed in another country's market. Since the same patented items get sold at different costs in different markets, a country's interest in performing parallel importation is to import the goods they need at the lowest price possible, without violating local patents. The mechanism of international exhaustion of rights could allow less affluent countries to get access to essential health-related products that they would not otherwise be able to afford (on their domestic market). However, such measure is controversial as many affluent countries fear that it could impact negatively on their economy if cheap products are exported back to their market and concurrence patented products. For an interesting paper on the issues arising with parallel importing see: K. E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries, Final Report to World Intellectual Property Organization*, Geneva, 2001, online on the website of WIPO: <http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf> (accessed: May 2nd, 2006).

impose more severe and contingent IP standards than those outlined in TRIPS.[562] This point is very well illustrated by the example of the lack of access to HIV/AIDS drugs in the developing world, as it will be discussed at length in the last chapter of the dissertation. Strong resistance from the most affluent countries toward any initiative from the developing world to take advantage of TRIPS and Doha's social welfare flexibility highlights the growing importance of strong and narrowly interpreted property rights on the global scene due to normative and political reasons.

We will first address the normative explanation for the poor application of Doha's and TRIPS' *flexibility clauses*. Although principles of the Doha Declaration have been adopted by the ministerial conference, the top decision-making body of the WTO, they remain very general and serve more as ethical guidelines (in the sense that they cannot be enforced in front of the WTO dispute settlement body). In addition, TRIPS' *flexibility clauses* contain important restrictions.[563] Art. 30, for example, stipulates that every exception to the patentees' exclusive rights should be limited to ensure that they do not "unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner." Moreover, art. 31 establishes a long list of conditions that have to be met before compulsory licensing can be allowed in circumstances other than emergency and public non-commercial use, leaving many issues unsettled and much space for interpretation. As for the WTO's August 30th, 2003 decision, it theoretically encourages cooperation between nations as a priority over protection of patent rights

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[562] Those agreements are referred to as TRIPS plus and are explicitly condemned by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in its April 2006 report: WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property*, Geneva, April 2006, online on the WHO website: <http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf> (accessed May 21, 2006), rec. 4.21 and 4.25; For more on those agreements, see: D. Vivas-Eugui, "Regional and Bilateral Agreements and a TRIPS-Plus World: The Free Trade Areas of the Americas (FTAA)" *TRIPS Issues Papers No 1*, QUNO, Geneva/ Ottawa, 2003 ; P. Basu, "International Patent Law—Boon or Bane of Biotech?" (Jan. 2005) 23:1 *Nature Biotechnology* 13; J. Reichman & C. Hasenzahl, "Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA", *Issue Paper No 5*, UNCTAD/ICTSD, Geneva, 2003.

[563] N. A. Bass, "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century" (2002) 34:1 *George Washington International Law Review* 191.

in certain extreme cases. However, it is associated with several conditions and many are expressing doubts about its practical applicability.[564]

This leads us to the political explanation of why the flexibility embodied in TRIPS and Doha is not translated in concrete results. In fact, because of the numerous conditions that countries in need have to meet to benefit from TRIPS' exceptions, and because of the existing space for competing interpretations, bargaining power has become crucial in establishing the scope of these exceptions. Needless to say, this exercise almost always benefits the most affluent countries and powerful stakeholders, who tend to object strongly to the use of these exceptions, often threatening to impose trade sanctions against countries that express interest in engaging in them.[565] More importantly, there is a strong tendency from developed countries to impose even stricter standards on developing countries with bilateral and regional free-trade agreements. Moreover, powerful countries and corporations not only try to prevent developing countries from using available flexibility in practice, but they also closely monitor how they construct their domestic patent laws.[566]

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[564] For example, see J. Lanjouw, *Complementarity of my FFL proposal and Canada's approach in its Pledge Legislation (C- 9): Comments for the CIPP Forum*, Montréal, January 2005.

[565] In fact, no generic drugs have been produced using compulsory licenses to treat patients in the last decade. Brazil is the only example of a country that resisted pressure and successfully used **the threat** of compulsory licensing in its price negotiations with pharmaceutical companies in the context of its national AIDS strategy. Brazil was in a position to do so because of its important research and manufacturing capabilities. However, very few countries are in this negotiating position, as appears from an investigation conducted in 2001 in about 70 developing countries, which found that only half of them were providing for international exhaustion of patent rights in their domestic patent legislation. UK Commission on Intellectual Property Rights, *supra* note 512, c. 8, at 160. See also: C. Correa, *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*, Geneva, October 2000, online on the South Center' website, <http://www.southcentre.org/publications/publichealth/publichealth.pdf> (accessed June 1st, 2006); M.M. Nerozzi, "The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being 'TRIPped' by Developed Countries" (2002) 47 *Vill. L. Rev.* 605; A. Attaran, "Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution" (2003) 17:2 *Emory International Law Review* 743.

[566] This is illustrated by the famous 2001 law suit filed by a consortium of the biggest drug companies against the South African government. Those companies wanted to challenge the 1997 South African patent legislation (which allows the government to manufacture and import cheaper retroviral AIDS drugs), maintaining that it is too broad and unfair for brand name drug producers. Those major multinational pharmaceutical companies thus launched this law suit as part of a strategy to strongly encourage and pressure developing countries to adopt stricter patent protection standards. However, with worldwide public pressure and massive outrage raised by the consortium's action, the pharmas were left with no choice but to back off and drop the case.

All of this clearly illustrates Drahos' view on proprietarianism and the fact that it occupies a large place in how the actual IPR system works and is justified. As it currently stands, the world economy is based on strong property rights mainly driven by market forces. This results in huge power concentration in the hands of a few elites who can run the system and prioritise their own values and interests. As discussed earlier, even if it should theoretically further a balance between protection and diffusion other than imposing mandatory public disclosure, the IP system does not impose enforceable and demanding corollary obligations on IP owners in exchange for the rights awarded. The proponents of strong IP rights do not see any problem or contradiction in this, as they view the return on investment as a means to promote general welfare through further investment in other research endeavours. But, in reality, IPRs foster the interests of patentees and the more affluent in priority, without worrying too much about the inequities they create and encourage, or the consequences they can have on the lives and health of individuals.[567] As May summarises, "[t]he knowledge structure ensures that, as science is commercialised, property based mechanisms are introduced because they are common sense in market transactions."[568]

For our goal of distributive justice for global health, we would need to replace this proprietarianist view with instrumentalist an attitude that would support a different social role for IP. Intellectual Property Rights should thus be conceived as tools to support better and broader access to health by every individual through principles of global distributive justice, instead of as a fixed system controlled by a few companies to support their own economic interests. Ownership should not be available when it works to exclude individuals from accessing crucial health-related goods and services, to delay their availability, and, consequently, to tacitly support more death and illness. Our cosmopolitan focus would instead require considering each individual, regardless of their country of origin, as a unit of moral concern for

[567] P. Drahos, *supra* note 380, at 195-203.
[568] C. May, *supra* note 366, c. 4, at 117.

access to health—not leaving the result to an economic battle between their government representatives and the world's most powerful agents. Until the international IP scheme stops functioning primarily to further innovation and comes to care about ensuring that the results of such innovation are diffused so as to reach those who need them throughout the world, we will not be able to conclude that IP works to advance global distributive justice principles to further access to common health standards and allow real equality of opportunities.

In this subsection, our purpose was to assess the international IPRs system through its effects on the availability and affordability of genetic technology, two elements of importance in our theory of distributive justice for global health. After briefly presenting different spheres of genetic access (availability of research tools, availability and affordability of products and services), we discussed the impact of IP on distributive justice in health and equality of opportunities. This analysis highlighted that while distributive justice in health focusses on securing access to health-related resources taking needs into account, the global IP system focusses less on equitable access and needs, and more on facilitating the production and the protection of innovation. This does not mean that IP, used differently, could not play a role in allowing, through its diffusion component, broader and better access to health. What our analysis says is simply that the IP scheme is mostly geared to a form of proprietarianism that leaves very little place for social welfare considerations. Indeed, we established that the international IPRs scheme and principles are being used and justified in a way that does not necessarily prioritise the elimination of socio-economic inequalities in health.

Conclusion

In this chapter, we analysed the international normative IP system to determine whether its underlying philosophy, structure, and functioning adequately account for

the values encountered by our global distributive justice framework. Our main goal was to assess the patent system to find out if it can facilitate the redistribution of potential genetic benefits, taking health needs into consideration.

All through the chapter, we tested the international IP system with our benchmarks of justice through different access lenses. We began with the global aspect of access to genetic resources and realised that the application of strong and broad patent rights, particularly in this field, was more compatible with the reduction of the public commons, with the creation of some health gaps associated with people's capacity to pay, and with an international basic structure established by a few stakeholders for their own benefit—and not to support principles of justice, shared global health ideals, or universal consideration of every human being.

We pursued our analysis in assessing the compatibility of IP rights with access to genetics, this time in relation to availability and affordability of genetic products and services. We again noticed that the current application of most patents was very strict and primarily market-driven, geared towards protection more than diffusion, and establishing artificial shortage in intellectual goods. Consequently, this analysis brought us to conclude that the actual IP system was not oriented toward access and distribution of genetic products and services essential to attain the level of health required to benefit from equality of opportunities.

Our overall analysis confirms Drahos' critique of the proprietarianist version of IP. In fact, we conclude that one of the biggest problems with the international IP system in relation to global access is that intellectual property rights are viewed as private ends in themselves rather than as tools to further the public interest in accessing new knowledge and encouraging innovation. The politics of IP is characterised by the powerful defenders of strict and protectionist IP standards on one side, and the less powerful on the other side who campaign for more focus on the public and social welfare aspects of the IP system.[569] The

[569] S.K. Sell, *supra* note 369.

strongest and most powerful actors, both politically and economically, run the system now. They adopt strict enforcement strategies against the poorer majority, going as far as imposing more and more demanding conditions in order to further their economic values and interests.[570] Most of these stakeholders have no major interest in voluntarily getting involved in a market with poor potential for return, even if it could result in important human benefits. After all, their main reason to be in business is to make profit. However, it creates a vicious circle, as "the failure to address the health care needs of poor people is to permanently consign them to both illness and poverty."[571]

This is what makes the system, as it functions now, incompatible with our global distributive justice framework. If the IP system were to meet our goal of global distributive justice for global health, it would need to adopt a totally different social role, more focussed on diffusion and needs than on production and protection of innovation, supporting broader access to health and considering every individual, not just the inventors, as units of moral concern. IPRs can play an important role through knowledge and innovation diffusion in allowing individuals to reach the health level they need to be able to profit from available opportunities. International trade and IP agreements will remain priorities for powerful industrialised countries but, as they currently operate, they are not working to ensure equitable access to health. Until there is a major change in IP philosophy and politics to allow social welfare concerns to be taken into consideration, we will not be able to conclude that IP works to advance global distributive justice principles towards access to common health standards.

As more and more people come to realise that taking care of the more pressing global health issues is critical for the creation of a more just and stable world order, coming up with balanced and fair IP mechanisms appears to be one of the many

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[570] These agreements reproduce TRIPS-plus standards. To consult some of those agreements, refer to the website of the Office of the US Trade Representative, online: <http://www.ustr.gov/> (accessed May 19th, 2006).

[571] D. Richards, supra note 380, c. 6, at. 160; see also, F.M. Scherer, "The Pharmaceutical Industry and World Intellectual Property Standards" (November 2000) 53:6 *Vanderbilt Law Review* 2245.

important steps in the right direction. While TRIPS cannot and will not disappear, it is important for developing countries to be able to take advantage of its existing mechanisms to help them focus on their health priorities and, most importantly, to present strong and coordinated opposition to expansion initiatives. Thus, the growing post-TRIPS involvement of international NGOs and of a strong African leadership on health care issues is crucial in framing IP issues differently and tempering the industry-dominant influence over the IP agenda.[572]

As we saw at the beginning of this dissertation, the benefits arising from genetics have a real potential for improving global health; much may depend on how widely they get distributed. This does not mean that IP protection should be abolished altogether, as it can be an important trade mechanism for managing innovation and, if used and balanced adequately, it can play a major role in achieving better global health equity.[573] However, finding the right balance in the application of IP protection to genetics is an important challenge. Indeed, the system should, at the same time, prevent the more vulnerable from being left out of progress with diffusion while preserving a certain level of protection for inventors. Much more needs to be done to get to this point, either within the actual IP system or outside of it, and many different strategies have been proposed to this end. For example, some suggest using regime-shifting strategies to expand IP law making in other international legal fora to address and revise TRIPS' problematic dispositions; others favour the idea of a more widely coordinated initiative, a *counter hegemonic discourse* toward IP. Some instead favour transforming the public-realm aspect of IP to a role of primary consideration, to change the system accordingly, and to relegate the interfering private rights to a secondary rank. Others, on the contrary, argue for the creation of a body to work with the current system and focus on the

[572] S. K. Sell, *supra* note 369; P. Drahos, *Developing Countries and International Intellectual Property Standard Setting*, UK Commission on Intellectual Property Rights, Study Paper 8, London, 2002, at 26.
[573] E. R. Gold et al., *supra* note 353, at 312.

problem of managing IP for global health, with existing exceptions.[574] These are only a few examples of policy solutions that have been proposed to address some of the concerns highlighted in this chapter. We will come back to practical policy options in more length in the conclusion of the dissertation to set some basis for further reflection.

The next chapter will focus on international human rights law. The purpose of this chapter will be to present another international normative system and to determine if its structure and functioning adequately account for the values encountered in our global distributive justice framework.

[574] L. R. Helfer, "Regime Shifting: The Trips Agreement and New Dynamics of International Intellectual Property Lawmaking" (Winter 2004) 29 *Yale J. Int'l L.* 1, at 58; D. Richards, *supra* note 380, c. 6; C. May, *supra* note 333.

Chapter IV: International Human Rights Law: a Second Tool?

Do international human rights help or hinder the realisation of benefit sharing?

Introduction

The first part of the dissertation set a theoretical framework to support equitable access to health, and more specifically distribution of genetic research benefits and resources to come. For this purpose, we argued for equal and universal consideration of every individual's basic health needs in support of a rationale to secure equal opportunities for all on the global scene. The second part of the thesis is dedicated to the assessment of two normative systems using the parameters established by our theoretical framework. In the last chapter, we assessed the intellectual property law system. The purpose of this chapter is to determine if the basis, functioning, and conceptualisation of the existing international human rights legal system, especially socio-economic rights, helps or obstructs the realisation of global distributive justice in health.

We will start with a brief introduction to the system of international human rights and its main philosophical foundations. The second part of this chapter will assess international human rights law with reference to notions of equality, global distribution, and justice, once again using the standard of access. To this end, we will first provide an analysis of the global aspect of access to health in the context of international human rights and evaluate the global order under which they develop. We will then focus on how the definition and implementation of international human rights take health protection and access to genetic innovations, our benchmarks of distributive justice, into account. Finally, in the third and last part of this chapter, we will provide an analysis of how human rights are conceptualised through the reality of the market.

4.1 The Field of International Human Rights Law

4.1.1 Presentation

The notion of human rights emerged from the need for universal respect for human beings' freedom, dignity, and equality. It has been translated into a common language and set of identified human rights. This system is the result of a long struggle to gain universal support for individual protection from oppression, and to give all people an equal chance to develop to their potential be able to take advantage of different opportunities. [575] Indeed, since the Enlightenment, various human rights claims resulted in slowly liberating individuals and communities from repressive regimes and institutions,[576] but the human misery and atrocities that have happened during and following the Second World War are viewed as having been a turning point in the reintroduction of the modern ideal of human rights. [577] Indeed, the *Universal Declaration of Human Rights* (UDHR) adopted by the UN General Assembly in 1948 marked a crucial step in the effort of the international community to establish a *common standard of achievement for all peoples and all nations.*[578] Together with the UDHR, the *International Covenant on Civil and Political Rights* (ICCPR) and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)

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[575] J. Donnelly, *Universal Human Rights in Theory and Practice* (London: Cornell University Press, 1989).

[576] Indeed, some of the most important efforts in the development of human rights in the late-seventeenth and eighteenth century are the *British Bill of Rights* (1690-91), the *American Declaration of Independence* (1776), and the *French Declaration on the Rights of Man and the Citizen* (1779). A. Eide, "Economic, Social and Cultural Rights as Human Rights" in A. Eide et als., eds., *Economic, Social and Cultural Rights: A Texbook*, 2nd ed., (London: Maartinus Nijhoff, 2001) 9; S.R.Benatar, *supra* note 2.

[577] T. Ball & R. Dagger, *Ideals and Ideologies: a Reader* (New York: Pearson Longman, 2004).

[578] The early 1960s was marked by a new wave of human rights activity, which led to various international documents, including, for example, the 1959 *Declaration of the Rights of the Child*, the *European Convention on Human Rights* of 1963, the *International Convention on the Elimination of All Forms of Racial Discrimination* of 1965, the *International Covenant on Economic, Social, and Cultural Rights*, and the *International Covenant on Civil and Political Rights* (opened for signature and ratification in 1966 and coming into force in 1976), the 1975 *Declaration on the Rights of Disabled Persons*, and the 1979 *Convention on the Elimination of all Forms of Discrimination Against Women*. For international legislation on human rights, see I. Brownlie, *Basic Documents on Human Rights,* 3rd ed. (Oxford: Clarendon Press, 1992).

form what has been called the *International Bill of Human Rights.*[579] The conception of modern human rights can be described as rights recognised for all individuals simply because he or she is a human being. Human rights aim to enhance people's quality of life and involve a direct link between them and their state, whose actions should be in conformity with the established international human rights regime.[580] Indeed, even if human rights are primarily established on the international scene, they also have to be developed at the national level, where they become legally enforceable.

There are two main categories of human rights. First, there are civil and political rights, including democracy, due process, and freedom of expression, which have to be guaranteed immediately by signatory states. Second, there is the category of economic, social, and cultural rights, which can be realised progressively, and which can include rights to social security, work, adequate food, and the highest attainable standard of health. Although they have not yet been accepted as legally enforceable, there is increasing support for an emerging third category of human rights called solidarity rights, asking for more equitable distribution and protection of common resources to benefit not only individuals, but also communities at the international level.[581]

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[579] Contrary to the UDHR, the two Covenants are legally binding on the states that ratified them, who thus have to comply with the treaties' provisions and submit reports on concrete actions take toward this end. *International Covenant on Civil and Political Rights* (ICCPR) G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966); *International Covenant on Economic, Social and Cultural Rights* (ICESCR), G.A. Res. 2200 (XXI/, UN GAOR, 21st Sess., Supp. No. 16, at 49, UN Doc. A/6316 (1966).

[580] J. Mann *et al., Health and Human Rights* (New York: Routledge, 1999) c. 1, at 8; M.C. Naussbaum, "Capabilities, Human Rights and Universal Declaration" in B.H. Weston & S.P. Marks, eds. *The Future of International Human Rights* (Ardley: Transnational, 1999); art. 1 of the Vienna Declaration and Programme of Action, UN Doc. A/CONF.157/24 (part 1).

[581] This third category refers, for example, to a right to peace, to a clean environment, to benefit from the common heritage of humankind, and to development. For more on solidarity rights, refer to P. Alston, "A Third Generation of Solidarity Rights: Progressive Development or Obfuscation of International HRlaw" (1982) 29:3 *Netherlands International Law Review* 307; A. Rosas, "The Right to Development" in A. Eide et al., eds., *Economic, Social and Cultural Rights: A Texbook*, 2nd ed., (London: Maartinus Nijhoff, 2001), c. 7, at 119 ; G. Kardos, "Right to Peace, Right to Development, Right to a Healthy Environment: Part of the Solution or Part of the Problem" in A. Rosas & J. Helgesen, eds., *Human Rights in a Changing East-West Perspective* (New York : Pinter Publishers, 1990) 216; J. Mann et al., *supra* note 580; S.R.Benatar, *supra* note 2.

As mentioned earlier in this dissertation, the notion of rights is often criticised on the basis that rights can remain meaningless in cases where taking advantage of them is not a real option for the right-holders. This objection clearly highlights the need for a better interconnectedness between socio-economic rights and civil and political rights. Indeed, even if it seems quite easy to grant rights like the right to vote, the right to freedom and security, or the right to free speech, if personal health, material and economic conditions of the right-holders are such that it is literally impossible for them to profit from those rights, they become meaningless. As Pogge clearly states, "in a situation where there is formal freedom but extreme poverty, the poor are in many obvious ways unfree on account of their poverty."[582] Even if economic, social, and cultural rights (the human rights most frequently breached) are highly criticised for their lack of justiciability and conceptual precision[583], it might make more sense to eliminate what is now a clear separation between civil and political rights and economic, social, and cultural rights.[584] This is consistent with guideline 4 of the 1997 *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, which states that "[i]t is now undisputed that all human rights are indivisible, interdependent, interrelated and of equal importance for human dignity. Therefore, states are as responsible for violations of economic, social and cultural rights as they are for violations of civil and political rights."[585] Consequently, since poverty and ill health are important obstacles to a satisfying human existence as established earlier, economic and social rights should rank alongside civil and political rights,[586] and all

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[582] T. Pogge, *Realising Rawls* (Ithaca: Cornell University Press, 1989), at 133; on this same point, see also M. Robinson, "The Universal Declaration of Human Rights: Hope and History" (1998) 3:2 *Health and Human Rights* 27.

[583] See for example B. Toebes, "Towards an Improved Understanding of the International Right to Health" (1999) 21:3 *Human Right Quarterly* 662.

[584] The strong connection between the two categories of rights and the fact that there is no hierarchy between them has been specifically emphasised by the UN: United Nations Committee on Economic, Social and Cultural and Economic Rights, *General Comment No. 3(1),* 2002, online on the website of the UN: <http://www.unhchr.ch/html/menu2/6/cescr.htm> (accessed: June 1st, 2006).

[585] Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Guideline 4 (1998) 20 *Human Rights Quarterly* 692.

[586] B. Terence & R. Dagger, *Political Ideologies and the Democratic Ideal*, 5th. ed. (New York: Addison Wesley, 2004).

of these rights should thus be envisioned as essential values for a better world.[587] However, although we acknowledge the indivisibility, interdependence and interrelation among rights, it is important to note that our main focus will be on the content, conceptualisation, and realisation of socio-economic rights as we argue for global distribution and access to genetics research benefits in support of better health. Now, before getting to the core analytical part of the chapter, we will briefly present the two main discourses on which human rights are based.

4.1.2. Theoretical and legal foundations of international human rights

> *The existence and validity of human rights are not written in the stars... [They] have been conceived and taught by enlightened individuals in the course of history.*[588]
>
> - Albert Einstein

The nature and underlying justification of the concept of rights have undergone considerable change over time.[589] As mentioned previously, the view of rights put forward by Hegel, Kant, and other philosophers during the 19th and the 20th centuries was heavily criticised for reducing the concept of rights to *social constructs*.[590] This explains why rights were absent from the vocabulary of political philosophy for decades before coming back, after the Second World Was, in legal and philosophical discourse.[591] This section seeks to present briefly those two main discourses and understand how they sometimes complement and contradict each other while also giving rise to debate outside their respective frameworks.

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[587] J. Waldron, supra note 259, at 7-8; G.B. Hebert, *supra* note 252.
[588] A.P. French, *Einstein: a Centenary Volume* (Cambridge: Harvard University Press, 1979) 305.
[589] For a comprehensive analysis of the evolution of the concept of right, see G.B. Hebert, *supra* note 252.
[590] J. Bentham, *supra* note 252; K. Marx, "Capital", in F. Engels, ed., *Manisfesto of the Communist Party,* Translated from the 3d German ed. by S. Moore & E. Aveling. Rev (Chicago: Encyclopædia Britannica, 1955); G.B. Hebert, *supra* note 252, at 277.
[591] G.B. Hebert, *supra* note 252, at 286.

4.1.2.1 The legal discourse of international human rights

As mentioned in the previous section, an important body of international human rights instruments has been established on the global scene and further developed at the national level. This highlights an inherent conflict between, on the one hand, a universal and cosmopolitan way of envisioning human rights and, on the other hand, the notion of state sovereignty, a basic principle of international law.[592] This can be resolved when states agree to concede some portion of their sovereignty by ratifying international norms. Human rights are often envisioned as a basis for justifying demands and imposing obligations. Indeed, one purpose of this legal system is to ensure that a right-holder can demand that the content of his or her right be guaranteed. Rights are meant to allow a connection between human well-being and related obligations. Because of the way the system is built, individuals' rights are directly related to the status of citizen. In other words, individuals can take advantage of human rights only when their states have decided to recognise and enforce those rights based on a sense of "justified outrage and political empowerment".[593] These rights are included in legal instruments that serve to recognise the fundamental and general political values agreed to by the international community. They place individuals at the centre of national and international legal concerns, with a clear recognition of the concepts of human respect and dignity.[594] The purpose of the legal discourse is not to question the content, the essence, or the interests that lie behind these norms, but instead to recognise, clarify, and enforce the general legal rules emerging as a product of international law (which give them a global reach). As Evans notes, "[t]he legal discourse focuses upon the internal logic of the law, its

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[592] State sovereignty refers to the freedom of states to establish legal norms and undertake normative actions within the limits of their borders without any intrusion from other states.

[593] K. Robinson, "False Hope or a Realizable Right? The Implementation of the Right to Shelter under the African National Congress' Proposed Bill of Rights for South Africa' (1993) 28 *Harvard Civil Rights-Civil Liberties Law Review* 505, at 517.

[594] W. Austin, "Using the Human Rights Paradigm in Health Ethics: The Problems and the Possibilities" (2001) 8:3 *Nursing Ethics* 183; Report of the United Nations High Commissioner for Human Rights, A/53/372, September 11, 1998, New York; L.W. Sumner, "Rights", in H. LaFollette, ed., *The Blackwell guide to ethical theory* (Oxford: Blackwell, 2000) 288; B. Duner, *The Global Human Right Regime* (Lund: Studentlitteratur, 2002) at 21.

elegance, coherence, extent, and meaning, which the application of legal reason is said to reveal."[595]

Many scholars are opposed to the legal discourse of human rights for a variety of reasons.[596] First, many talk about the numerous deficiencies in the legal mechanisms needed to support such legal discourse. Indeed, solid legal infrastructures, strong enforcement strategies, and real sanctions are still lacking in international human rights law.[597] This position is clearly explained by Kennedy when he says: "[t]he attachment to rights as a measure of the authenticity, universality, and above all as the knowledge we have of social justice binds our professional feet, and places social justice issues under the governance of the least effective institutional forms available."[598]

Others are opposed to this discourse because it seems to conceal an arrogant assumption of what is good for people, encouraging an empty sense of entitlement on the part of individuals, all of which has the perverse effect of fostering passivity among individuals and communities. In other words, some critique the very institution of granting legal human rights because it can (wrongly) incite a sense of accomplishment in governments and stasis in individuals who theoretically have individual legal rights, but can hardly enforce them. For opponents of legal human rights, this system seems to encourage focus on complex and deficient legal dilemmas and institutional procedures which gives the illusion of control over human rights

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[595] T. Evans, "International Human Rights Law as Power/Knowledge" (2005) 27:3 *Human Rights Quarterly* 1046, at 1050.

[596] There exist numerous critics of the legal approach to human rights, represented in a wide variety of literature. However, the purpose of this section is not to present and analyse them all, but instead to highlight some of the major objections, some of which will be analysed further in the course of the chapter.

[597] In fact, even if some international UN agencies are responsible for promoting human rights, there is no consistent monitoring, reporting, or enforcement practice, and only very weak judicial and quasi-judicial activities in this field. This explains the vagueness and deficient conceptual clarity of many of these legal rights. For more information on this topic, refer to A.R. Chapman, "Monitoring Women's Right to Health Under the International Covenant on Economic Socio and Cultural Rights" (1995) 44 Am. U. L. Rev. 1157, at 1159-1160; M. Kirby, "The Right to Health Fifty Years On: Still Sceptical? (1999) 4:1 *Health Hum. Rights* 6; W. Austin, *supra* note 594; Kate O'Regan's judgment in S *v Makwarryane* 1995 (3) SA 391 (CC), 1995 (6) BCLR 665 (CC) at para 325.

[598] D. Kennedy, "The International Human Rights Movement: Part of the Problem?" (2002) 15 *Harvard Human Rights Journal* 101, at 140.

violations instead of concentrating actions and efforts on better and more inclusive modes of action.[599]

A third category of opposition to the legal discourse concerns the limits of legal positivism and the fact that it precludes any deeper analysis on what lies at the source of the norms encoded in the law. In fact, it can be argued that the system endorses a kind of realism regarding established powers—what has been called engagement with the *realpolitik* of human rights.[600] This can limit the means to address abuses in preventing broader political, economic, and philosophical analysis of right violations.[601]

These criticisms highlight certain limitations of the dominant legal discourse of human rights and illustrate the importance of serious inquiry about the real nature and justification for the principles enshrined in those legal instruments. This brings us to a different, less legal and institutional way of envisioning human rights within a theoretical context.

4.1.2.2 The moral discourse

As highlighted by various scholars, there is a tension between the legal and moral discourses on rights.[602] The moral discourse on human rights refers to a justification based on more profound and objective reasons than what the legal approach offers. Theoretically, we can say that human rights are recognised and understood as having been founded on the basic interests that individuals have in the content of those

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[599] *Ibid.*

[600] N. Stammers, "Social Movements and the Social Construction of Human Rights" (1999) 21:4 *Human Rights Quarterly* 980, at 991.

[601] T. Evans & E. Hancock, "Doing Something Without Doing Anything: International Human Rights Law and the Challenge of Globalisation" (1998) 2:3 *Int J Hum Rights* 1.

[602] C. Brown, "Universal Human Rights: A Critique" in T. Dunne & N. J. Wheeler, eds, *Human Rights in Global Politics* (Cambridge: Cambridge University Press, 1999) c.3, 103; P. Jones, *Rights* (London: Macmillan, 1994) *is* the best single-volume survey, followed by the briefer, less substantial, but still useful, Michael Freemen, *Rights* (Minneapolis: University of Minnesota Press, 1991); S. Shute & S. Hurley, eds., On *Human Rights: The Oxford Amnesty Lecture* (New York: Basic Books, 1993).

rights. As explained earlier, an argument for a right "is an argument showing that an individual interest considered in itself is sufficiently important from a moral point of view to justify holding people to be under a duty to promote it."[603] Some criticise the human rights system because it seems to lack a uniform ideal of what should count as a human right.[604] Many different theories can act as a foundations for human rights claims, the most important being natural law, which focuses on neutral values like individual freedom, equality, and universalism.[605]

Brown states that any "idea of natural law must underlie all genuinely universal approaches to human rights."[606] Natural law implies that the emerging principles are not relating to specific types of societies, institutions, or enforcement procedures but arise instead from the protection of characteristics associated with human agency or personhood. Features of agency have been regrouped in four categories: a) capacity to make life decisions without undue pressure; b) ability to acquire a certain basic level of education and knowledge; c) capacity to undertake some chosen projects; and d) liberty to pursue what one perceive as the good life. [607] This supports our cosmopolitan view that all individuals are equal members of a single moral universe, that they all have dignity, and that all require fulfilment of similar basic conditions to be able to grow and live a good and dignified life. Therefore, all individuals have human rights because they are equal human beings, and rights serve to protect what they need to be able to create what they wish and pursue certain life goals. It does not

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[603] O. O'Neill, "Hunger, Needs and Rights", *supra* note 88; J. Waldron, *The Right to Private Property*, *supra* note 259 at 3. On the interest notion see also: J. Waldron, *supra* note 259 at 11 & 212; J. Raz, *The Morality of Freedom* (Oxford: Clarendon Press, 1986) at 166; N. MacCormick, "Rights in Legislation" in P. M. S. Flacker & J. Raz, eds., *Law, Morality, and Society: Essays in Honour of H. L. A. Hart* (Oxford: Clarendon Press, 1982).

[604] For example, see J. Griffin, "Discrepancies Between the Best Philosophical Account of Human Rights and the International Law of Human Rights" (2001) 101 *Proceedings of the Aristotelian Society* 1

[605]The notion of natural law emerged long ago and has been used by many to justify individual rights only by reference to human nature. For more on the concept of natural rights, see C. Brown "Universal human rights", *supra* note 602; J. Locke, *supra* note 386; T. Paine, *Rights of Man* (Ware: Wordsworth Editions, 1996); T. Evans, "Universal Human Rights: As Much Round and Round As Ever Onward" (Winter 2003) 7:4 *The International Journal of Human Rights* 155; J. Finnis, *Natural Law and Natural Rights* (Oxford: Clarendon Press, 1980), at 23; W. Austin, *supra* note 594.

[606] C. Brown, "Universal human rights", *supra* note 602, at 106.

[607] J. Griffin, "First Steps in an Account of Human Rights" (2001) 9:3 *European Journal of Philosophy* 306.

mean that any injustice constitutes a violation of human rights, but only that when it touches elements of human agency, such as health, special protection is needed to ensure that individuals benefit from equal treatment and access to basic requirements to be able to pursue personal life goals and take advantage of available opportunities.[608]

One important step in establishing a theoretical discourse of human rights is thus to identify which characteristics of human nature deserve special protection and which values should be respected everywhere. Some argue that rights should be ranked according to the nature of the interest they help defend and their normative weight in the process of reaching a stage where individuals can function as human agents taking advantage of equal opportunities.[609] Others believe in the protection of basic rights associated with the primary necessities and preservation of human life. Such basic rights can emerge from the basic needs shared by every human, such as food, water, shelter, and health care.[610]

Some relativists criticise the underlying universality of the international system of human rights; they argue that there is no true universality or universal community, and that human nature and basic moral principles are instead constructed by external factors like history and culture. They argue that this would explain the existing important variation between moral practices around the world.[611] Others criticise the individualistic aspect of human rights on the basis that it seems to encourage the construction of individuals outside any form of community and to support a disturbing and harmful individualism typically observed in the western world.[612]

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[608] J. Griffin, *supra* note 604.
[609] O. O'Neill, "Hunger, Needs and Rights", *supra* note 88; P. Jones, *Rights* (London: MacMillan, 1994), at 13-15.
[610] H. Shue, *Basic Rights*, *supra* note 245; O. O'Neill, *supra* note 82, at 155 et ss.
[611] W. Austin, *supra* note 594; K. Booth, "Three Tyrannies" in T. Dunne & N. Wheeler, eds. *Human Rights in Global Politics* (New York: Cambridge University Press, 1999) 31; S. James, "Recognizing International Human Rights and Cultural Relativism: the Case of Female Circumcision" (1994) 8:1 *Bioethics* 1.
[612] Since we decided to adopt a cosmopolitan focus to analyse the justice issues arising with genetic access for the reasons explained in the theoretical part of the dissertation, we consider that, although rich and fascinating, a deep analysis of the individualistic aspect of human rights would be outside of our the main focus of this chapter. For more on this topic, we encourage the reader to refer to these

We will come back to those criticisms in the next section when we assess the universalism of human rights principles.

An important point of a moral account of human rights relates to the nature and content of correlative duties. As we mentioned previously in our theoretical chapter, some, like O'Neill, go as far as making the very existence of a right depend on correlative duties to respect and fulfill those rights. They consequently express considerable scepticism toward welfare human rights due to implementation challenges. In other words, for those opponents, although rights-talk is rhetorically powerful, it is not ethically founded because it does not deal with the powerful actors who could do something about international injustice. Others, like Shue and Pogge, differentiate between positive duties (protection and aid) and negative duties (avoidance). Shue ranks human rights protection and puts basic rights at the top of his list. He establishes special responsibilities to fulfill the most urgent and serious rights without necessarily taking responsibility for rights violation into account.[613] Pogge, on the other hand, argues that obligations should be linked to responsibility for deprivation, giving rise to a duty to avoid causing harm to others. He associates human rights protection with a negative duty not to uphold an unjust international order, and believes that everyone who supports the unjust global structure is responsible for the human rights violations it causes.[614] We will not say more on the question of correlative duties for now as they will be analysed at length later, in sub-section 4.2.2.2, which is dedicated to human rights implementation and access to health.

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classics: J. Waldron, *Nonsense upon Stilt, supra* note 269; K. H. Marx, *On the Jewish Question.* (Written in 1843); G.W. Hegel, *Hegel's Philosophy of Right.* (T.M. Knox, trans.) (Oxford: Clarendon Press, 1964).

[613] H Shue, *Basic Rights, supra* note 245, at 52 and 118.

[614] T. W. Pogge, *World Poverty and Human Rights, supra* note 284; T. W. Pogge, "Symposium on World Poverty and Human Rights", *supra* note 284; N. E. Kass, "Public Health Ethics: From Foundations and Frameworks to Justice and Global Public Health" (2004) 32 *Journal of Law, Medicine and Ethics* 232, at 238-239; T.Pogge, "Eradication Systematic Poverty: Brief for a Global Resources Dividend" (2001) 2 *Journal of Human Development* 59; T. W. Pogge, "Reponsabilities for Poverty-Related Ill Health" (2002) 16:2 *Ethics and International Affairs* 71, at 73; C.R. Beitz, *supra* note 55; L. Doyal & I. Gough, *supra* note 92.

A different way of envisioning a philosophical account of human rights, instead of questioning the moral foundation of the very notion of human rights, is to refer to the concept as part of a theory of justice. As Kymlicka clearly puts it, "justice can be considered as the system of entitlements upon which people can base their demand for recognition of their legitimate claims for resources and opportunities."[615] This allows human rights to exist without actual claims of specific duties against identifiable actors, as they are associated with the ideal justice values and principles to which we aspire globally.[616] Rawls, for example, envisions human rights as a component of his theory of justice, as an important aspect of what should drive the interaction between different states, and also between citizens and their government. In fact, respect for human rights is one of the eight principles of the law of people, principles that should be followed by every decent society. For Rawls, human rights establish the limits of what should be tolerated from other societies, and are common to every decent society, liberal or not.[617] This narrow definition justifies including only a few rights in the list—such as rights to life, liberty, freedom of expression and religion, property, and equality before the law—and excluding most equality and welfare rights.[618] This vision elicits much criticism, some of which have been addressed in the theoretical section. However, our goal with this brief subsection is not to provide a detailed analysis of how human rights have been integrated in all different justice theories. Our purpose here, instead, is to present some of the main theoretical aspects of human rights to lay the groundwork for an assessment of the international human rights system with our global distributive justice benchmarks in the remaining part of this chapter.

As with the legalist approach, some criticise the fact that the moral discourse on human rights does not seem to consider the political values at the source of the

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[615] W. Kymlicka, *Liberalism, Community and Culture*, *supra* note 257, at 234.
[616] A. Gewirth, *supra* note 279, at 330.
[617] C. R Beitz, "Human Rights as a Common Concern" (2001) 95:2 *American Political Science Review* 269; A. Buchanan, "Rawls's Law of Peoples" (2000) 110 *Ethics* 697; F. Teson, "Some Observations on John Rawls' The Law of Peoples" (1994) 88 *American Society of International Law Proceedings* 18.
[618] J. Rawls, *Law of People*, *supra* note 79, at 65 and 74; C.R. Beitz, "Rawls's Law of Peoples", *supra* note 56.

norms, considering instead that these rights emerge from the very humanness of protected individuals.[619] In fact, people in general talk more about the link between the moral and legal discourses, the latter referred to as a concrete display of the former.[620] However, there is another important factor that should inform discussions on human rights foundations: the political discourse. Indeed, politics is involved in many spheres of the human rights regime. For example we can see the influence of politics in the basic moral judgments leading to human rights content, in pre-codification negotiations, and in giving key responsibilities to existing statist entities for enforcement of and safeguarding human rights. A political analysis highlights that social movements and, above all, the forces of hegemony play a crucial practical role in the preservation of the human rights system. Indeed, looking at human rights with a political lens can help to put legal and moral values in context while emphasising the real interests and powers lying at the source of the very production and preservation of particular *truths*.[621] In doing so, power issues and dominant interests need to be identified and exposed to disturb the order already in place; this can be done by questioning some crucial elements of a system supposedly based on neutrality and universality. Getting a sense of the political discourse underlying human rights therefore appears crucial to a real and complete understanding of the institution of human rights and to avoiding the trap of the *illusion of concord* often wrongly associated with human rights. It does not appear appropriate to envision the human rights discourse as a neutral moral system with which every state and

[619]M. MacDonald, "Natural Rights" in J. Waldron, ed., *Theories of Rights* (Oxford: Oxford University Press, 1984) 21; R.A. Wilson, *Human Rights, Culture and Context* (London: Pluto Press, 1997).

[620] K. Hessler, "Resolving Interpretive Conflicts in International Human Rights Law" (2005) 13:1 *The Journal of Political Philosophy* 29; T. Pogge, "Recognized and Violated by International Law", *supra* note 1; C. Brown, "Universal human rights", *supra* note 602; The preambles of the two 1966 Covenants (CCPR and CSECR) also state that human rights derive from the inherent dignity of human beings.

[621] T. Evans, *Us Hegemony and the Project of Universal Human Rights* (London: Macmillan 1996); J. A. Lindgren Alves, "The Declaration of Human Rights in Postmodernity" (2000) 22:2 *Human Rights Quarterly* 478; T. Carver, *The Postmodern Marx* (Manchester: Manchester University Press, 1998).

individual agree,[622] as we will see in more detail in section 4.2.3. when we discus human rights conceptualisation.

In the remainder of this chapter, we will ensure that these three different aspects of human rights are taken into account to provide a more complete and realistic account of the system in relation to our global distributive justice ideals.

4.2. Distribution, Access, Justice and the International Human Rights System: An Assessment

This second part of the chapter aims to assess the international human rights system with the benchmarks of justice established in the theoretical part of the dissertation. In fact, we will compare the ideal role that international human rights should play in terms of access and distribution of health and genetic advancements with the current reality. We have already established principles of global distributive justice to guide us towards our goal of a more equitable distribution of genetic research benefits. As briefly explained in the first part of this chapter, the international human rights regime is very important in the larger picture of international law, and includes socio-economic rights like the right to health and the right to benefit from the profits of scientific endeavours. Even if it could be seen as having an important role to play in fostering equitable access to genetic innovation, it appears crucial to evaluate whether this system is adequately constructed to accomplish such a goal. To examine these issues, we need to assess the human rights system with the analytical approach developed earlier. Our main standard to test the human rights system is universal access to some benefits of genetics to improve health while seeking the broader goal of equality of opportunities. This second part will be split into three main sections. We will beging with an evaluation of the international aspects human rights, discussing the notion of universalism and assessing the global order as a platform for human rights development. To this end, we will analyse the connection between

[622] A. J. Langlois, "Human Rights: The Globalization and Fragmentation of Moral Discourse" (2002) 28 *Rev. Int'l Stud.* 479, at 484; T. Evans, *supra* note 591.

international human rights, true cosmopolitanism, and universalism. Then, we will address the existing relationship between human rights, health-related duties, and access to health and genetics. We will conclude with a third part on human rights conceptualisation to assess the real importance of the market reality in the realisation of access to health through the application of human rights.

4.2.1. The global/universal aspect of access to health in the context of the international human rights system

Adopting a global and international focus, we need to first study the compatibility of the IHR system with the concept of universalism to see if the system is truly geared towards a cosmopolitan ideal where every human being is considered as a unit of moral concern. To this end we will discuss universalism in relation to relativism, individualism and "westernalisation". We will then provide a succinct evaluation of the global order under which human rights developed.

4.2.1.1. International human rights and universalism

Different critiques of the universal aspect of human rights have been brought forward. Indeed, it has been criticised for not being sensitive to cultural specificities, for encouraging harmful individualism, and for being unduly influenced and shaped by western values. We will review each of those critiques in the next few pages.

Universality vs relativism of human rights principles

The universal aspect of human rights principles gives rise to important debates. While some endorse a universal position that transcends nationality, religion, and culture and from which a limited number of principles emerge, others reject such a position,

arguing instead for moral and cultural relativism on the basis that the common foundation of human nature and universal community are lacking.[623]

The proponents of the latter position believe that there cannot be a single vision of right and wrong; it depends on traditions, geography, culture, and history. They think that human rights are shaped by human agents in specific contexts and that relying on one version only would be inappropriate and too constraining. Relativists believe that even when visions and values converge across cultures, such agreement is not morally meaningful but only represents some kind of coincidence. They believe that the reality of the fragmented world prevents universal acceptance of values that are often very contextual.[624] The only universality relativists are willing to accept is one that could emerge almost accidentally from a common justification of human rights coming from different people of various traditions adopting their own references. Rorty says that rights exist to "summarise our culturally influenced intuitions about the right thing to do in various situations, [...] thereby heightening the sense of shared moral identity which brings us together in a moral community."[625] This position implies that human rights are not a reality that we can take out of context and support as a universal answer, but instead are more a part of a culture endorsed by specific societies and communities.

While the language of human rights can be broad and neutral enough to allow respect and sensitivity to various cultural and contextual differences,[626] this dissertation focuses on the idea that these rights are grounded in the equal respect that each human being deserves. This egalitarianism arises from human agency and from some

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[623] On these two positions, see S. R. Benatar, A. S. Daar & P. Singer,*supra* note 182; K. Booth, *supra* note 611

[624] On this relativist position, see J. Chan, "A Confucian Perspective on Human Rights for Contemporary China" in J. R. Bauer & D. A. Bell, eds., *The East Asian Challenge for Human Rights* (Cambridge: Cambridge University Press, 1999) 212; B. Kausikan, "Asia's Different Standard" (1993) 92 *Foreign Pol'y* 24.

[625] R. Rorty, "Human Rights, Rationality, and Sentimentality" in S.Shute & S. Hurley, eds., *On Human Rights: the Oxford Amnesty Lectures 1993* (New York: Basic Books, 1993) 117.

[626] Some even say that human rights and their basic principles are echoed in every tradition of the world. For more on this view, refer to R. Coomaraswamy, "Reinventing International Law: Womens' Rights as Human Rights in the International Community" in P. Van Ness, ed., *Debating Human Rights: Critical Essays from the United States and Asia* (London: Routhledge, 1999) 167, at 169.

objective features, shared by everyone, which deserve universal consideration.[627] Some of those typically human characteristics refer to the capacity to think, to connect morally with others, to have a conception of the good life; to feel hunger, pain, and sexual desire; and to want our needs to be fulfilled, to judge, to dream, etc.[628] Therefore this calls for universally requiring the protection of socio-economic rights to ensure the preservation of humans' potential for self-realisation. These rights should not be defined or justified in relation to any particular legal system, state, or community. Martin is clear when he defines human rights as values that should be considered "reasonable by persons at different times or in different cultures... principles, [that] would be thought to have connection with a fairly wide range of differing conventional moralities."[629]

Another way to justify universal principles is to refer to shared understandings and conceptions of crucial elements related to the perception of human nature. For example, many experts from various disciplines like anthropology, sociology, philosophy, and the social sciences have demonstrated, with empirical research, that human beings often share comparable ideas of acceptable and unacceptable conduct and behaviour towards other individuals.[630] It thus appears possible to reach, through a flexible and cross-cultural exchange, some sort of agreement on universal rights we can all respect.[631] This illustrates a sense of unity transcending borders and cultures, the existence of a single moral community in certain identified spheres, and standards of social justice and human dignity, all of which support our cosmopolitan perspective. This is

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[627] This position is shared by M. C. Davis, "Constitutionalism and Political Culture: The Debate over Human Rights and Asian Values" (1998) 11 *Harv. Hum. Rts. J.* 109; F.R. Tesón, "International Human Rights and Cultural Relativism" (1985) 25 *Va. J. Int'l L.* 869; A.F. Bayefsky, "Cultural Sovereignty, Relativism, and International Human Rights: New Excuses for Old Strategies" (1996) 9 *Ratio Juris* 42.

[628] B. Parekh, "Non-Ethnocentric Universalism" in T. Dunne & N. J. Wheeler, eds, *Human Rights in Global Politics* (Cambridge: Cambridge University Press, 1999) c. 4, 128, at 143; W. Austin, *supra* note 594, at 190.

[629] R. Martin, *A System of Rights* (Oxford: Clarendon, 1993) at 75; See also R. J. Vincent, *Human Rights and International Relations* (Cambridge: Cambridge University Press, 1998) who refers to human rights as a *lowest common denominator* (at. 49).

[630] For more on this, refer to M. Naussbaum, "Human Functioning and Social Justice: in Defence of Aristotelian Essentialism" (1992) 20 *Political Theory* 222.

[631] B. Parekh, *supra* 628.

why relativism and particularism associated with specific states' actions and cultures should not be prioritised, as they can encourage passivity towards the shared universal concerns for human wrongs translated in international human rights.[632]

As discussed before, although a communitarian approach can be of great relevance in resolving numerous justice issues, this dissertation takes a universal perspective on health and the role it can play in the pursuit of the good life. Indeed, health is a crucial factor in bringing people to the level where they can benefit and profit from equality of opportunity. This is why we argue that health protection should not be left to different states' voluntary initiatives, but instead to more global and coordinated actions.[633] In this sense, we consider that the "universality" aspect of the international human rights legal and moral discourse is appropriate for health and compatible with our justice framework.

Universality of rights and individualism

In their inclusiveness and by granting the same rights and privileges to everyone, universal human rights are also criticised for allowing detachment from the reality in which individuals evolve. If we take this view, rights seem to be the cause of a deep sense of selfishness and individualism cultivated in modern societies. They can isolate people from one another.[634] Indeed, some argue that even if international human rights are supposed to be established to ensure assistance from an entity that can facilitate individual prosperity, there are more useful ways to encourage commitment, solidarity, and accountability than human rights.[635] Those who support this vision argue against the individual focus typical of the universal human rights language because it can have the perverse effect of ignoring collective responsibilities. For example, societies where the majority of

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[632] K Booth, *supra* note 611.
[633] J. Mann et al. *supra* note 580, at 21 et ss.
[634] J. Waldron, *Nonsense upon Stilts: Bentham, supra* note 269, part 1; A. Renteln, *International Human Rights: Universalism vs Relativism* (Newbury Park: Sage, 1990).
[635] D. Kennedy, *supra* note 598.

wealth is controlled by a few agents while many others have rights, but still end up with much less than what they need, are not rare. In this sense, universal human rights can be viewed as passively encouraging a social division that can prevent a true community from flourishing. This powerful quote from Wendy Brown exemplifies this argument: "[i]n the same gesture with which rights draw a circle around the individual, in the very same act with which they grant her sovereign selfhood, they turn back upon the individual all responsibility for her failures, her condition, her poverty, her madness—they privatise her situation and mystify the powers that construct, position, and buffet her." [636] In reaction to what they call the ethnocentric and patriarchal tone of the language of rights,[637] Sen and Nussbaum adopt the concept of human beings' capabilities. Instead of granting human beings individual rights, they argue that we should provide them with an appropriate social basis to develop their capabilities. Even if they believe in the same special nature of human beings and in the fact that all should somehow benefit from equal and universal treatment, they do not believe that rights are always the appropriate tools to safeguard universal and global equality.

In response to this critique of rights, we could say that the language of human rights is not at all incompatible with the concept of human solidarity, but that it really exists to bring all people—regardless of their citizenship—to a level where they can enjoy full lives within their community and to the benefit of their fellow community members.[638] Indeed, the universal aspect of human rights by which our similarities are acknowledged encourages cohesion for sharing the benefits of rights and burdens of associated duties. In other words, rights should be seen as part of a "reciprocal universality" which makes it impossible to see right-holding as a totally selfish and individual experience. [639] Mandela, when he refers to his country's liberation,

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[636] W. Brown, *States of Injury: Power and Freedom in Late Modernity* (Princeton: Princeton University Press, 1995), c.5, at 128.
[637] C. Brown, *supra* note 61.
[638] W. Austin, *supra* note 594; Len Doyal & Ian Gough, *supra* note 92, at 136.
[639] C. Jones, *supra* note 78 at 80-83; A. Gerwirth, "Rights", in L.C. Becker & C. Becker, eds., Encyclopedia *of Ethics* (London: Garland, 1992) at 1108; S. Bowles & H Gintis, Democracy and Capitalism : Property, Community, and the Contradictions of Modern Social Thought (New York: Basic Books, 1986) at 170.

highlights the importance of rights' universality in fostering a global sense of solidarity: "[o]ne of the striking features of modern times is the number of men and women all over the globe, in all continents, who fight violation of human rights."[640]

Universalism vs the influence of western values

A common critique of the international system of human rights is directed at strong influence of western values and interests in the construction of this so-called universal structure. As discussed above, international human rights law mainly governs relations between state governments and their citizens—highlighting, for some, a strong western influence hardly compatible with human rights' universality. Indeed, it is argued that liberal and economic theories have greatly influenced the development of the dominant human rights discourses, and that these influences embrace a philosophy where individualism prevails and in which people are seen as isolated abstractions focussing on their own interests.[641] For Donelly, the human rights system is mainly concerned with civil and political rights of citizens from liberal and democratic welfare states.[642] Some East Asian political leaders agree, arguing that the public disputes and individual pursuit of private interests typically associated with political and civil human rights are in no way universal, because they are incompatible with traditional Asian values of social harmony and community interests.[643] Indeed, many more scholars from various perspectives criticise the system on the basis that it does not reflect universal human values but instead endorses a unique, western, bourgeois, liberal, and masculine way of envisioning humaneness.[644] In this picture,

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[640] Cited in K Booth, *supra* note 611 at 57.
[641] J. Mann et al., *supra* note 580, c. 16.
[642] J. Donnelly, "Human Rights and Asian Values: A Defense of "Western Universalism" in J. R. Bauer & D. A. Bell, eds., *The East Asian Challenge for Human Rights* (Cambridge: Cambridge University Press, 1999) 60, at 68.
[643] As reported in C. R Beitz, "Human Rights as a Common Concern" (2001) 95:2 *American Political Science Review* 269.
[644] For example, see R. McCorquodale & R. Fairbrother, "Globalization and Human Rights" (1999) 21:3 *Human Rights Quarterly* 735, at 740;C. Brown, *supra* note 61, at 121; J. Slaughter, "The Question of Narration: A Voice in International Human Rights Law" (1997) 19 *Human Rights Quarterly* 406; P. Gabel & D. Kennedy, "Roll Over Beethoven" (1984) 36 *Stan. L. Rev.* 1;

the UN is perceived as an entity whose goal is to support and promote the liberal values enshrined in normative documents. Those liberal human rights standards are often used as universal civil and political thresholds that countries must meet to receive support from the wealthiest. However, in most cases, these norms do not play a great role in actually improving countries' socio-economic reality, but instead accept and even encourage persistent inequalities within the existing order "where market efficiency, discipline and confidence, economic policy credibility and consistency are often awarded higher priority than issues of dignity and rights".[645] In response to this, some instead view the western influence on human rights as very contextual, associated with a period and context that could have been completely different at other times, and that could also change in the coming years with, for example, the ascent of Asian powers.[646] The argument about the strong influence that western values have on human rights raises important concerns about the true universalism of human rights. We believe that it is important to differentiate between human rights' content and application. Indeed, even if socio-economic rights have been establish in a western liberal context, the values they defend—for example rights to health, nutrition, and work—can remain universal. In our view, the strong western influence has a negative impact on human rights universalism when the time comes to implement and enforce those rights and nothing is done to reassure excluded groups about the protectiveness and inclusiveness of human rights.[647] We will come back to the dominant political discourse that lies behind the realisation of human rights in section 4.2.3., when we address the conceptualisation of human rights within the reality of the market.

R. Pannikar, "Is the Notion of Human Rights a Western Concept?" (1982) 120 *Diogenes* 76; M. Shapiro & H. R. Alker, *Challenging Boundaries: Global Flows, Territorial Identities* (Minneapolis: University of Minnesota Press, 1996); A. Hunt, "Rights and Social Movements: Counter-Hegemonic Strategies" (1990) 17 *J.L. & Soc'y* 309.

[645] T. Evans, "Universal Human Rights", *supra* note 605, at 166; S. Gill, "Globalization, Market Civilization and Disciplinary Liberalism' (1995) 24:3 *Millennium: Journal of International Studies*; M. Mutua, *Human Rights: A Political and Cultural Critique* (Philadelphia: University of Pennsylvania Press, 2002) at 35 and c. 4.

[646] K Booth, *supra* note 611, at 52-53.

[647] T. Evans, *supra* note 645, at 166.

This last subsection demonstrates that the universal quality of human rights can be questioned on many fronts. Indeed, although the international human rights system appears to be based on the protection of individual interest, it can foster different outcomes, depending on how it is interpreted and circumscribed. In order to get a better idea whether and how each individual's interests get taken into consideration through the application of international human rights, we need to say a few words about the global order in which they develop.

4.2.1.2. Assessment of the global order under which international human rights develop

Article 28 of the UDHR says that, "[e]veryone is entitled to a social and international order in which the rights and Freedoms set forth in this Declaration can be fully realised." As Pogge clearly explains, this article does not add new human rights to those already existing, but serves to establish that human rights are "claims on the institutional order of any comprehensive social system,"[648] and that institutional orders should be evaluated in relation to the impact they have on the realisation of human rights.

States are at the center of the human rights system. Even if, as we just saw, a strong argument can be made to support human rights' universality, granting, implementing, and enforcing rights remains the first responsibility of states in international law.[649] This can be problematic in that state sovereignty can conflict directly with the universality principle. Indeed, one important rule in international law is that states are sovereign entities and are entitled to set up their own rules and norms within their territorial borders.[650] However, states can cede part of their sovereignty voluntarily in agreeing to comply with international standards like international human rights.

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[648] T.W. Pogge, "Human Rights and Global Health: A Research Program" (Jan. 2005) 36:1/2 *Metaphilosophy* 182, at 196.
[649] R. McCorquodale & R. Fairbrother, *supra* note 644; M. Koskenniemi, "The Future of Statehood" (1991) 32 *Harv. J. Int'l L.* 397; R. McCorquodale, "Self-Determination: A Human Rights Approach" (1994) 43 *Int'l & Comp. L.Q.* 857.
[650] This principle is codified in the Charter of the United Nations, 892 *U.N.T.S.* 119, art. 2(1).

When they do, they become accountable for their actions in that sphere. In reality, however, things are not that simple; affluent states are typically reluctant to concede any of their sovereignty to supranational institutions.[651] Sovereignty remains an essential principle of international law and plays a crucial role in how states behave and interact with one another. The exercise of one's human rights is directly linked with the nature of existing national legislative and institutional mechanisms in place. This is especially relevant as the reference to international human rights enforcement mechanisms is conditional on prior exhaustion of all national remedies.[652] This also means that, contrary to what universalism requires in terms of equal consideration for all human beings' interests, people can best exercise their rights as citizens as opposed to human beings.[653]

However, the world has become so interrelated in every sphere of activity that individuals are increasingly linked to each other through different modes of interaction and dependence. As explained by Monshipouri et al., "what has happened through conditions of chronic globalisation is that the fate of communities throughout the world has become linked through complex and dynamic systems that create moral connections between the agents and the subjects of social action regardless of territorial and political boundaries."[654] In such a context, human rights are meant to assert universal claims that people can have to resources and also to the protection of their inherent dignity as actors in this global reality.[655] This is compatible with the recognition, in international law, of the role of states in the protection of human rights—not only inside but also outside of their national borders, for the benefit of non-citizens.[656] Indeed, when states agree to UN membership, they commit to

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[651] E. O'Keefe & A. Scott-Samuel, "Human Rights and Wrongs: Could Health Impact Assessment Help?" (Winter 2002) 30:4 *The Journal of Law Medicine & Ethics* 734.
[652] J. Mann *et al.*, *supra* note 580, c. 2.
[653] C. R Beitz, "Human Rights as a Common Concern" (2001) 95:2 *American Political Science Review* 269, at 274.
[654] M. Monshipouri, C.E. Welch & E.T. Kennedy, "Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities" (2003) 25:4 *Human Rights Quarterly* 965, at 969.
[655] J. Mann *et al.*, *supra* note 580, c. 16.
[656] For a clear exposé of this topic, especially on the link between states' obligations and the activities they undertake across borders, refer to S. Skogly & M. Gibney, "Transnational Human Rights Obligations" (2002) 24:3 *Human Rights Quarterly* 781.

"achieve international cooperation in solving international problems".[657] Also, when the ICESCR requires states to take all necessary action within their means to achieve the full realisation of protected rights, it really asks that they do so with their budgetary capacities but also with the help of technical assistance and international cooperation.[658] In other words, the ICESCR clearly provides a normative foundation for state obligations to foreigners located outside their territories, in part through their external trade and cooperation activities. The role of international cooperation in human rights enforcement has been highlighted by the former UN High Commissioner for Human Rights when she refers to protection of the right to health, saying, "[s]pecifically, State parties should recognise the essential role of international cooperation and comply with their commitment to take joint and separate action for the full realisation of the right to health, taking into account the gross inequality in the health status of people, particularly between developed and developing countries."[659]

The requirement to meet such extraterritorial obligations can infringe on state sovereignty (both on the giving and receiving end), and achieving a balance between human rights protection and respect for state sovereignty can be somewhat challenging in practice. In that sense, international human rights can contribute to ending the unlimited sovereignty that states traditionally have on their people's entitlements.[660] Those changes in state sovereignty are not properly addressed by human rights. Indeed, although the global community has changed significantly over the last fifty years—with more members, more diversity, new powerful agents, closer ties and, at the same time, greater divisions—international human

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[657] UN Charter, art.1 (3), signed June 26, 1945, 59 Stat. 1031, T.S. No. 993, 3 Bevans 1153 (entered into force Oct. 24, 1945).

[658] ICSECR, art. 2 and 23; Committee on Economic, Social and Cultural Rights, *General Comment No 14: The right to the Highest Attainable Standard of Health, Article 12 of the Covenant,* May 12, 2000, E/C. 13/2000/4, online on the website of the UNHCHR: <http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument> (accessed: May 30th, 2006), par. 75.

[659] UN Economic and Social Council, "Report of the High Commissioner: The impact of the Agreement on Trade- Related Aspects of Intellectual Property Rights on Human Rights", June 27, 2001, E/CN.4/Sub.2/2001/13, par. 35

[660] On the topic of human rights globalisation, see *Vienna Declaration and Programme of Action*, U.N. Doc. A/CONF.157/23, 1993, part. I, art.4.

rights have not managed to adapt to these changes.[661] For example, international human rights do not provide remedy for violations committed by non-state actors like transnational corporations, asking states to take on responsibility for what is happening within their territories and focussing on what they can do to improve their people's well-being. Doing so, the language of international human rights does not acknowledge that states' control, freedom, management abilities, and flexibilities are, in reality, eroding to the benefit of non-state actors who are shaping the global society

This changing role of states due to globalisation can have important effects on the realisation of true universal human rights. Indeed, more and more, states must respond to market forces and act to support the broader global order which favours freedom of production and appropriation. Consequently, the global protection of international human rights standards loses its universal character and becomes a tool to further economic ends rather than being an end in itself.[662] In other words, some powerful external agents involved in changing the face of international relations and whose actions are not easily controlled by national or international agencies can end up with much control over the way human rights are realised within the global order.[663] This explains, at least in part, why most socio-economic rights have not been considered seriously, despite the fact that the universal character of human rights calls for their inclusion in the emerging global consensus. This means that state sovereignty is transforming to serve different, more powerful interests, a situation that brings Chimni to say that "[a]s things stand now, the neo-colonial third world states will continue to exist but essentially in the service of the TCC [transnational capitalist class] and the global

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[661] A. J. Langlois, "Human Rights: the Globalisation and Fragmentation of Moral Discourse", *supra* note 622; P. Willets, "Transnational Actors and International Organisations in Global Politics" in L. Baylis & S. Smith, eds., *The Globalisation of World Politics* (Oxford: Oxford University Press, 2001) 287.

[662] R.W. Cox, "Civil Society at the Turn of the Millennium: Prospects for an Alternative World Order" (1999) 25 *Rev. Int'l Stud.* 3; T. Evans, "International Human Rights Law as Power/Knowledge" (2005) 27:3 *Human Rights Quarterly* 1046

[663] M. K. Addo, *Human Rights Standards and the Responsibility of Transnational Corporations* (Boston: Kluwer Law International, 1999); P. Alston, "The Myopia of the Handmaidens: International Lawyers and Globalization" (1997) 8 *Eur. J. Int'l L.* 435; R. McCorquodale & R. Fairbrother, *supra* note 644.

state. The Northen/Wester state, on the other hand, will continue to shape the form and content of the emerging global state to realise TCC interests."[664]

Another problem identified with the existing global order is that it seems to support institutions involved in human rights violations. In fact, international economic organisations with effective enforcement powers—like the WTO, the Bretton Woods Institutions (including the World Bank and the International Monetary Fund), as well as transnational corporations and other central features of the present global order—are often described as institutions of artificial global unity that systematically contribute to the persistence of severe poverty.[665] For example, although the World Bank has recently undertaken over 600 judicial reform projects aimed at improving the condition of the least well off,[666] it seems to be part of a larger effort to facilitate transactions, protect property rights, and establish a stable investment environment in priority.[667] Some respond to this criticism by saying that the international order and its economic institutions are just since they give an equal chance to sovereign states to bargain and negotiate with each other and consent to the outcome. This argument ignores the fact that parties do not have the same economic bargaining power[668] and that the weakest countries almost always have to make concessions that go against their basic interest.[669]

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[664] B. S. Chimni, "International Institutions Today: An Imperial Global State In The Making" (Feb. 2004) 15 Eur. J. Int'l L. 1, at 6; see also A. Eide, "Obstacles and Golas to be Pursued" in A. Eide *et al.*, eds., Economic, Social and Cultural Rights: A Textbook, 2nd ed., (London: Maaetinus Nijhoff, 2001), c. 31, at 553.

[665] For example it has been reported that the OECD *Convention on Combating Bribery of Foreign Public Officials in International Business Transactions* is ineffective in preventing bribery by companies. For more on this, refer to 'The Short Arm of the Law' (March 2, 2002) *Economist* 63; R. Baker, *Capitalism's Achilles Heel: Dirty Money and How to Renew the Free-Market System* (John Wiley & Sons, Hoboken: New Jersey, 2005); on this topic, see also F. Furet, *Marx and the French Revolution* (London: University of Chicago Press, 1995).

[666] World Bank Legal Vice-Presidency, *Legal and Judicial Reform: Strategic Directions*, 2003, online <http://www4.worldbank.org/legal/legalr/GreyBookFinal2003.pdf> (accessed May 28th, 2006).

[667] K. Rittich, "The Future of Law and Development: Second Generation Reforms and the Incorporation of the Social" (Fall 2004) 26 *Mich. J. Int'l L.* 199, at 217.

[668] According to recent statistics, developed countries represent 15.5% of the world's population while controlling 80.4% of the world's income. World Bank, *World Development Report 2005* (New York: Oxford University Press, 2005) at 257.

[669] We refer the reader to chapter III on this matter, where we addressed this topic at length under our discussion of the TRIPs negotiations. See also, A. Anghie, "Time Present and Time Past:

Many suggestions have been put forward to transform the current world order and make it less burdensome for the less affluent.[670] Some have proposed to impose the same human rights standards on the activities of non-state actors—especially transnational corporations and international economic organisations—to support a more humane globalisation.[671] It actually seems that unless we proceed with this shift, the human rights dialogue will be designed in a way to disturb those powerful actors' activities as little as possible. Going one step further, we also have to question the real nature of the human rights standards whose application we want to extend. Indeed, as briefly mentioned above, today's human rights are viewed by some as inspired by cultural imperialism, and more specifically by western liberal values linked with the global political economy and aimed at protecting liberal freedoms to ensure the satisfaction of private interests, especially those lying in property rights.[672] The content and the true importance of socio-economic rights need to be reaffirmed and strongly enforced. However, many obstacles stand in the way of such an exercise.

This section assessed one aspect of human rights: the universal perspective of the international human rights discourse with a cosmopolitan standard of global access. Our analysis of the global aspect of access to health and human rights highlights a progressive weakening of the cosmopolitan approach to solidarity that should be fostered by the very institution of international human rights. We

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Globalization, International Financial Institutions, and the Third World" (2000) 32 *N.Y.U. J. Int'l L. & Pol.* 243, at 274.

[670] For example, it has been suggested that third world nations be helped to become real participants in WTO negotiations, to reduce existing obstacles to their exportation into affluent countries, to guarantee developing countries some share in the value of the harvested seabed, to make state sovereignty conditional on the safeguard of some basic human rights, and to ask developed countries to compensate for the negative externalities inflicted on the poorer ones. We will revisit this topic when we address duties and responsibilities associated with human rights implementation under section 4.2.2.2. T. Pogge, *Recognized and Violated by International Law*, *supra* note 1.

[671] S. Picciotto, "Democratizing Globalism" in D. Drache, *The Market or the Public Domain, Global Governance and the Asymmetry of Power* (New York: Routhledge, 2001) 335; A. Clapham, "Globalization and the Rule of Law" in A. Dieng, ed., *Globalization, Human Rights and the Rule of Law* (Geneva: International Commission of Jurists, 1999) at 31.

[672] T. Evans, *supra* note 645; K. Marx, "On the Jewish Question", in J. O'Walley, ed., *Early Political Writing* (Cambridge: Cambridge University Press, 1994); M. Mutua, *supra* note 645.

realised that the concept of universalism, crucial to justifying global distributive justice and access in health, is a morally contested notion in the field of international human rights, and also not always supported by the institutional structures and the politics of human rights. Indeed, the capitalist and undemocratic features of the global order seem to reduce the potential for real and universal global distributive justice supported by international human rights principles. This is illustrated by the fact that the most obvious economic disparities and injustices remain unnoticed and unpunished by international law, and that the most vulnerable groups do not receive the protection they deserve under the legal system.[673] In other words, instead of fostering a universal application of human rights, economic globalisation supports some groups, interests, and rights over others.[674] It therefore does not recognise, in practice, the universal importance of health for every human being. This problem is rarely addressed under the dominant legalist voice of the human rights discourse, which can be seen as eluding the real power relations lying at the core of many human rights violations. Because of the importance of this dominant discourse, most people ignore how human rights ideals have been transformed and modeled by external powers that often bring them, wrongly, to believe in a just world.[675] This is why it is crucial to undertake a deeper analysis of the complex global political reality within which the system of human rights evolves. We will come back on this in the third part of this section, when we discuss the conceptualisation of human rights within the reality of the market.

Before doing so, now that we have assessed the international and universal dimensions of the human rights system, we need to evaluate whether this system is compatible with other benchmarks of our framework of distributive justice in health. To this end, we will first discuss human rights in connection with legal access to genetic products and services for health improvement to facilitate equality of

[673] For example, this appears from how the AIDS crisis has been handled so far. We will come back on this specific case in the last chapter. A. Anghie, *supra* note 669, at 273.
[674] A. Hoogvelt, *Globalization and the Postcolonial World: The New Political Economy of Development* (Basingstoke: Palgrave, 2001).
[675] S.R.Benatar, *supra* note 2.

opportunities; secondly, we will address human rights in relation to the responsibility to distribute genetic technologies in order to foster real access to health improvement.

4.2.2. Legal access to health, responsibility for distribution of health and human rights

The main goal of this section is to determine how the need for health improvement through genetic access materialises in legal rights, entitlements, and related responsibilities for distribution, and whether the actual human rights system is working toward this goal. We will start with an assessment of socio-economic rights, and more specifically, health-related rights with benchmarks of distributive justice. In the second part, we will address the integration of these rights with the associated responsibility to distribute genetic technologies to promote real access to health improvement and equality of opportunities, within the mechanism of human rights implementation.

4.2.2.1. Envisioning socio-economic rights with benchmarks of distributive justice

Rights can be crucial in a theory of justice as they can impose restrictions on actions (civil and political rights) and obligations to undertake other actions (socio-economic rights). Brown states that "the language of rights has become the way in which humanitarian impulses are expressed in the modern international system."[676] If we take human rights as an important element of our global distributive justice theory, they will accordingly impose restrictions on distributive arrangements (social, political and economic) supported by the global order, and serve as a basis to rectify injustices created by unequal distribution. In this sense, just distribution will be achieved when individuals obtain what they are entitled to, by right, in terms of resources and opportunities. As briefly explained at the beginning of this chapter, our main focus is on the content, conceptualisation, and realisation of socio-economic

[676] C. Brown, *supra* note 61, at 103.

rights. These rights represent claims to social equality and refer to prospects and circumstances that can allow individuals to live as actors and enjoy a good standard of living.[677] They are critically important with respect to health issues, to ensure that each individual has equal access to appropriate health care, technology, and resources to have a normal range of opportunities in other spheres of activities, as well as to be able to take advantage of other civil and political rights. One major issue with the enforceability of economic, social, and cultural rights is the confusion between the recognition of rights in themselves and the degrees of realisation of those rights in terms of implementation and protection. Indeed, as mentioned previously, the realisation of health-related rights is dependent on legal interpretation, decisions on resources allocation, and political convictions.[678]

Definition of the right to health

In the last few decades, human rights have been associated with the crucial goal of achieving acceptable standards of health.[679] As briefly discussed in the first part, rights emerge from our general theory of global distributive justice in health. It gives us indications as to which kinds of claims should be viewed as rights, which needs should be codified as rights, and against which standards *just* social rules, institutions, and people who establish and support them should be assessed. Rights are grounded in the basic moral interests that individuals have in their content. Some associate basic rights-protection with primary necessities and the preservation of human life. Such basic rights can emerge from the basic needs shared by every human being—

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[677] G.A. Mower, *International Cooperation for Social Justice: Global and Regional Protection of Economic/Social Rights* (Westport: Greenwood Press, 1985) at 3.

[678] J.K.Mapulanga-Hulston, "Examining the Justiciability of Economic, Social and Cultural Rights" (Winter 2002) 6:4 *The International Journal of Human Rights* 29, at 42-43; J. Hausermann, "The Realisation and Implementation of Economic, Social and Cultural Rights" in D.M. Hill & R. Beddards, eds., Economic, Social and Cultural Rights – Progress and Achievement (New York: St Martin Press, 1992) at 49; L. London, *supra* note 2.

[679] For example, refer to V. A. Leary, "The Right to Health in International Human Rights Law" (1994) 1 *Health and Human Rights* 24; L. Freeman, "Reflection on Emerging Frameworks of Health and Human Rights" in J.M. Mann et al., eds., *Health and Human Rights: A Reader* (New York: Routledge, 1999) 227.

such as subsistence, water, housing and health care[680]—and they can be ordered according to the nature of the interest they aim to protect. Shue establishes some priorities among rights, putting the fulfilment of basic rights first,[681] followed by non-basic rights, culture enrichment, and, finally, mere satisfaction of preferences.[682] Meeting basic rights in priority is crucial in that it helps free people from oppression and discrimination, removes a certain degree of vulnerability that exposes them to the power of others, and allows them to exercise many other rights.[683] Another way to describe it is to refer to the notions of "social citizenship", "personhood" or "moral agency," which justify demands for access to basic necessities for survival and potential for a good life.[684] This relates to our argument for a cosmopolitan approach to genetic access and distribution; the superior basic human interest in health is shared by everyone, it represents an appropriate focus for a duty not to harm and ensures that individuals are in a position to profit from equality of opportunities, plan for a good life, and pursue their goals. When we use the language of socio-economic human rights in our specific context, it can refer to the right to health (art. 12 ICESCR) and to the right to enjoy the benefits of scientific progress and its applications (art. 15 (1) b) ICESCR). However, for the need to assess tangible genetic access and distributive justice, it appears appropriate to focus more on the right to health, which is a controversial and inclusive right that can cover a wide range of activities, products, and technologies. The right to enjoy the benefits of science, on the other hand, although also relevant, appears less pertinent to our analysis. Indeed, this article was adopted with a somewhat different perspective, in response to the rise of intellectual property protection to ensure that quality scientific innovations would be published and made accessible to the collectivity. Much of what we are saying about the human right to health, aside from the content and definition, could be used in an analysis of other socio-economic rights.

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[680] H. Shue, *Basic Rights*, *supra* note 245; O. O'Neill, *supra* note 82 at 155 et ss; O. O'Neill, "Hunger, Needs and Rights", *supra* note 88; P. Jones, *Rights* (London: MacMillan, 1994) at 13-15.

[681] Basic rights are those grounded in basic human needs and establishing the threshold under which no one should be entitled to fall to avoid degrading inequalities.

[682] H. Shue, *Basic Rights*, *supra* note 245, c. 5, at 111.

[683] P.D. Jacobson & S. Soliman, "Co-opting the Health and Human Rights Movement" (Winter 2002) 30:4 *The Journal of Law, Medicine & Ethics* 705; A.R. Chapman, "Conceptualizing the Right to Health: A violation Approach" (1998) 65 *Tenn. L. Rev.* 389.

[684] S. R. Benatar, A. S. Daar & P. Singer, *supra* note 182.

The right to health, including health care, services, and technologies, is accepted as a human right in regional and international law. Indeed, it has been protected by the WHO Constitution since 1946[685] and was further enshrined in numerous other human rights treaties.[686] The ICESCR offers the strongest and ambitious version of the right to health in its article 12:

> 1. The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:
>
> (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>
> (b) The improvement of all aspects of environmental and industrial hygiene;
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The Committee on Economic, Social and Cultural Rights interprets the right to health broadly as including the right to facilities, goods, services, education, and research required to achieve the highest attainable standard of health.[687] Nevertheless,

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[685] *Constitution of the World Health Organization*, adopted by the International Health Conference, New York, signed on 22 July 1946 by the representatives of 61 States

[686] For example, the right to health has been codified in: *Universal Declaration of Human Rights*, art. 25; *International Covenant on Economic, Social and Cultural Rights*, *supra* note 579, art.12; *Convention on the Elimination of all Forms of Discrimination against women*, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, entered into force Sept. 3, 1981, art.12; *Convention on the Rights of the Child*, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), *entered into force* Sept. 2 1990, art.24; See also, *African Charter on Human and People's Rights*, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), *entered into force* Oct. 21, 1986 Art. 16; *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights*, 1988, Art. 10.1.

[687] A.R. Chapman, "The Human Rights Implications of Intellectual Property Protection" (2002) 5 *Journal of Int'l Eco. L.* 861 at 880.

although the right to health is codified in many legal instruments and is meant to be interpreted broadly, it nevertheless lacks "conceptual clarity."[688]

Despite these lacunae, there seems to be some agreement on some of the essential elements that the right to health should include, irrespective of state resources and of individuals' economic situation. These elements can be divided into two categories, the first related directly to health care (including, for example, access to basic medical treatment and services for severe diseases, maternal and child care, and immunisation against infectious diseases) and the other related to determinants of health (such as access to education and prevention methods, drinkable water, food, and adequate sanitation).[689] To ensure that the right to health can be respected as much as possible, another important aspect of its content relates to the international obligations associated with preventing violations of the right, facilitating access to health-related products and services, and providing aid to other countries.[690] As discussed at the very beginning of the dissertation, the science of genetics has the potential to be used and developed to help address and resolve most of the essential elements included in the right to health.

Nonetheless, what often happens in reality is that, when referring to health rights, people only include basic rights to emergency health care and subsistence, indirectly endorsing the fact that access to adequate and adapted health care remains reserved for a privileged few.[691] This is in line with the application of Rawls' difference principle. As already discussed in the first part, this position is unsatisfactory since

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[688] A.E. Yamin, "Protecting and Promoting the Right to Health in Latin America: Selected Experience from the Field" (2000) 5:1 *Health and Human Rights* 117; B. Toebes, "Towards an Improved Undertading of the International Right to Health", supra note 583, at 662; P. Alston, "Out of the Abyss: The Challenges Confronting the New U.N. Committee on Economic, Social and Cultural Rights" (1987) 9 *Human Rights Quarterly* 332, at 351-355.

[689] *Declaration of Alma-Ata*, 12 Sept. 1978, repr. in Report of the International Conference on Primary
Health Care (Geneva: World Health Organization, 1978), art.VII; Committee on ESCR, *General Comment No 14*, *supra* note 658, par. 4, 11 & 12; J. Mann et als., *supra* note 580, at 8; B. Toebes, "The Rights to Health" in A. Eide *et al.*,eds., *Economic, Social and Cultural Rights: A Texbook*, 2nd ed., (London: Maartinus Nijhoff, 2001), c.10, 169.

[690] Committee on ESCR, *General Comment No 14*, *supra* note 658, par. 39 and 45.

[691] S. Caney, *supra* note 128.

the scope of the underlying elements of the difference principle remains very unclear. It gives no precise indication as to what criteria must be met to be considered as belonging to the least privileged group. Also, it does not go into detail about what is required to reach the *greatest benefit of the least advantaged group* threshold, as it does not impose a floor below which no one should be allowed to fall. We argue that focussing on the most urgent health needs of any individual or on the category of the absolute poorest people is far from enough, as many individuals can still be left in need of the benefits of genetics outside of the distribution realm. It also does not guarantee that people's basic needs will be met so they are in a position to enjoy other rights and create a good life. Indeed, respecting rights to health, health care, and genetic technologies (as we consider that they could become the new standard of care) is essential to the broader goal of achieving equality of opportunities for all. In fact, as explained earlier in the dissertation, access to health in terms of availability and affordability of genetic products and services will allow people to seize opportunities towards achieving rewarding lives, and this should be the ideal threshold for distribution. However, even if true equality of opportunities remains out of reach in a world where there are limited health resources for unlimited health needs, we believe that the interpretation of the right to health should nevertheless be widened so that it does not only refer to the most urgent needs or the absolute worst-off, but instead aim at broader and more inclusive thresholds of health, like, for example, basic health-needs satisfaction in light of existing medical and genetic technology.[692]

Having established a clear link between genetics and the content of the right to health, the next step is to determine if the human rights system is built to ensure that the benefits of genetics will actually reach those who need them the most.

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[692] A. K. Acharya, *supra* note 5; L. Doyal & I. Gough, *supra* note 92, at 130-135; T. Nagel, *supra* note 318.

Efficacy of the right to health in terms of justice

In addition to issues relating to the content and validity of human rights, there is also the problem of true efficacy of international socio-economic rights and of the right to health more specifically. Many question the real justiciability of socio-economic rights because of their prevailing political character, the vagueness of the scope and content of the rights, the associated obligations of conduct (not of result), and weak supervision and compliance mechanisms.[693] Indeed, very few countries monitor and gather data on their realisation of the right to health.[694]

The *Limburg Principles* and the *Maastricht Guidelines* state that economic, social, and cultural rights violations can arise following both acts of commission and acts of omission at the national and regional levels.[695] For instance, member states can be brought before the European Committee of Social Rights (ECSR) to respond to alleged violations of the European Social Charter (ESC) dispositions.[696] On the international scene, the Committee on ESCR is in charge of revising periodic reports submitted by State parties to monitor implementation of socio-economic rights. To conduct its evaluation and analysis of how the right to health is respected by member states, the CESCR refers to four broad categories: general issues (proportion of

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[693] A. Eide, "Future Protection of Economic and Social Rights in Europe" in A. Bloed *et al.*, eds., *Monitoring Human Rights in Europe: Comparing Internationa Procedure and Mecanisms* (Boston: Maartinus Nijhoff, 1993) 187; M. Scheinin, "Economic and Social Rights as Legal Rights" in A. Eide *et al.*, eds., *Economic, Social and Cultural Rights: A Textbook, 2nd ed.* (London: Maartinus Nijhoff, 2001) 29.

[694] A. R. Chapman, *supra* note 597.

[695] *The Limburg Principles on the Implementation fo the International Covenant on Economic, Social and Cultural Rights* (1987) 9 *Human Rights Quarterly* 122, UN doc E/CN.4/1987/17, at 131; *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, *supra* note 585.

[696] For example, in the case *International Federation of Human Rights Leagues (FIDH)* v. *France* (complaint no. 14/2003), the ECSR was asked to interpret art. 13 (1) of the ESC on the right to medical and social assistance in relation to the *French Finance Amendment Act*. The complaint related to access to medical care by illegal immigrants with very low income. The claimant, the *International Federation on Human Rights Leagues* (FIDH) argued that illegal immigrant status should not, in any case, justify denying medical assistance to individuals, and that ensuring free treatment in case of emergencies and life-threatening conditions was not sufficient. The French Government, on the other hand, submitted that illegal immigrants did not fall within the scope of the charter's protected individuals. The ECSR admitted that the practical applicability and definition of health emergencies and life-threatening conditions were vague, but since some form of medical assistance, even minimal, was in place, it was enough for the Committee to conclude that the French Act did not violate art. 13 of the ESC.

countries' GNP dedicated to health, public/private standards); healthcare (provision in rural and urban regions, availability and affordability of health care and services); determinants of health (access to food, water, and sanitation); consideration of more vulnerable groups (indigenous population, HIV-infected individuals and communities).[697] Also, in its 2000 general comment on the right to health, the Committee established four different criteria to evaluate the achievement of the right to health, namely, availability, accessibility, acceptability, and quality.[698] We will come back to some of these criteria in the next chapter, when we discuss the intersection of intellectual property and human rights in health with practical examples. As things stand now, the Committee has no mandate to review individual complaints concerning violations of economic, social, and cultural rights. However, a draft Optional Protocol could be established to this end in the near future, depending on the conclusion of the working group in charge of evaluating this issue.[699]

Our principles of distributive justice demand that, in the course of distributive endeavours, we consider the health needs of every individual as critically important and consider them as rights to the extent necessary to ensure that they have the capacity to take advantage of available opportunities. Some, like Kennedy, believe that rights are not the best instrument to help us achieve equitable distributive endeavours. In fact, he says that the very legal nature of rights does not allow us to prioritise and ensure equitable distribution among different right-holders—some more deprived, with greater and more urgent needs than others.[700] Instead, he argues, it too often allows institutions to protect some people's preferences even when others are unable to enjoy any rights.

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[697] UN Committee on ESCR, *Guidelines on Reporting, Questions relating to art. 12 of the CESCR*. UN doc. E/1991/23, at 88-110; B. Toebes, "Towards an Improved Understanding of the International Right to Health", *supra* note 583, 666-667.
[698] Committee on ESCR, *General Comment No 14*, *supra* note 658.
[699] Economic and Social Council, Commission on Human Rights, *Report of the Open-Ended Working Group to Consider Options Regarding the Elaboration of an Optional Protocol to the International Covenant on Economic, Social And Cultural Rights on its First Session*, E/CN.4/2004/44, March 15, 2004.
[700] D. Kennedy, *supra* note 598.

Others, like Cullet, believe that although they are universal and awarded to all, human rights are meant to focus on the most deprived individuals and communities.[701] Indeed, the Committee on ESCR, in its analysis, seems to prioritise economically deprived people's claims over the states' limited resources.[702] This is also the position that the European Court of Human Rights adopted in the case *Airey* v. *Eire* in 1979.[703] Indeed, the Court interpreted the right to a fair trial very broadly, so as to include the right to civil legal aid protection. In so doing, the Court gave this right some teeth and offered tangible support for the equal treatment of everyone, with a special focus on the least affluent individuals and communities. As Scott notes, this decision illustrates that "human rights protection can, and should, be a result of a contextual interpretive analysis of what is needed to make a right truly a right of "everyone".[704] Applying this decision to the right to health allows us to argue for the provision of a sufficient and adequate amount of health care to secure equality of opportunities, regardless of socio-economic factors.

This brings us to the realisation that, depending on how they are implemented, human rights can impact the health of both individuals and communities, replacing our strictly medical perspective with a broader "social good" vision of health. Indeed, the rights to health, health care, and related technologies, resources, and services are inherently valuable in their goal of protecting individual welfare, basic needs, and interests. In itself, it justifies their recognition as a normative foundation for justice in a just global structure. However, realising these rights necessarily entails correlative duties by identified duty-bearers against whom rights are claimed. Indeed, as rights can found certain socially-guaranteed claims, they can also provide a basis for related duties of states and other members of the global community. This second section seeks to address the relationship between human rights, correlated duties, and access to health.

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[701] P. Cullet, *supra* note 449.
[702] C. Scott, "Reaching Beyond (Without Abandoning) the Category of Economic, Social and Cultural Rights" (1999) 21:3 *Human Rights Quarterly* 633; A. Eide et al., *supra* note 576.
[703] *Airey* v. *Ireland*, 32 Eur. Ct. H.R. (ser. A) (1979), *reprinted in* 2 Eur. H.R. Rep. 305 (1979).
[704] C. Scott, *supra* note 702, at 641.

4.2.2.2. Implementing the Right to Health

In the last subsection, we established some links between the existing right to health, the potential benefits of genetics, and the somewhat doubtful efficacy of the concept of rights for securing access to health-taking needs and deprivation into account. Another very important aspect of the right to health, which is too often forgotten, concerns duties involved in creating the conditions necessary for ensuring practical right enforcement and fulfilment resulting in efficient and just distribution. Indeed, our very capacity to benefit from rights is directly linked to our acceptance of responsibilities.[705] On the importance of related duties, Shue says that "[i]t is only because rights may lead to demands and not something weaker that having rights is tied as closely as it is to human dignity."[706]

Notion of duty

Focussing on duties can be helpful at many levels for realising global distributive justice in health. It can encourage a dialogue on who has to do what, in which priority order, for the realisation of the right to health. It can also help to highlight some problems with the political and economic context within which human rights are conceptualised.[707] We will discuss the former issue in the present sub-section and the latter will be addressed in the third and last section of this chapter.

Vincent states that rights are composed of five essentials: namely the subject and the object of the right, the way to exercise the right, the duty-bearer and the justification of the right.[708] Discussions on human rights should therefore not only cover the

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[705] S. Benatar, A.S. Daar & P. Singer, *supra* note 182.
[706] H. Shue, *Basic Rights*, *supra* note 245, at 14.
[707] A. Chapman, "Reintegrating Right and Responsibilities" in K.W. Hunter & T.C. Mack, eds., *International Rights and Responsibili.ties for the Future* (Westport C T: Praeger, 1996) 3; A. Robertson, "Critical Reflection, on the Politics of Need: Implications for Public Health" (1998) 47 *Social Science and Medicine* 1419.
[708] R.J. Vincent, *Human Rights and International Relations* (Cambridge: Cambridge University Press, 1986) at 8; T. Dunne & N. J. Wheeler, *supra* note 602.

essence of what should be granted, but should also deal with what is necessary to achieve these rights and by whom they should be respected. This is the focus of this section. As discussed in Part I, rights to health and equality of opportunities give rise to an obligation not to harm and to take practical distributive steps towards protecting the interests of rights-holders.

The UDHR and the ICESCR implicitly refer to the obligation of states to secure a right to health for their people and for foreigners through international cooperation, without any discrimination. These obligations are demanding; they require "action to create freedom."[709] Other soft-law initiatives have also been undertaken to establish and propose specific duties for states in relation to socio-economic rights to secure a minimum quality of life for individuals and an adequate environment for future generations. [710] Duties are assigned both to countries and to the international community, which needs to take global inequalities between countries into account in the realisation of the right to health.[711] Indeed, human rights cannot be respected in less affluent countries if the rich countries do not respect their related duty to refrain from adopting detrimental political, military, and economic strategies against them. However, since practical implementation is almost uniquely national, international supervision is very limited, as we will see in the next section.

The right to health can give rise to three main types of obligation: the obligation to respect, protect, and fulfill (ensure and promote) individual and community health needs within and across borders.[712] These, in turn, can be divided into two broad categories: positive duties (to perform actions toward equal access to quality health

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[709] E. O'Keefe & A. Scott-Samuel, *supra* note 651.
[710] *The Limburg Principles on the Implementation fo the International Covenant on Economic, Social and Cultural Rights*, *supra* note 585; *Trieste Declaration of Human Duties: A Code of Ethics and Shared Responsibilities*, 1995; *Universal Declaration of Human Responsibilities*, September 1997.
[711] UN Economic and Social Council, *Report of the High Commissioner: The impact of the Agreement on Trade- Related Aspects of Intellectual Property Rights on Human Rights*, June 27, 2001, E/CN.4/Sub.2/2001/13, para. 35, on line on the UNHCHR website: <http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa023802566870051 8ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf> (accessed June 4th, 2006); Committee on Economic, Social and Cultural Rights, *supra* note 658.
[712] H. Shue, *Basic Rights supra* note 245; W. Austin, *supra* note 594; A. Eide, *supra* note 576.

care and against interference with this right; to assist; to promote health and disease prevention through legislative and policy mechanisms) and negative duties (to refrain from performing certain health-harming actions and from establishing institutions that could undermine individuals' right to health).[713]

Positive duties

Positive duties to fulfil the right to health imply undertaking actions to secure sufficient amounts of goods and services to meet individuals' basic health needs with the help of existing medical and genetic technology. Negative duties involve refusing to endorse an institutional order that entails avoidable and foreseeable violation of those rights. [714] Proponents of positive duties believe that refraining from institutionally denying and undermining access to health goods and services will not always be enough to make a difference in helping the most vulnerable. Indeed, their view is that maintaining fair institutions does not necessarily ensure that severely disabled individuals will be able to get what they should be entitled to from those institutions. They also believe that basic needs and interests are so important that they should give rise to both institutionally grounded positive assistance duties and duties of non-interference.[715]

Fulfilling positive duties to aid raises a number of questions with regard to availability and allocation of scarce resources across time and space, imposition of budgetary priorities, income distribution, public policy making, and legislative and judiciary powers.[716] Indeed, the limited resources (human, budgetary etc.) of states, the numerous unfulfilled basic health needs, and the difficulty of finding accountable

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[713] J. Narveson, *The Libertarian Idea* (Philadelphia: Temple University Press, 1988) at 57; R. Cruft, "Human Rights and Positive Duties", *supra* note 277, at 30.
[714] T.W. Pogge, "Severe Poverty as a Violation of Negative Duties", *supra* note 278, at 66-68.
[715] R. Cruft, "Human Rights and Positive Duties", *supra* note 277, at 35-37.
[716] M. Jackman, "The Protection of Welfare Rights under the Charter" (1988) 20 *Ottawa L. Rev.* 257; C. Scott, "The Interdependence and Permeability of Human Rights Norms: Towards a Partial Fusion of the International Covenants on Human Rights" (1989) 27 *Osgoode Hall* 769; H. Shue, *Basic Rights*, *supra* note 245, at 91.

actors and institutions can raise scepticism about the very existence of a right to health and thus can be seen as obstacles to the positive implementation and enforcement of welfare claims.[717] Nervertheless, universal human rights, such as the right to health, should be appraised from a global and long-term perspective, and should be awarded the most resources and attention in comparison to preferences and other non-basic rights. As discussed in the Part I, health is of universally great importance. Protecting health is an essential part of the duty not to harm, as it aims to bring individuals to a situation in which they are able to function, seize opportunities, and make the most out of them. Ensuring a certain level of good health for all helps avoiding the persistence of degrading inequalities.[718] In this sense, as we explained in our critique of Rawls' difference principle, allowing some individuals to focus on their own preferences while denying positive duties to fulfil others' most basic needs is not morally justifiable.

Although the broad language of the Covenant does not clearly establish specific actions states must take to fulfill the right to health as a means to ensure equality of opportunities, this right can give rise to different positive duties. For example, the right to health can imply a duty to establish mechanisms to prevent deprivation and encourage the provision of preventive and therapeutic health products by third parties (regulating selling costs, establishing incentives to encourage the development of health products and services for specific needs, etc.). It can also include a duty to provide available health products and services to those in need with the help the transfer of resources at affordable cost and it can require states to review their research priorities to take objectively serious health needs of poorer countries into consideration.[719] This latter duty to aid is often critical as it arises after some have failed in their duty to protect and to avoid harm. Many indicators can be used to assess the fulfilment of positive duties vis-à-vis the right to health.

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[717] R. Nozick, *supra* note 71; C. Wellman, *An Approach to Rights: Studies in the Philosophy of Law and Morals* (Boston: Kluwer Publishers, 1997) at 112-114; Cranston, *What are Human Rights?* (New York: Tapling Publishing Co, 1973).
[718] H. Shue, *Basic Rights*, *supra* note 245, c.5, at 111.
[719] A. Attaran, "Human Rights and Biomedical Research Funding for the Developing World: Covering State Obligations Under the Right to Health" (1999) 4:1 *Health Hum Rights* 26.

Robertson suggests five types of resources relevant to measuring human rights compliance: human, technological, informational, natural, and financial.[720] States are thus free to decide which resources they assess and in what proportion to fulfill specific human rights; they just have to be sufficient and diversified enough to protect individuals. This evaluation is undertaken by the Committee on ESCR, which has, for example, compared some states' military and health expenses to measure their priorities and resulting compliance with the right to health.[721]

Another issue with positive duties to implement socio-economic rights relates to the separation of powers and respective roles of the legislative, executive, and judiciary branches. Some view these as completely independent and consider that only the executive can initiate changes in the law to better comply with welfare human rights.[722] For these people, governments have a duty to identify priorities and take action to bring the object of the rights to the rights-holders; the judiciary only become involved afterwards, to enforce already-established mechanisms.[723] This vision appears too limited as it does not take the potential creative role the courts can play in the reinvention and protection of socio-economic rights. Indeed, judicial review can be seen as a crucial tool for ensuring the development of the normative content of socio-economic rights and their full and dynamic realisation.[724]

Until now, very few courts have judicially reviewed the right to health, but there have been a handful of cases. For example, in a matter involving the Yanomami Indians, the *Inter-American Commission on Human Rights* (IACHR) concluded that the right to health enshrined in the American Declaration had been violated by the

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[720] R. Robertson, "Measuring State Compliance with the Obligation to Devote the Maximum Available Resources to Realising Economic Social and Cultural Rights" (1994) 16 *Human Rights Quarterly* 693, at 703-713; A Attaran, *supra* note 719.

[721] The Committee has done this in the past for Chile, UN doc. E/C.12/1988/SR.13, par. 12 and Noth Koream UN doc, E/C.12/1987/SR 22, p. 5 and 17; see also, B. Toebes, *supra* note 583.

[722] For example, see R. Calland & M. Taylor, "Parliament and the Socio-Economic Imperative - What is the Role of the National Legislature?" (Nov. 1997) 1 *Law, Democracy and Development* 193; S. Liebenberg, "Socio-Economic Rights" in M. Chaskalson *et al.*, eds, *Constitutional Law of South Africa* (Cape Town: Juta & Co., 1998) c. 41.

[723] N. Haysom, "Constitutionalism, Majoritarian Democracy and Socio-Economic Rights" (1992) 8 *SAJHR* 451, at 456.

[724] S *v Makwarryane and another* 1995 (3) SA 391 (CC), 1995 (6) BCLR 665 (CC), at par. 325.

Government of Brazil. The Commission stated that in refraining from taking appropriate actions to prevent mining and other harmful utilisation of the rainforest, authorities failed to protect their people's health and cultural traditions.[725] In reaction to this decision, Brazil modified its constitution and established the Yanomami Reserve to ensure solid protection of the community, their lands, and their health.[726] Also, in 1997, the Supreme Court of Canada broadly interpreted the right to equality, a traditional civil right, expanding its protection to include an equal right to resources required to take advantage of public health services offered to everyone, without discrimination in *Eldridge* v. *British Columbia (Attorney General)*.[727] In so doing, the Court used civil and political rights to indirectly protect the socio-economic right to health. More recently, in *Chaoulli* v. *Québec (Attorney General)*[728], the Supreme Court of Canada ruled that the Québec province's ban on private health insurance for services covered by the public universal system violates the right to life and to security protected by the Québec Charter. Indeed, it was decided, by a majority of four judges against three, that the right to life, liberty and security of persons protected by the Québec charter also includes a right to health care financed by the public or the private sector.[729] However, there seems to be an unresolved tension between the individual and the collective aspects of Canadians' right to health. Indeed, many are worried that this decision could end up threatening the integrity of the Canadian public health care system while encouraging different level of socio-economic rights enforcement based on ability to pay and to qualify for

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[725] IACHR Res. No. 12/85, Case 7615 (Yanomami Indians v. Brazil), Mar. 5, 1985, reprinted in Annual Report of the IACHR 1984-85, OEA/Ser.L/V/II.83, Doc. 14, corr. 1, at 33, Oct. 1, 1985 quoted in B Toebes, *supra* note 583.

[726] S. J. Anaya & R.A. Williams, Jr., "The Protection of Indigenous Peoples' Rights over Lands and Natural Resources Under the Inter-American Human Rights System" (Spring 2001) 14 *Harvard Human Right Journal* 33

[727] [1997] 3 S.C.R. 624, 1997 CanLII 327 (S.C.C.) In this case, the Court held that the failure of the BC authorities to provide sign language interpretation to deaf patients violated the equality rights of disabled people to fully benefit from the medicare system.

[728] [2005] 1 SRC 791.

[729] In the later case, the private services can only be performed by "non participating" physicians who chose to work only in the private system and who represent less than 1% of all Québec's physicians. This controversial judgment has been interpreted restrictively by many experts who argue that it only slightly opens the door the private insurance in health while preserving the clear division between public and private health professionals. For an analysis of this controversial ruling, see C. M. Flood & T. Sullivan, "Supreme Disagreement: The Highest Court Affirms an Empty Right" (July 19, 2005) 173:2 *CJMA* 142; H. Brun et al., "Privatisation des Soins de Santé au Québec- Il n'y a pas d'Ordre de la Cour Suprême" *Le Devoir*, Thursday, November 17th, 2006.

private insurance.[730] It will be interesting to follow the actions that the Québec government will take to comply with this ruling and the longer term implication it will have on the future of Canadians' right to health and more generally, of public health care in Canada.

Negative duties

Limited negative duties emerge in reaction to the vagueness of human rights and associated unspecified obligations. Pogge is one of the main advocates of the view that human rights give rise to negative duties not to harm others through the imposition of unfair institutional orders on them.[731] For Pogge, institutional orders should be evaluated according to the effect they have on the fulfilment of human rights. This is compatible with art. 28 of the UDHR and with Darwin's statement that, "if the misery of our poor be caused not by laws of nature but by our own institutions, great is our sin."[732] Pogge therefore supports an institutional conception of rights that sanctions claims against institutions only, as opposed to an *interactional* conception that would accept claims against anyone capable of satisfying the rights.[733]

As discussed previously in section 4.2.1.2 under our assessment of the global order, current global institutional arrangements could be seen as a massive, collective infringement of human rights, especially socio-economic rights, by many of the

[730]T. Caulfield, "Chaoulli v. Québec (Attorney General): Supreme Court of Canada Deals a Blow to Publicly Funded Health Care" (2006) *Health Law Perspectives*; F. Béland, "The Supreme Court Missed a Good Opportunity" (June 2005) *Law and Governance*; A Maioni & C. Manfredi, "When The Charter Trumps Health Care — A Collision Of Canadian Icons" (September 2005) *Policy Options* 52.

[731] Pogge deliberately refuses to take a stand on positive duties, even if he does say that he agrees with indirect positive duties to aid when people's basic human rights are at risk. He remains uncommitted to the issue of positive duties without denying them, and focusses only on negative duties. T.W. Pogge, "Severe Poverty as a Violation of Negative Duties", *supra* note 278, at 65-66.

[732] Cited in S. J. Gould, "The Moral State of Tahiti- and of Darwin" (1991) 10 *Natural History* 12, at 19 and in T.W. Pogge, *supra* note 615.

[733] T. Pogge, "Cosmopolitanism and Sovereignty" (October 1992) 103 *Ethics* 49, at 50-51; T.Pogge "How Should Human Rights be Conceived?" (1995) *Jahrbuch fur Recht und Ethik* 3; C.R. Beitz, *supra* note 55.

world's most powerful and affluent agents.[734] Indeed, governments of the most developed countries and important multinational corporations are the main artisans behind the functioning of the global order. This order, through numerous international treaties and agreements on trade, labour, intellectual property protection and investment, shapes most international economic transactions and contributes to the production of serious socio-economic inequalities and human rights violations.[735] For Pogge, the governments of affluent countries, and the citizens who elect and empower them, share a responsibility for human rights violations that unjustly disadvantage less affluent countries and their people, when these disadvantages are foreseeable and avoidable with practicable reforms. Instead of arguing that human rights encourage individualism and promote western values, the proponents of negative duties consider associated socio-economic human rights as individual moral claims on coercive institutions and on those involved in upholding them. Therefore, even if they do not have an individual positive duty to fulfill everyone else's basic rights, the emphasis on duties should encourage individuals to behave properly toward others and exert pressure on their representatives to respect their national and international duties.[736]

The negative duty not to impose and uphold an unfair institutional order can be seen as universal. It generates limited and definite positive obligations on the part of states and, sometimes on citizens. States, empowered by citizens, must create effective institutions (or support and preserve existing ones), undertake reforms if those institutions are not adequate, and compensate those whose human rights are not fulfilled under the existing global order. Compared to sporadic and voluntary donations from wealthy countries, structural and institutional reforms would offer long-term consistency and fairer cost division among countries. Such reform should be undertaken to bring the global scheme to a level of justice where people could not be deprived of their right to health and where prevention and screening of serious medical conditions would be undertaken to meet a threshold of

[734] T. Pogge, *Recognized and Violated by International Law*, *supra*, note 1.
[735] *Ibid.*
[736] H. Shue, *Basic Rights*, *supra* note 245, at. 131; C. Brown, *supra* note 61.

basic health needs—all in the broader framework of an ideal of equality of opportunities. To this end, respect for state sovereignty should be conditional on those states meeting minimal compliance with the protection of universal basic rights.[737] We will come back to the main obstacles to the efficient implementation of such negative duties in more length in the next section of this chapter, when we analyse the conceptualisation of human rights within the broader reality of the market.

This subsection has highlighted the imperfect nature of the duty and responsibility components of the human rights discourse. We have seen that, although positive and negative duties exist and can be allocated to different agents, they often are difficult to comply with and to enforce on states through judicial processes. For example, a requirement to meet extraterritorial obligations related to human rights to health can infringe on state sovereignty (both on the giving and receiving end); achieving a balance between human rights protection and respect for state sovereignty can be somewhat challenging.[738] This corresponds with the limited duty to fulfill (provide and promote) the legal right to health, that only requires states to undertake specific acts (reject discrimination and enforce minimum core obligations)[739] to realise the right in question, to the maximum of their available resources. However, as mentioned earlier, even when positive duties have not yet been allocated to specific persons or agencies, and even when rights are hard to realise, they can still exist and have great influence on how things evolve.[740] In other words, the imperfections of the duties discussed in this section should not discredit the whole human rights discourse but are certainly symptomatic of a greater malaise.

In this last section, we discussed issues of access to health and distributive justice in connection with socio-economic human rights and related duties. We realised that

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[737] H. Shue, *Basic Rights*, *supra* note 245, afterwords, at 158 et ss.
[738] S.P. Marks, *The Human Rights Framework for Development: Five Approaches*, FXB Working Paper Series no. 18, 2003, online on the website of the FXB Center <http://www.hsph.harvard.edu/fxbcenter/FXBC_WP18--Marks.pdf> (accessed May 30th, 2006).
[739] Maatricht Guidelines, *supra* note 585, guidelines 8, 9 and 10.
[740] For an inspiring discussion on this point, see A. Sen, "Consequential Evaluation and Practical Reason" (2000) 17:9 *The Journal of Philosophy* 478, at 495-498.

although the system in place elevates health to the status of a universal value in international law and is supposedly designed and aimed at enforcing responsibilities in relation to this goal, things do not exactly work this way in practice. This is exemplified by the fact that the most deprived, health-wise, are neither protected nor taken in charge under this system; other, more powerful and affluent agents take control of the distribution of health and health-related goods and services, without having to acknowledge and respect the universal importance of health.

This clearly demonstrates the importance of taking our analysis one step further and undertaking a deeper evaluation of the complex global political and economic context within which the system of socio-economic human rights evolves. As Shue states, "[k]nowing how to protect the right against violation, or to restore the right after violation, depends as well on historical and empirical understanding of the relevant social, economic, political, legal, and psychological factors."[741] This will be the focus of the last section of this chapter.

4.2.3. The conceptualisation of human rights within the reality of the market

> *Rights can never be higher than the economic structure of society and its cultural development conditioned thereby.*[742]

With this last section, we aim to present a more complete and balanced understanding of the system reviewed in the previous sections of this chapter. Outwardly, the human rights system seems to consider health as a universal value, asking for equal treatment of every human being in accordance with a cosmopolitan approach, and for the provision of an adequate amount of health care to protect equality of opportunities, regardless of socio-economic factors. However, in reality, fulfillment of positive and

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[741] H. Shue, *Basic Rights*, *supra* note 245, at 158.
[742] K. Marx & F. Engels, *Selected Works Vol. Three, 1875-1895* (Moscow: Foreign Languages Publishing House, 1970) at 19.

negative duties to secure a basic level of health for all has not occured, raising doubts about true universality of human rights principles. There seem to be a gap between acknowledging such universal values in the form of human rights and giving them a real voice and impact within the economic and political reality of the world. We touched on some of those issues when we analysed the global order under which human rights develop, but here we go one step further and question the real nature of human rights—the interests lying at the basis of the system, both in term of human rights content and implementation.

4.2.3.1. How is the institution of human rights shaped by the market and the powers in place?

Different modes of social organisation exist, and the most important and influential in the current world order is the market. States which adopt an ideology that considers the market as the best way to distribute goods and services accept to limit their intervention and to prioritise privatisation and economic development.[743] For Evans, the ideology of the market refers to a set of normative relationships that exist without coercion, with a global reach, supported by discourses of truth, and widely accepted as "common sense."[744] Within this conceptualisation, rights like liberty, property, and free markets, which best contribute to secure important production and exchange, are often preferred to other more demanding and less economically-rewarding welfare rights.[745]

Different theoretical and practical arguments in favour of free markets exist and have been put forward in the literature. Those who endorse such a vision of the world typically maintain that minimally regulated international markets remain the best instruments for fostering innovation, technological development, individual freedom,

[743] S. Gill, "Market Civilisation and Disciplinary Neoliberalism" (1995) 24:3 *Millennium* 412.
[744] T. Evans, *supra* note 595, at 1055.
[745] British Medical Association, *The Medical Profession and Human Rights: Handbook for a Changing Agenda* (London: Zed Books, 2001), at 24-26; House of Commons Foreign Affairs Committee, *Report on UK Ethical Foreign Policy*, HC100 4, 1997; T. Evans, *ibid.*, at 1057.

democracy and optimal distribution of resources worldwide.[746] A deep analysis of this position is beyond the scope of this dissertation. However, the following sections demonstrate why one cannot rely on the market to attain global distributive justice in health and that, in fact, the market frequently leads to economic and health inequalities.

The role of globalisation

The key barrier to the realisation of socio-economic rights like the right to health is related to persistent gross economic inequalities observed within and between nations.[747] This is exemplified by the fact that globalisation is often not managed in the interest of developing countries and their people. Indeed, although globalisation has been beneficial for some countries which have chosen to gradually liberalise trade, most developing countries do not choose their own terms of participation, but have to comply with what the most powerful dictate. Due to the lack of democratic supervision at the global level, and because of the type of market pursued by the most powerful agents, strong economic interests tend to be prioritised, and agents with different priorities tend to be excluded, with negative consequences for their long-term interests.[748] The neo-liberal ideology promoted by developed countries in their international negotiations demands that markets be driven by efficiency, which means that "concerns about any resulting poverty or inequality are externalised from the

[746] However, their views as to what qualifies as a minimally regulated market do not converge. For example, partisans of the libertarian school favour a strong non-interventionist policy and reject egalitarian redistribution of wealth whereas other economists would recommend some form of intervention through national and international regulation in certain cases. For more on different schools of thoughts related to the market theory see: M. Friedman, *Capitalism and Freedom* (Chicago: University of Chicago Press, 1962); A. Smith, *Adam Smith's Wealth of Nations: a New and Condensed Edition* (New York: T.Y. Crowell, 1904); J. E. Stiglitz & L. Squire, "International Development: Is It Possible?" (Spring 1998) 11 *Foreign Policy* 138; T.H. Engelhardt Jr, *The Foundations of Bioethics* (New York: Oxford University Press, 1986); R. Nozick, *supra* note 71.

[747] A. Eide, *supra* note 576, at 555.

[748] A good example is taken from the Uruguay Round negotiations which, as discussed at length in chapter III, were undertaken and conducted on unfair terms, characterized by gross inequalities in bargaining powers, with an agenda that reflected those inequalities. For a more complete discussion on this, see J. E. Stiglitz & A. Charlton, *Fair Trade for All, How Trade can Promote Development* (New York: Oxford University Press, 2005); J. E., *Globalisation and its Discontents*, *supra* note 152; see also A. Anghie, *supra* note 669, at 274.

debate over markets"[749] In such a context, distributive justice in health is not a priority at all. Indeed, providing appropriate goods and services to meet a threshold of basic health ends up being dealt with as a matter of sporadic assistance or charity, constrained by other requests and available resources. Socio-economic rights are therefore prevented from realising social wefare improvement, and can easily become empty provisions without effect.[750]

Some advocates of globalisation believe that human rights can only be realised through mechanisms of globalisation, as they both imply the same common language and associations among individuals all over the world.[751] Although critical of some of the possible negative effects of globalisation, international bodies have refrained from condemning it altogether.[752] However, globalisation has been heavily criticised by many organised social groups and academics from various disciplines,[753] who have nevertheless not succeeded in challenging and eradicating the impact that these forces have on the realisation of human rights. Market efficiency measured through protection of private property, contract enforcement, and a stable investment environment remains a priority and is the main factor used to assess policy initiatives.[754] This is in part due to the power of the strong financial alliance Bhagwati refers to as the "Wall Street Treasury Complex," which represents a conglomeration of international financial institutions (IFIs), the US Treasury and State Departments, and Wall Street and which greatly influences globalisation with their strategic actions, confound their interests with the interests of the whole world, and

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[749] K. Rittich, "Transformed Pursuits: The Quest for Equality in Globalized Markets" (Spring 2002) 13 *Harv. Hum. Rts. J.* 231, at 257.

[750] *Ibid.*

[751] On this point, see: M. A. Warner, "Globalization and Human Rights: An Economic Model" (1999) 25 *Brook. J. Int'l L.* 99; see also W. H. Meyer, "Human Rights and MNCs: Theory Versus Quantitative Analysis" (1996) 18 *Human Right Quarterly* 368; M. Pendleton, "A New Human Right, The Right to Globalization" (1999) 22 *Fordham Int'l L.J.* 2052.

[752] A good example of this is art. 14 of the 1995 *Copenhagen Declaration on Social Development*, which notes some worries about globalization, but at the same time also mentions its potential positive effects on economic growth and progress in developing countries.

[753] R. Wade, "Japan, the World Bank and the Art of Paradigm Maintenance: The East Asian Miracle in Political Perspective" (1996) 217 *New Left Rev.* 3; J. Stiglitz, *supra* note 152.

[754] K. Rittich, "The Future of Law and Development" *supra* note 667; K. Rittich, Recharacterizing Restructuring: Law, Distribution and Gender in Market Reform (The Hague: Kluwer Law International, 2002).

consequently threaten the substance of human rights.[755] Baxi is clearly addressing this when she says:

> I believe that the paradigm of the Universal Declaration of Human Rights is being steadily supplanted by a trade-related, market-friendly, human rights paradigm. This new paradigm reverses the notion that universal human rights are designed for the dignity and well being of human beings and insists, instead, upon the promotion and protection of the collective rights of global capital in ways that "justify" corporate well-being and dignity over that of human persons.[756]

Powerful market actors and their impact on human rights

As mentioned earlier, international human rights implementation is almost exclusively national due to the relatively low priority that powerful countries award to other nations' human rights issues in their foreign policy agendas.[757] This being said, even when they make domestic moves in relation to human rights, states often find themselves driven by a larger agenda: helping and supporting the global economy built on the market ideology.[758] This means that the real importance given to the universal values enshrined in international human rights treaties mainly depends on their compatibility with the overall purposes of the market. In other words, human rights end up being defined by powerful agents who often argue for a narrow conception, often only including civil and political human rights.[759] This way, the fact that socio-economic human rights violations are often caused by powerful market forces is not addressed in the dominant legal human rights discourse; this failure takes our attention away from the universal values enshrined in legal human

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[755] J. Bhagwati, "The Capital Myth: The Difference Between Trade in Widgets and Dollars" (May-June 1998) 77:3 *Foreign Aff.* 7, at 10-12; A. Anghie, *supra* note 669.
[756] U. Baxi, "Voices of Suffering and the Future of Human Rights" (1998) 8 *Transnat'l L. & Contemp. Probs.* 125, at 163; cited in A. Anghie, *ibid.*, at 249; R. Bauer & D.A. Bell, eds., *The East Asian Challenge for Human Rights* (Canmbridge: Cambridge University Press, 1999) 241.
[757] C. Brown, *supra* note 602.
[758] R.W. Cox,"Civil Society at the Turn of the Millennium: Prospects for an Alternative World Order" (1999) 25 *Rev. Int'l Stud.* 3.
[759] B. S. Chimni, *supra* note 664, at 10.

rights in an insidious way.[760] This can bring people to wrongly believe in a just world where human rights are valued and respected when, in reality, so many suffer from serious deprivation at so many levels.[761]

Another aspect of the contemporary world order is the tremendous power of transnational corporations, which now affects every state's ability to control its socio-economic agenda, even within its own borders.[762] States face strong pressure to adopt efficiency as their top priority and this ends up affecting different sectors of their activity, such as labour and trade. As Kothari puts it, "[c]apitalism is entering a new phase and economic processes are becoming autonomous of political authority."[763] There is also a growing presence of private corporations within the UN structure. The *Global Compact*, an initiative of Kofi Annan that encourages responsible corporate actors to get involved in finding solutions to the challenges of globalisation, illustrates this.[764] Moreover, increasing corporate contribution to UN financing is reflected in the management philosophy adopted by the organisation and, consequently, "reduces the possibility of UN forums being at the center of collective action by third world states to constrain these giant private actors."[765] Since transnational corporations can exert a powerful influence on the socio-economic framework of states and of the global order, they can have positive and negative effects on the realisation of human rights.[766] However, most powerful transnational

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[760] T. Evans, *supra* note 595, at 1068; T. Evans, *supra* note 605.
[761] M. J. Lerner, *The Belief in a Just World: A Fundamental Delusion* (New York: Plenum Press, 1980).
[762] T. Freidman, *The Lexus and the Olive Tree* (New York: Farrar Straus Giroux, 1999).
[763] R. Kothari, "Globalization: A World Adrift" (1997) 22 *Alternatives* 227, at 228.
[764] To learn more about the Global Compact, its functioning and its progress, refer to this website: <http://www.unglobalcompact.org/> (accessed June 2nd, 2006).
[765] B. S. Chimni, *supra* note 664, at 15; see also J. Bennett, "Multinational Corporations, Social Responsibility and Conflict" (2002) 55 *Journal of International Affairs* 403; K. Lee, D. Humphreys & M. Pugh, "Privatization in the United Nations System; Patterns of Influence in Three Intergovernmental Organizations" (1997) 11 *Global Society* 339.
[766] For example, strong enforcement of corporate genetic patents can increase the price of essential therapeutic products through high royalty payments, and therefore prevent compliance with art. 12 and 15 (1) b) of the CESCR, which aim to protect the right to health and to access the benefits of science. On the negative effect of transnational corporationss on human rights, see S. R. Ratner, "Corporations and Human Rights: A Theory of Legal Responsibility" (2001) 111 *Yale L. J.* 461; on potential positive effects of TNCs on developing countries refer to W. H. Meyer, *Human Rights And International Political Economy In Third World Nations: Multinational Corporations, Foreign Aid, And Repression* (Westport: Praeger, 1998).

corporations have consistently refused to take any responsibility for the negative effect they may have on human rights. This is why some argue that they should, like states, be held accountable for human rights abuses not only through voluntary codes of conduct, but also through national and international regulations.[767] Some have proposed to establish, through international consensus, a governing body to act as a kind of international court to examine corporate actions.[768] However, many are sceptical about the practicability of such a project, at least as long as real power remains in the hands of a few influential corporations. They suggest focussing instead on civil actions and media exposure to encourage public stigmatisation of private economic actors, when required.[769] Indeed, the expanding social movement can make power visible while playing an important role in questioning power structures in a form of "globalisation from below."[770] As Stammer notes, "[t]here is a possibility that under contemporary conditions of globalisation—social movements might become more effective agents of global socio-cultural change in respect of human rights than existing nation-states and emerging supranational institutional structures."[771]

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[767] G. Meintjes, "An International Human Rights Perspective on Corporate Codes" in O.F Williams, ed., *Global Codes of Conduct: An Idea Whose Time has Come* (Indiana: University of Notre Dame Press, 2000) 83; S. R. Ratner, "Corporations and Human Rights: A Theory of Legal Responsibility" (2001) 111 *Yale L. J.* 461; M. Monshipouri, C.E. Welch & E.T. Kennedy, *supra* note 654; A. Eide, *supra* note 576.

[768] K. T. Jackson, "A Cosmopolitan Court for Transnational Corporate Wrongdoing: Why its Time has Come", (May 1998) *J. Bus Ethics* 758; see also Monshipouri, C.E. Welch & E.T. Kennedy, *supra* note 654.

[769] M. Winston, "NGO Strategies for Promoting Corporate Social Responsibility" (2002) 16 *Ethics & Int'l Aff.* 71; N. Stammer, *supra* note 600.

[770] This is a fascinating topic that requires much more attention, and which is unfortunately beyond the scope of our dissertation. To learn more about the practical and political role and influence of social movements, refer to A. Melucci, *Nomads of the Present: Social Movements and Individual Needs in Contemporary Society* (Philadelphia : Temple University Press, 1989) at 76; A. F. Chadwick, "Transnational Social Movements, World Politics and Global Governance" in J. Smith, C. Chatfield & R. Pugnucco, *Transnational Social Movements and Global Politics: Solidarity Beyond the State* (Syracuse, NY: Syracuse University Press, 1997); J.L. Richardson, "Contending Liberalisms: Past and Present" (1997) 3 *Eur. J. of Int'l Rel.* 5; R. Falk, "The Global Promise of Social Movements: Explorations at the Edge of Time" (1987) 12 *Alternatives* 173; R. Falk, "Social Movements and World Politics" (Winter 1997) 23:3 *Millenium* (Special Issue).

[771] N. Stammer, *supra* note 600.

The most affluent and powerful agents (countries, private corporations, and international economic organisations) often argue that they contribute to protecting and fostering socio-economic rights in developing countries through their development and economic growth initiatives.[772] However, this is not always true. In fact, most loans from international financial institutions are targeted to specific projects often unrelated to basic subsistence needs, health care, and education; when they are, these loans are part of "adjustment lending processes," which frequently target decentralising and privatising reform initiatives.[773] These projects have greatly reduced developing nations' capacity to establish social programs compatible with their level of development.[774] Moreover, in focussing on their main creditors' short-term demands and interests, international financial institutions do not pay enough attention to the importance and role of investment in meeting basic health needs to improving many other sectors of economic activity, like employment.[775] Therefore, international financial institutions often end up acting like charitable lending

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[772] In terms of industrialisation and economic growth.

[773] Indeed, many argue that structural adjustment programs established by international financial institutions have had negative effects on states' abilities to meet their human rights obligations. For more on this argument, refer to: M. Chossudovsky, The Globalisation of Poverty: Impacts of IMF and World Bank Reforms (London: Zed Books, 1997); M. Chossudovsky, The Globalization of Poverty and the New World Order, 2nd ed, (Shanty Bay: Global Outlook, 2003); E. Carrasco & M. A. Kose, "Income Distribution and the Bretton-Woods Institutions: Promoting an Enabling Environment for Social Development" (1996) 6 Transnat'l L. & Contemp. Probs. 1; B. Sadasivam, "The Impact of Structural Adjustment on Women: A Governance and Human Rights Agenda" (1997) 19 *Human Rights Quarterly* 630; see also more generally A. Anghie, *supra* note 659, at 252; R. McCorquodale & R. Fairbrother, *supra* note 644; S.S. Akermark, "International Development Finance Institutions: The World Bank and the International Monetary Fund" in A. Eide et als., eds., Economic, Social and Cultural Rights: A Texbook, 2nd ed., (London: Maartinus Nijhoff, 2001), c. 28, 515; Y. Osinbajo & O. Ajayi, "Human Rights and Economic Development in Development Countries" (1994) 28 *Int'l Law* 727, at 731; M. Nzomo, "The Political Economy of the African Crisis: Gender Impacts and Responses" (1996) 51 *Int'l J.* 78; B. Sadasivam, "The Impact of Structural Adjustment on Women: A Governance and Human Rights Agenda" (1996) 19 *Human Rights Quarterly* 630; S.A. Agbacka, "Reclaiming Humanity: Economic, Social and Cultural Rights as the Cornerstone of African Human Rights" (Annual 2002) *5 Yale Human Rights and Development Law Journal* 177; A. E. Yamin, *supra* note 688.

[774] J. Braithwaite & P. Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000); J. Levinson, 'The International Financial System: A Flawed Architecture" (Winter/Spring 1999) 23:1 The Fletcher Forum on World Affairs 1; J. Dohnal, "Structural Adjustment Programs: A Violation of Rights" (1994) 1 *Austl. J. Hum. Rts.* 57, at 82;

[775] Indeed, promoting employment is one of the IMF's priorities. Articles of Agreement of the International Monetary Fund, Dec. 27, 1945, art. 1, para. 3, 2 U.N.T.S. 39 on the importance of maintaining high levels of employment.

organisations which have great powers of reform but do not necessarily use them to invest in nations' sustainable growth. They can consequently fail to acknowledge (and thereby violate) some of the most basic human rights of the citizens of borrowing nations.[776] This engenders and amplifies the horrible situation prevailing in many developing countries where children and young adults die every day of preventable and curable diseases partially associated with a tremendous debt repayment burden and a critical lack of public spending on health.[777]

Also, if we talk about private investors, given their mode of operation and their need for quick results, their notion of "economic growth" will not necessarily result in needed long-term infrastructure investment, the promotion of employment and worker safety, initiatives that ensure environmental protection, or investments that truly help the citizenry and contribute in building their economy.[778] The initiatives supported by these actors, even if they objectively improve a state's circumstances with certain economic measures, will most often increase inequities and poverty among the vulnerable.

This clearly demonstrates that economic growth fostered by powerful national, international, and transnational agents, and often only targeted at improving macroeconomic variables, cannot automatically be associated with the realisation of

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[776] This problem is best illustrated by what happened in Latin America in recent years. While those nations experienced rapid growth at the beginning of the 1990s with IMF assistance, today it appears that this mainly represented a "catching up" on the IMF's bad management during the 1980s debt crisis, and was also not sustainable in that it was too risky for countries, like Argentina, which was still in too delicate a position to handle it. For more on this, refer to J. E. Stiglitz, *Globalisation and its Discontents, supra* note 152; see also more generally on ESCR violations: J. Oloka-Onyango, "Beyond the Rhetoric: Reinvigorating the Struggle for Economic and Social Rights in Africa" (1995) 26 *Cal. W. Int'l L.J.* 1, at 20-26; A. Escobar & S.E. Alvarez, *Three Making of Social Movement in Latin America: Identity, Strategy and Democracy* (New York: HarperCollins, 1992) at 53-56.

[777] Indeed, in Africa, many countries have to spend four times more money on debt repayment than they do on education and health care for their people. For more discussion and statistics on this, refer to A. Anghie, *supra* note 669, at 257-258; D. Ransom, "The Dictatorship of Debt" (Oct. 1999) *World Press Rev* 6; P. Engberg-Pedersen et al., *Limits of Adjustment in Africa : The Effects of Economic Liberalization, 1986-94* (Copenhagen: Centre for Development Research, 1996); see also Secretary-General Pursuant to Commission on Human Right Resolution 1989/45, *Question of the Realization of the Right to Development: Global Consultation on the Realization of the Right to Development as a Human Right*, Geneva, 1990, U.N. Doc. E/CN.4/1990/9/Rev.1.

[778] UNDP, *Human Development Report 1995*; R. McCorquodale & R. Fairbrother, *supra* note 644.

socio-economic rights like the right to health.[779] Economic growth is too rarely evaluated in terms of capability and enhancement of human choices.[780] As a result of intense pressure from global civil society, international financial institutions have begun to approach these issues differently in promoting the social dimension of development for its positive effects on economic growth.[781] However, even if welfare goals are acknowledged, their reach is considerably restrained as they are defined within "market promoting parameters" and ranked accordingly; equity and justice are important as long as they contribute to economic development. Liberalisation and privatisation remain the main tools for *securing* socio-economic rights.[782] The ICESCR notes, however, that those who signed and ratified the treaty have a human rights obligation of international assistance. Those states should therefore all work toward full implementation of the Covenant, even when they act through international bodies like the IMF or the World Bank.[783] Although every State party to the treaty has this obligation,[784] it can be challenging for smaller and less-affluent countries to get their ideas across in the process of implementing economic, social, and cultural rights, as international financial institutions use a voting scheme weighted by economic contribution, considerably advantaging the affluent northern nations.

In the current political world order, legal human rights end up directly supporting powers in place[785] while the UN represents the main actor engaged in the promotion

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[779] In that sense, the *Human Development Index* is a much more complete indication of real growth as it highlights differences between economic growth and welfare. See K. Rittich, *supra* note 749.
[780] M. Monshipouri, C.E. Welch & E.T. Kennedy, *supra* note 654, at 967.
[781] For example, see World Bank, *International Bank for Reconstruction and Development, Development and Human Rights: The Role of the World Bank*, Washington, 1998, at 2, online on the World Bank website: <http://www.worldbank.org/html/extdr/rights/hrtext.pdf> (accessed: June 4th, 2006); See also IMF, *Guidelines on Conditionality*, September 25, 2002, online on the website of IMF: <http://www.imf.org/External/np/pdr/cond/2002/eng/guid/092302.htm> (accessed June 4th, 2006) aiming at promoting sustainable development and growth; see also D. Forsythe, "The United Nations, Human Rights, and Development" (1997) 19 *Human Rights Quarterly* 334.
[782] F.J. Garcia, "The Universal Declaration of Human Rights at 50 and the Challenge of Global Markets: Trading Away the Human Rights Principle" (1999) 25 *Brook. J. Int'l L.* 51; A. Anghie, *supra* note 669, at 262.
[783] S.S. Akermark, *supra* note 773.
[784] As of May 8, 2006, 153 states had ratified the CESCR, online on the website of the OHCHR, <http://www.ohchr.org/english/countries/ratification/3.htm> (accessed May 17th, 2006).
[785] N. Stammers, *supra* note 600; J. Donnelly, *supra* note 575, at 29.

of this neo-liberal agenda on the global scene.[786] Although all human rights are meant to be equal and interrelated, in reality, respecting civil and political rights will be given absolute priority and socio-economic issues will only be addressed later, if they are addressed at all.[787] Alston notes that,

> In the world of globalization, a strong reaction against ... the denial of primary education or health care, can often require not only showing that the relevant practices run counter to human rights standards but also a demonstration that they are offensive to the imperatives of economic efficiency and the functioning of the free market... [I]n order to be validated, a purported human right must justify its contribution to a broader, market-based "vision" of a good society.[788]

This last section has demonstrated that although international human rights law (IHRL) theoretically aims precisely to address and eliminate socio-economic inequities, those same inequities are caused by more dominant forces of globalisation. In this system, the promotion of the market is the absolute goal even if it does not further welfare and justice as powerful agents prefer to stay in their advantageous position and not loose some of their power. Also, as we noted, the faults and weaknesses of the human rights system in terms of structure and functioning are not disconnected from the fact that the system has been put into place by those same forces, in this same neoliberal context. It is therefore safe to say that socio-economic rights enforcement has been directly influenced by the commercial and political agenda of the most powerful agents of the world.[789] As powerfully summarised by Doyal and Gough: "[i]n assuming the state to be the key actor safeguarding human rights, the West's approach ignores the very real inequalities between states stemming front the political/military domination of the big powers and the economic dominance of the central capitalist states, financial institutions and corporations within the world economic order."[790]

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[786] M. Mutua, *supra* note 645, at 35.
[787] *Ibid.*
[788] P. Alston, *supra* note 663, at 442.
[789] K. E. Smith & M.M. Light, *Ethics and Foreign Policy* (Cambridge: Cambridge University Press, 2001).
[790] L. Doyal & I. Gough, *supra* note 92.

Conclusion

In this chapter, we analysed the international human rights system to establish whether its underlying discourses, scope, structure, and functioning adequately account for the values encountered by our global distributive justice framework. Our principal goal was to assess the human rights system to determine if it can be useful in the redistribution of potential genetic research benefits, taking health needs into consideration.

After a brief introduction to international human rights, we presented and critiqued the legal and moral discourses at the basis of the human rights system. We realised that both discourses had strengths and weaknesses and identified another important facet of the human rights discourse: the political. Throughout the chapter, we evaluated the international human rights system with the benchmarks developed in our global distributive justice framework. We began with the international aspect of human rights, comparing the notion of universalism with other concepts in order to determine whether the system is truly oriented toward a cosmopolitan ideal where every human being is considered as a unit of moral concern. We realised that the universalistic character of human rights could sometimes be used as a way to keep real people's needs at a distance, and that it could be criticised for its strong western influences. Then, our assessment of the global context under which human rights evolve highlighted the strong capitalist roots that have led to a tolerance for economic disparity and injustice in health. With this section, we realised that the international human rights system, through its institutional structure and its politics, does not necessarily protect the cosmopolitan approach to the solidarity and true universalism needed to support global distributive justice and access initiatives related to health and genetics.

In the second section, we studied how the human rights system deals with the crucial need for health and genetic-research access in terms of rights, entitlements, and related duties. Our goal was to envision socio-economic rights

with our benchmarks of distributive justice. We specifically analysed the human right to health in terms of validity, content, and efficacy; this led us to discuss associated responsibilities to undertake distribution to facilitate access to health and genetic innovation. We realised that the concept of a "right" was not the most useful in securing real access to health for the most needy and deprived, and that associated duties where hard to comply with and to enforce.

The first two sections laid the foundation for a deeper political analysis of human rights in the third section. In this last section, we considered how human rights are conceptualised in order to understand the role of market forces in realising the human right to health and ascertained that the same inequalities that the human rights system is meant to address are generated by powerful agents who control the way this same system works. With this last section, we were brought to realise that the real problem is with the powerful interests lying at the core of existing political and economic institutions that undermine the realisation of important socio-economic rights.[791] Legal norms therefore create "entitlements" without considering the broader political and economic contexts created by the society's structures and institutions and which greatly influence decisions on resource allocation.[792] We should therefore work to alter these well-established economic forces if we are to rebuild trust in human rights, and create just distributive arrangements in the field of health and genetic technology. As Fidler states, "[j]ust as capitalism has become a truly global dynamic, the protection and promotion of health must also rise to the challenge of the new global order."[793]

There are considerable political challenges to any reliable and sustainable implementation of socio-economic rights like the right to health. Even if socio-economic rights are legally protected, the whole context in which this happens helps

[791] K. Hossain, "Globalisation and Human Rights: Clash of Universal Aspirations and Special Interests" in E. Burns, H. Weston & S. P Marks, eds., *The Future of International Human Rights* (Transnational Publishers: New York, 1999).
[792] K. Rittich, *supra* note 749, at 260; see also M. Sandel, *Liberalism and the Limits of Justice* (New York: Cambridge University Press, 1998); A. Petter, "Immaculate Deception: The Charter's Hidden Agenda" (1987) 45 *The Advocate* 857, at 860.
[793] D.P. Fidler, "International Law and Global Public Health" (1999) 48 *Kansas Law Review* 1.

safeguard capitalist market values, encourages passivity among the less affluent, and consequently discourages redistribution in health and other crucial sectors.[794] This highlights the enormous challenge of realising universal values of socio-economic equality and justice in a structure driven by a completely different agenda. This contributes to the lack of attention awarded to the ethical basis of socio-economic rights and to the false interdependence of human rights, all of which considerably weakens the practical implementation of the human right to health, as discussed earlier. In this sense, we have to agree with Kennedy when he says that the human rights movement can sometimes legitimate more injustice than it eliminates.[795]

This is what makes the system, as it currently operates, incompatible with our global distributive justice framework. If the human rights system were to meet our goal of global distributive justice in terms of global health, it would need to adopt an entirely different mode of functioning. This would require undertaking institutional reforms to realise socio-economic human rights and, more specifically, to allow genetic technology and health-related goods and services to reach those for whom it can do the most good. To this end, "[w]e should not just assume that past forms of power will stay the same and have the same implications, nor should we assume that new forms of power will not arise."[796] A fitting example of this is the growing social movement that has played an important role in generating pressure, resistance, and change in support of fairer resource distribution in various areas, sometimes in collaboration with international institutions and states.[797] However, to obtain effective and lasting results, they will need considerably more economic

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[794] M. Mandel, *The Charter of Rights & the Legalization of Politics in Canada* (Toronto: Thompson Educational Publishing, 1994).
[795] D. Kennedy, *supra* note 598, at 134.
[796] N. Stammer, *supra* note 600.
[797] One example of this is the social ecologist movement, which has been very aggressive and efficient in challenging power relations and structure for a better and increased protection of environment rights. For more on this example, refer to N. Stammer, *supra* note 600; see also B. Rajagopal, "From Resistance to Renewal: The Third World, Social Movements, and the Expansion of International Institutions" (2000) 41 *Harv. Int'l L.J.* 529, at 533 & 578; R. Khan, "The Anti-globalization Protests: Side-show of Global Governance, or Law-making on the Streets?" (2001) 61 *Heidelberg Journal of International Law* 323.

resources and much more political power to structure and rally a majority of people to their cause, particularly in the developing world.[798]

As more and more people come to realise that addressing the more pressing global health issues is critical for the creation of a more just and stable world order, developing efficient and enforceable human rights mechanisms appears to be one of the many important steps in the right direction. However, until there is a major change in human rights politics, we will not be able to conclude that it works to advance global distributive justice principles in terms of access to common health standards. This clearly highlights the important challenge associated with bridging the gap between the expression of universal values of cooperation, solidarity, and justice and the contingencies of modern world politics and economics.[799]

Our next and last chapter will focus on introducing practical examples to illustrate the intersection of intellectual property and human rights. The purpose of this chapter is to present examples of the practical impact that these two normative systems have had on global access to health benefits in developing countries. It will provide us with an opportunity to see how both schemes analysed in depth in the last two chapters have performed in dealing with serious, real-life issues of access to health.

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[798] B. S. Chimni, *supra* note 664.
[799] C. Brown, *supra* note 61; A. J. Langlois, "Human Rights: the Globalisation and Fragmentation of Moral Discourse", *supra* note 622.

Chapter V: Illustration of the Intersection of IP and Human Rights Law with Practical Examples Relating to Global Access to Health in Developing Countries

Introduction

As we have argued from the beginning of this dissertation, health is crucially important for every individual, regardless of his or her socio-economic situation and country of origin. Nevertheless, our analysis of two different normative frameworks (intellectual property and human rights) and of their political and economic contexts of application has demonstrated that, in practice, health is given a lower level of priority and importance than is appropriate within these frameworks. Indeed, we realised that although they have a potential to contribute to global health improvement, these systems instead work to prioritise efficiency, often to the detriment of distributive justice. Following our analysis of the relationship existing between access to health and genetics and the functioning of both, human rights and IP rights law, this chapter will study the interaction of those two systems. We will indeed rely on a combined perspective on IP and human right law to complement our analysis of chapter III and IV. To this end, we will present a few examples to demonstrate the practical effects of the junction of the IP and human right law regimes in scientific data-sharing, availability, and affordability of genetics research tools, products, and services in developing countries. This chapter will allow us to get a better sense of the tension that lies at the intersection of IP and human rights in health. Our analysis will bring us to conclude that, even when taken together and simultaneously applied to a same issue, the IP and human right systems do not, in most cases, work towards global distributive justice in health.

It is important to specify that this chapter will not provide an exhaustive analysis of the topic, but will instead use a small number of practical cases to illustrate how and when patents and socio-economic rights can be involved in the battle for global

access to health. We should remember that because of the advanced scientific infrastructure needed, the cost of development and the price of genetic technologies, genetics has been mainly developed and used in the most affluent countries, even though it has clear potential for the developing world. In other words, even if genetic technologies and related patents are mostly issued in developed countries for the moment, developing nations that wish to benefit from such technologies will often be affected by those exclusive rights. Two types of examples illustrate this situation: first, genetics-specific examples from the developed world; second, a direct example from the developing world, having taken place in a different but somewhat similar sector: the pharmaceutical drug industry. Following the presentation of these examples, we will conclude this chapter with a brief analysis of the intersection between IP and human rights in health.

5.1. Challenges in Availability and Affordability of Genetic Technologies

Access to genetic treatments and technologies can touch on many different practical issues and, for the purpose of this section, we will focus on the influence of patents and socio-economic rights on genetic research needed to further innovation and on access to genetic products and services to be provided to populations.[800] We will continue to refer to access in terms of availability and affordability of genetics.

5.1.1. Genetics research

As we know, the developments observed in genetics over the last few decades have arisen from important research progress in this fast-growing and promising field. The

[800] Another important aspect of availability of genetics research tools relates to data access stored in databases. These databases are often protected by copyrights that call for different access rules and mechanisms. While this is a fascinating and very contemporary issue, it is not our focus as we concentrate on patents. For more information on this particular topic, see: WHO, *Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries, supra* note 19.

availability of research tools has been critical to the development of genetic innovation. As we saw earlier, DNA, genes, gene sequences, cell lines, SNPs, and genetic knowledge can all be considered as "genetic research tools". Because of the propagation of gene patents, some have expressed fear that these exclusive rights will prevent researchers from undertaking research on specific parts of the human genome, for which too many exclusive rights have been granted.[801] This is especially important for large-scale research endeavours like the public branch of the human genome project, which was simultaneously piloted by a large group of experts around the world acting more as a community than as competitors racing against each other with the results we have come to know.

A number of existing intellectual property and human rights mechanisms exist to limit the potential negative effects of research tool patents. One example is the research exception clauses that appear to be permitted by TRIPS.[802] These clauses can allow researchers to make use of patented tools for very specific purposes without having to compensate the patent holder.[803] However, this mechanism is often

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[801] To this effect, Justice Michael Kirby commented on the changes that have operated in the scientific tradition, stating that it has been turned "from a discipline that was open, at least in the field of pure science, to one which is now significantly affected by intellectual property imperatives." M. Kirby, *supra* note 477, at. 11; see also T. Caulfield, "Sustainability and the Balancing of the Health Care" *supra* note 23 ; M.K. Cho, "Ethical and Legal Issues of the 21st Century" in Preparing for the Millennium: Laboratory Medicine in the 21st Century 2nd ed. (Washington, D.C.: AACC, 1998) 47; M. A. Heller & R. S. Eisenberg, *supra* note 358.

[802] Sections 30 and 8 of TRIPS presumably allow States to make use of flexibilities and provide restricted limitations on patent rights.

[803] Most European countries included research exception clauses of different scope and wording in their patent legislation. In the US, experimental-use exceptions have traditionally been very narrow, not covering most basic research, applying exclusively to research for amusement, to satisfy one's curiosity, or for philosophical investigation, as it appears from two important decisions: *Madey v. Duke University*, 307 F3d 1351 (Federal Circuit Court of Appeal 2002) and *Embrex, Inc.* v. *Service Engineering Corp.*, 216 F.3d 1343, 1349, 55 U.S.P.Q. 2d 1161, 1163 (Fed. Cir. 2000). However, the recent Supreme Court decision in *Merck KGAA* v. *Integra Lifesciences I, Inc.*, 2005 WL 1383624, *1, 8 (U.S. June 13, 2005) makes a distinction between the study of a "research tool" and the use of such a tool for research purposes. This indicates a possible broadening of research exceptions in the US (for more details on this case, see Y. Joly, *Integra v. Merck: The resurrection of the American research exemption?* (Montreal: Centre for Intellectual Property Policy, 2005). In Canada, art. 55.2.(1) of the *Canadian Patent Act* does not expressly create a research exemption but allows use of the existing common law exemption. It was recently suggested to include clear research exceptions to allow investigation into the properties of patented material, research aimed at improving upon the object of the patent, and research aimed at discovering new patentable elements, products, and technologies (CBAC, Rationalizing Patent Law in the Age of Biotechnology, Ottawa, September 2004, online on CBAC website,

subjected to important restrictions and remains very difficult and risky to employ because of the vagueness often associated with the uses permitted, particularly with genetics research.[804] This can cause uncertainty, which might push researchers to seek licences in any case.

An aspect of patent rights that can influence availability of research tools relates to the licensing strategy adopted by patent holders when they grant licenses. A license is a limited authorisation for use granted by the patent holder to licensees in exchange, in most cases, for some form of compensation. Licensees therefore become entitled to make use of the object of patents, but also have to respect the conditions established by the patent holder.[805] Depending on the conditions that the latter chooses to impose on his licensees (cost, type of license, length, conditions, etc.) it can affect further research.[806]

The scope of gene patents can also impact genetic research. In fact, as discussed in chapter III, there was, until recently, a tendency for patent holders–who are

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<http://cbac-cccb.ca/epic/internet/incbac cccb.nsf/vwapj/Rationalizing_Patent_Law_Final_E.pdf/$FILE/Rationalizing_Patent_Law_Final_E.pdf > (accessed May 29th, 2006) rec. 5; Ontario Ministry of Health and Long-Term Care Genetic, *Testing and Gene Patenting: Charting New Territory in Healthcare*, Toronto, 2002, online on the Ontario government website: <http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf> (accessed May 29th, 2006) at 40. Some developing nations like Brazil, India and China have also integrated a research exception clause in their patent legislation (*Brazilian Patent Law* 9.279 of 1997; *Indian Patents Act*, 1970, at s. 47 (3); *China Patent Law* 1982, amended in 1992, at s. 62).

[804] For example, it could be hard to determine if a research exception is meant to cover all research involving the patented invention, research only aimed at investigating the properties of the patented genetic material, and/or genetic research that is not meant to but might result in commercial products. M.A. Flores & C. Campbell, "Re-examining the Research Exemption" (2005) 23:5 *Nature Biotechnology* 659; M. Rimmer, "The Freedom to Tinker: Patent Law and Experimental Use" (2005) 15:2 *Expert Opinion* 167; E.R.Gold and A. Gallochat, "The European Directive: Past and Prologue" (2001) 7:3 *European Law Journal* 331, at 358; C. Correa, "Pro-Competitive Measures under TRIPS to Promote Technology Diffusion in Developing Countrie" in P. Drahos and R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 41.

[805] Countries can also intervene to regulate licensing practices with hard or soft law mechanisms. For an example of a recent initiative, see: National Institute of Health, "Best Practices for the Licensing of Genomic Inventions" (2005) 70 *Federal Register* 18413.

[806] For example, some licenses remain unavailable or very costly and can, in some cases, result in slowing down fundamental research or blocking any external research aimed at validating the inventor's results:J.F. Merz, "Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine" (1999) 45:3 *Clinical Chemistry* 324.

principally in affluent countries–to try to obtain broad patent rights over genes and gene-related processes and products[807], and for the courts to interpret those patent rights broadly.[808] Although applicants now tend to present much narrower claims and patent examiners have become more reluctant to award broad gene patents, the exclusive privileges they grant often end up covering elements, functions, and uses that were still unknown at the time of filing the patent claim.[809] In genetics, this means that a patent awarded on a gene involved in a particular disease could allow much control to the patent holder over all genetic research undertaken on this particular disease. There is, however, no evidence that gene patents have reduced the amount invested in research or created major hurdles for the use of existing research tools, except in the area of genetic diagnostics.[810]

From a human right perspective, the priority is to encourage the use of existing research tools, patented or not, and the easy exchange of information to facilitate crucial discoveries. This approach supports meaningful scientific innovation to further the needs of the most vulnerable and therefore "goes well beyond a simple

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[807] This is exactly what happened with the patent awarded on the gene coding for the CCR5 receptor more than 10 years ago when the standards were lower. Indeed, after the US Company Human Genome Sciences Inc. (HGS) had identified that CCR5 was a cell-surface receptor, it filed and obtained a US patent on the gene that coded for the CCR5 receptor, and on all its possible medical applications. Meanwhile, another research team discovered that CCR5 was also viral receptor and, most importantly, a key entry site for the HIV virus into the cell, something that was not known by HGS at the time of their filing in 1995. However, because of its initial very broad claim, HGS had exclusive rights over all medical uses of CCR5, including those discovered by others. In this specific example, HGS fortunately adopted a very permissive and reasonable licensing strategy that allowed numerous researchers to carry on with their research on CCR5 and HIV. For more on this case, see: UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights in Development Policy, supra* note 426; Nuffield Council on Bioethics, *The ethics of Patenting DNA: a Discussion Paper, supra* note 473.

[808] This tendency to provide broad judiciary interpretation of patents is well illustrated in the Canadian case *Schmeiser* v. *Monsanto Canada Inc* [2004] 1 S.C.R. 902, 2004 SCC 34. This matter took place in the field of agriculture biotechnology and concerns the interpretation of a patent claim on a genetically-modified gene integrated into canola seeds to make them resistant to herbicides. In its decision, the Canadian Supreme Court interpreted this claim on the modified gene very broadly by extending the scope of exclusive patent rights to whole plants. For more details on this case refer to: E.R. Gold & d. Castle, *supra* note 47.

[809] This appears from a study conducted in 2003-2004 in the US in which 1000 patent claims on human genes have been analysed and more than 1/3 where qualified as problematic due to written description and novelty issues. For a detail of this analysis, see: J. Paradise, L.B. Andrews & T. Holbrook, "Patents on Human Genes: an Analysis of Scope and Claims" (March 11, 2005) 307:5715 *Science* 1566.

[810] For more on this point, refer to discussion and references of note 438, chapter III.

economic calculus often governing intellectual property law."[811] Socio-economic rights are awarded with the purpose of improving human well-being and fostering the interests of society rather than encouraging private property rights over important resources and maximising economic benefits of a few wealthy agents in priority. Following this approach, research addressing health needs of people living in the poorest parts of the world should be encouraged and facilitated. A human rights solution might be to encourage the use of these tools in wealthy countries, where they can be exploited to their full potential for addressing the needs of the less affluent until the less affluent countries are able to act on their own behalf. This solution would represent cooperation with the most disadvantaged people, as required by international law.[812]

However, apart from a few recent large scale international initiatives to address global health crisis, very little investment is being made in R&D for the special needs of patients from the developing world.[813] On the private front, biotechnology and pharmaceutical companies almost always prefer to invest in research dealing with health conditions that represent a lucrative market, like heart disease, obesity, impotence, etc.[814] On the public front, although it would be quite simple to establish research programs and directives to this end, most states are passive and seem to adopt national public research funding policies that focus on their national health priorities and do not take their international human rights commitments and

[811] A. R. Chapman, "Approaching intellectual property as a human right: obligations related to Article 15 (1)(c)" (July-Sept 2001) 35:3 *Copyright Bulletin* 4, at 13.

[812] art. 2 & 23 ICESCR; art. 55 & 56 *Charter of the United Nations*; art. 3 *Declaration on the Right to Development*.Even those who do not agree with this view because they argue it violates state sovereignty believe that exceptions should be accepted for health protection: L. Henkin, "Human Rights and State 'Sovereignty'' (1995) 25:1/2 *Georgia Journal of International and Comparative Law* 131; A. Attaran, *supra* note 719, at 33.

[813] The *Global Fund to fight AIDS, Tuberculosis and Malaria* and the *Drugs for Neglected Diseases Initiative*, both established in 2002, are two examples of those large scale initiatives that will be briefly addressed in the next section. On research on the needs of developing countries more generally, see: P. Cullet, *supra* note 449; Committee on Economic, Social and Cultural Rights, *General Comment no. 14, The Right to the Highest Attainable Standard of Health, supra* note 658; M. MacLean et al., "Making Malaria Research Bite" (1997) 3:1 *Nature Medicine* 14; J. Anderson et al., *Malaria Research: An Audit of International Activity* (London: The Wellcome Trust, 1996); A. Attaran, *supra* note 719, at 33.

[814] After all, they are for profit enterprises and still do not bear human rights responsibilities under international law. For more on this: A-M Tabor, "Recent Development: AIDS Crisis" (2001) 38 *Harv. J. on Legis.* 514.

obligations into account.[815] As clearly put by Attaran, "[i]f States are to begin to fulfill their ICESCR obligations and animate the moribund right to health, the work should begin in their science ministry."[816]

This brief discussion illustrates the importance that both IP rights and human rights can have on real access to genetic research by the most vulnerable, for the most vulnerable. It all depends on the perspective adopted by those who control genetic research endeavours, both private and public, much of which is strongly influenced by profit considerations, political motivations, and national and international regulatory obligations. We will now address the practical accessibility of existing genetic products and services.

5.1.2. Access to genetics products and services

Because of their economic role in allowing investors and inventors to recoup their R&D investment, patents do not encourage innovation in fields with very little potential for profits. In fact, as mentioned above, most existing genetics related products and services have been developed in the industrialised world to

[815] There are exceptions to this trend. Indeed, one of the unfortunately too-rare initiatives to this end has taken place here, at the Montréal Genome Center and the McGill Centre for Host Resistance, where cutting edge genomics technology has been used for global health purposes. In February 2003, Drs. Hudson, Mira, and Schurr from McGill, leading an international research team, published an important breakthrough in understanding the cause of leprosy. They had managed to isolate a segment of a chromosome that makes individuals susceptible to leprosy. As most Canadians would probably assume that leprosy had been eradicated, this study drew attention to the fact that, on a global scale, there are still 500 000 to 700 000 new cases each year, mainly in India and Brazil. The next steps of this project are to identify the genetic and molecular nature of the defect and develop a more effective vaccine. The Canadian part of the study was directly financed by Canadian and Québec funding agencies. This is a clear example of a public research initiative that has been established using our expertise and technology to address issues that have little to do with the Canadian population, but which remains essential for improving global health with a collaborative human rights approach. For more on this initiative see: M.T. Mira, "Chromosome 6q25 is Linked to Susceptibility to Leprosy in a Vietnamese Population" (March 2003) 33 *Nature Genetics* 412; S. Comeau, "Genetic Key to Leprosy" (Feb. 2003) 35 *McGill Reporter* online on McGill website: <http://www.mcgill.ca/reporter/35/10/leprosy/> (accessed May 28th, 2006).

[816] A. Attaran, *supra* note 719.

address the needs of the industrialised world,[817] due both to the high cost of research and to the increased possibility of financial return. This being said, genetic products and services produced in the developed world may also be relevant in addressing developing countries' health problems. Therefore, patents awarded on these products and services might influence their accessibility both in affluent and less-affluent countries.

Some are of the view that patent rights are essential to encouraging more inventions and better disclosure of innovation for the benefit of societies. In this sense, they argue that these rights further important social goals that could not be achieved otherwise.[818] Others believe that IP rights regimes do not achieve this balance between creators' and society's interests, but tend instead to favour economic interests of a minority of powerful agents, to the detriment of broader interests in public access to useful innovation. This is the view of some researchers who have come up with empirical results in the specific sphere of diagnostic genetic tests. Their work suggests that the possibility of obtaining patent rights is not a major motivation for those involved in developing and producing genetic tests.[819] They, in fact, found that patents can instead have detrimental effects on innovation in the field of genetic tests, as this quote illustrates:

> We conclude that patents and licenses have a significant negative effect on the ability of clinical laboratories to continue to perform already developed genetic tests, and that these effects have not changed substantially throughout the past 3 years. Furthermore, the development of new genetic tests for clinical use, based on published data on disease-gene associations, and information sharing between laboratories, seemed to be inhibited.[820]

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[817] World Health Organization, *World Health Report 1999: Making a Difference*, Geneva, 1999, online on the WHO website, <http://www.who.int/whr2001/2001/archives/1999/en/pdf/whr99.pdf> (accessed May 28th, 2006) at 137.
[818] World Intellectual Property Organization, *Intellectual Property Reading Material*, p. 5, Geneva, World Intellectual Property Organization, 1995 (WIPO Publication No. 476 (E)).
[819] J.F. Merz et al., "Diagnostic Testing Fails the Test", *supra* note 436.
[820] M. K. Cho et al., "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services" (2003) 5 *Journal of Molecular Diagnostics* 3, at 8.

Therefore, depending on their scope and on the sector of activity in which they are awarded, patents can grant substantial control to patent holders over the use of their products and services, as well as over the mode of analysis to be used in clinical environments, influencing their true availability to patients in need as we will see with the BRCA, heamatochromatosis, and Canavan examples. Also, countries where gene patents have not been granted can theoretically buy, use, and produce genetic products and services. However, since many countries do not have the minimum basic manufacturing capacities and resources necessary to produce such items, they often have to turn to developed countries to buy the (often patented) genetics products, technology, and services they need. Accessibility to the latter items will principally depend on their affordability. We know that patent rights allow patent holders to temporarily exclude others from using, making, importing, or selling their invention in exchange for the public release. Patent holders can thus grant licenses with almost any condition they want and sell their patented objects at a price they fix, subject to applicable legislation, competition and market forces. In other words, the patent system allows patent holders to transfer some of the costs invested in developing their invention to the licensees and to the users of these products in exchange for the disclosure and use of their invention. This temporary legal monopoly over the cost of products can generate access barriers for those who are unable to pay, and it can, consequently, engender health gaps within and among nations. Indeed, affordability directly impacts availability and, more generally, direct access to genetics in cases where no other alternative such as public insurance exist in the market. In such cases, potential users who are not capable of paying the amount required by the patent holder can end up deprived of access to genetic products and services. The limited ability of a population to pay for some products will also have a direct influence on their very availability in a given market.

This reality does not correspond well within a human rights framework that requires IP rights to be consistent with the realisation of other international

human rights, like the right to health of every individual, and, more specifically, of the most disadvantaged.[821] In other words, human rights require an approach to IP rights that supports scientific innovation and equitable access to its benefits evaluated in terms of needs.[822] Human rights demand the protection of the most vulnerable socio-economically and in terms of disabilities.

The *Declaration on the TRIPS Agreement and Public Health* (the Doha Declaration, already examined in chapter III) is a human rights initiative to limit patent holders' power over prices in the health sector, particularly with regard to essential drugs, as we will discuss in the next section. However, notwithstanding the special consideration awarded to health in the Doha Declaration, its practical impact is limited for now. TRIPS is based on a private property model and remains an international agreement applied mainly to foster the interests of intellectual property owners and to promote international trade.

The next examples demonstrate the influence that disease-gene patent rights and human rights have had (or not) on availability and affordability of genetic technology targeted at specific disease. Although these examples are taken from the developed world, they are also likely to find application in developing countries which often have to rely on the same technology.

BRCA

The restrictive licensing practice adopted by Myriad Genetics for the use of patented BRCA1 and BRCA2 genes and associated genetic tests is an example of the link that can exist between licensing practices and availability and affordability of genetic tests for disease. BRCA1 and BRCA2 are two genes associated with hereditary breast and

[821] Committee on Economic, Social and Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights; Statement on Human Rights and Intellectual Property*, Geneva, December 14, 2001, E/C.12/2001/15, par. 8.
[822] A. R. Chapman, "A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science" in WIPO, *Intellectual Property and Human Rights* Geneva, 1999, WIPO Publication No. 762 (E).

ovarian cancer.[823] Myriad was granted broad patents in many affluent countries, not just on the two genes, but also on their mutations; the diagnostic tests developed for screening for their existence; the therapeutic methods developed with information derived from them; and all other unforeseen applications of those two genes.[824] Myriad developed a genetic test to detect the presence of genes. Instead of negotiating license agreements with potential partners and allowing them to use BRCA1 and 2 in different settings, Myriad adopted a very restrictive licensing practice and refused to grant licenses for the use of those genes. It decided that, in countries where it had patent rights, it would be the only one to screen for the two genes and to conduct any related tests and analysis. Myriad therefore required that almost all samples be sent to its own facilities in Utah for analysis.[825]

Myriad's strategy created a difficult environment for breast and ovarian cancer research progress, and this probably explains why numerous challenges to Myriad's patents have been filed and so far almost all won in front of the European Patent Office since 2001.[826] Since patents cannot be enforced during legal proceedings in

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[823] Hereditary breast and ovarian cancer represent 5-10% of all breast and ovarian cancer cases.

[824] These patents have been successfully challenged by the Curie Institute and other stakeholders in Europe. One reason for contestation is that even if Myriad has done the final sequencing, most of the information on the BRCA1 had been previously gathered by the efforts of an international public consortium, including numerous families with hereditary breast cancer. There is also a controversy over whether it was Myriad or the International Research Consortium who actually discovered the BRCA2 mutation. For more information, refer to: The Canadian Cancer Society, *The patenting of BRCA1 and BRCA2 genes facts sheet,* Canada, 2002, online on the CCS website, <http://www.cancer.ca/ccs/internet/standard/0,3182,3172_31282995_32777862_langId-en,00.html> (accessed May 18th, 2006).

[825] In November 2004, the University of Utah Research Foundation (UURF) acquired Myriad's full share in BRCA1 and BRCA2 patents. Myriad is thus no longer the patent owner, but there is no substantial difference as it continues to hold exclusive licenses on the said patents.

[826] The challenge before the European Patent Office (EPO) to the validity of the Myriad patents on BRCA1 and 2 was initiated in 2001 by the Institut Curie, the Assistance Publique-Hôpitaux de Paris, the Institut Gustave-Roussy and other European opponents. The challenge is based on Myriad's lack of inventive steps, abusive use of patent rights, and hindrance to equitable access to genetic testing. In May 2004, in a very important decision, the EPO revoked Myriad's European patent EP 699 754 relating to a "method for the diagnosis of a predisposition to breast or ovarian cancer." In January 2005, the EPO rejected the main elements of Myriad's European patent claims on BRCA1 (on the gene and its application and on the mutations associated with breast and ovarian cancer). These decisions have been appealed by the UURF and the judicial developments will prove interesting. For more details on those opposition procedures, please refer to these very informative websites: <www.curie.fr> and <http://www.curie.fr/upload/presse/myriadpatents310105.pdf>; See also Nuffield Council on Bioethics, *The Ethics of Patenting DNA: a Discussion Paper*, *supra* note 473 at par 4.6.

front of the EPO, the UURF and Myriad are not in a position to prevent research in the field of breast and ovarian cancer with BRCA1 in Europe until a decision is made on the challenges and appeals.[827] They can however enforce their amended and limited patent on BRCA2 which was confirmed by an opposition division of the EPO in June 2005.[828]

As well as having a negative impact on research, Myriad's restrictive practices also constrained availability of genetic tests to patients around the world. In fact, since Myriad wanted to be the only company to use and perform analysis of the patented genes and tests, their strategy pushed many laboratories to stop offering the genetic screening tests they had developed for hereditary breast cancer. Numerous patients have been left without options in terms of availability of breast cancer screening services within their geographical region, and in terms of affordability of the only option henceforth legally available.

Indeed, Myriad's patents and attitude also directly impacted on the cost of screening for hereditary breast cancer. Myriad and UURF's monopoly on testing and analysis for mutations has affected the the price of the only diagnostic test *available* in Canada and the US.[829] In fact, the Myriad test is now priced at $3800, at least three times as

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[827] In other words, until a final and binding decision has been reached (which can take, on average, 3.2 years for a challenge and 2.8 years for an appeal before the EPO) the UURF's patents will remain unenforceable. However, if their patents are upheld, the UURF will be entitled to claim damages for the use of their exclusive rights undertaken during the opposition procedures. D. Harhoff, *Legal Challenges to Patent Validity in the US and Europe*, OECD Conference on IPR, innovation and economic performance, Munich, 2003, online on the OECD website, <http://www.oecd.org/dataoecd/14/31/11728549.pdf> (accessed May 18th, 2006), slide 6.

[828] Indeed, the Opposition division of the EPO decided to maintain Myriad's BRCA2 patent in its amended form June 29th, 2005. This patent claim now only relates to one single sequence of the gene and is used in the diagnosis of specific predispositions to breast cancer in Ashkenazi Jewish women. This decision considerably limits the scope of UURF's patent and many believe that it will likely not affect R&D activities in European laboratories. However, others are afraid that it could be discriminatory for the Ashkenazi Jewish population who could end up paying more for genetic testing. Again, the judiciary development in this affair will prove very interesting. For more on this last decision see: Human Genetic Commission, *The Study of Patenting and DNA*, online on the HGC website, <http://www.hgc.gov.uk/client/Content_wide.asp?ContentId=365> (accessed May 6, 2006); see also: http://www.curie.fr/upload/presse/brca2-myriad-6-juil-05.pdf.

[829] Recall that the situation is different in Europe, where some of Myriad's patents have been recently invalidated and others are being challenged in from of the EPO. During the challenge and appeal procedures, Myriad and UURF cannot enforce their patents.

much as equivalent, unpatented tests developed by other groups of scientists.[830] This can have direct consequences for many patients, as it appears that 5-10% of all breast and ovarian cancer have the heritable component that has been associated with BRCA1 and BRCA2 genes.[831] This means that UURF and Myriad's strict patent enforcement, coupled with the monopoly prices charged for the test, prevent many north American high-risk women with a clear familial history of breast and ovarian cancer from accessing existing diagnostic tools that could save their lives by giving them information needed to be in a position to make crucial preventive decisions to stay healthy. This is especially true for women who cannot benefit from a universal health care system and who cannot afford health insurance coverage.

One should note however that some stakeholders decided to resist Myriad and UURF's threat. In Canada, the British Columbia Cancer Agency, which had been testing for BRCA mutations for at least 5 years, stopped offering this service to their patients after receiving a cease-and-desist order letter from Myriad in 2001. They later resumed offering testing services by sending their patients' samples to Ontario, one of the provinces that decided to continue performing diagnostic testing with their own test, despite Myriad's patent.[832] Ontario is thereby defying UURF and Myriad's overly-broad patent rights, something that could possibly lead to a legal battle over patent infringement. However, since the Ontario and federal governments have not so far been sued by Myriad and UURF, since they did not seek a declaration of invalidity of Myriad's patents before the federal court (s. 60, *Patent Act*), and did not apply for a compulsory license to the Patent Commissioner (s. 19, *Patent Act*), they have not yet had to defend their position before the courts. We can imagine, however, that the strategy these governments would employ in a potential patent-infringement

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[830] H. Kent, "BC Sidesteps Patent Claim, Transfers *BRCA* Gene Testing to Ontario" (January 21, 2003) 168:2 *CMAJ* 211; L Eggesrston, "Ontario Defies US Firm's Genetic Patent, Continues Cancer Screening" (February 19, 2002) 166:4 *CMAJ* 494.

[831] W. Burke et al., "Recommendations for Follow-up Care of Individuals with an Inherited Predisposition to Cancer" (1997) 277:12 *Journal of the American Medical Association* 997.

[832] L.Sheremeta & E.R. Gold, *Creating a Patent Clearinghouse in Canada: A Solution to Problems of Equity and Access?* poster presentation, GE^{3}LS Winter Symposium 2003, February 6-8, 2003, Montreal, Quebec.

action would be to challenge the validity of Myriad's broad patent and enforcement strategy on technical grounds, as has recently been done in Europe.[833]

Apart from the very few mechanisms available within the patent system to further health needs, legal action to enforce the human right to health is very limited in Canada. [834] As stated by Yazdanian when speaking about the right to health entrenched in the South African Bill of rights, "[i]t seems astonishing that these clauses have no constitutional equivalent in Canada, where access to health care is considered a birthright and a keystone of the national identity."[835]

Despite this legislative lacuna, there are some indirect possibilities to enforce the right to health and health care in Canada. Indeed, since the Supreme Court of Canada decided, in 1999, that international law obligations should be recognised in the domestic statutory setting,[836] it could be argued that in signing and ratifying the ICESCR and the UNDHR, Canada (and the provinces) have committed to providing adequate and affordable health care to all citizens. On the legislative front, the federal government should ratify specific legislation for the protection of access to health.[837] The recent Supreme Court decision in *Chaoulli* briefly discussed in chapter IV indirectly provides this broad interpretation of the right to health, but in terms of rapidity and efficiency of services. However, it slightly opens the door to different levels of access based on individuals' ability to pay and to qualify for private insurance.[838] It will be interesting to follow the practical impact that this decision will have on Canadians' right to health both in the short and the longer term.

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[833] In Canada, s. 59 of the *Canadian Patent Act* states that a patent's validity can be challenged as a defence to patent infringement actions. For more details on the European case, refer to note 826.
[834] The situation is very different in countries where elaborate constitutional mechanisms have been put into place, as we will discuss in the next section.
[835] S. Yazdanian, "*Treatment Action Campaign (TAC)* v *South Africa (Minister of Health)*:Reflections on the Right to Health Care in Canada" (August 2004) 9:2 *Canadian HIV/AIDS Policy and Law Review*
[836] *Baker* v *Canada (Minister of Citizenship and Immigration)* [1999] 2 SCR 817
[837] Even though health matters are provincial jurisdiction, *Schneider* v. *The Queen* [1982] SCR 112 opened the door to federal legislative intervention to deal with national health matters.
[838] *Chaoulli* v. *Québec (Attorney General)*, *supra* note 728.

In comparison to the IP law system, the human rights system's legal mechanisms appear somewhat less direct, reliable, and efficient. However, what is happening now in Canada with Myriad's tolerance towards Ontario's strategy is symptomatic of the power that human rights values and considerations can have outside the legal framework. Equitable access to health and disease prevention are crucial social values.[839] In the current case, we could interpret Myriad's decision not to act on its threats of legal action as being driven by strong public pressure and fear of further damage to its corporate image by open insensitivity to equity considerations.

Haemochromatosis

Our second example relates to the haemochromatosis gene patent. Hereditary haemochromatosis is a genetic disease associated with two important genetic mutations of the haemochromatose gene or HFE (C282Y and H63D), and it can be easily treated when correctly diagnosed. In 2001, researchers conducted a survey and discovered that many US laboratories had already developed tests to screen for hereditary haemochromatosis and were administering them to their patients well before patents on the HFE gene and associated genetic test were awarded to Mercator Inc. in 1998.[840] Mercator Inc. decided to manage its patent rights by granting an exclusive license to Smith Kline Beecham Clinical Laboratories (Smith Kline) for diagnostic testing. Although Smith Kline proposed sub-licenses to numerous laboratories and offered them the use of the patented tests in exchange for high royalty fees, more than a third of the labs surveyed refused the offer and stopped offering their own tests, fearing patent infringement suits. This resulted in major cost increases for patients in need.

Also, in addition to obvious effects on affordability of the newly-patented diagnostic test, these broad patents have had a clear negative impact on the availability of

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[839] The Romanow report states that health is a *right of citizenship* and that access to health services should depend only on need, not on wealth, gender, or age, for example. R. Romanow, *Building on Values: The Future of Health Care in Canada*, Ottawa: Commission on the Future of Health Care in Canada, November 2002, at 48.

[840] J.F. Merz et al., "Diagnostic Testing Fails the Test", *supra* note 436, at 577-578; D.J. Willison & S.M. Macleod, *supra* note 6.

genetic testing for haemochromatosis in general. Since many laboratories stopped producing and performing any diagnostic tests after the patents and exclusive licenses were granted, some patients ended up with very few options. Health care institutions and professionals affiliated with these labs became unable to offer the same test to their patients and had to direct them to other labs offering another, more expensive test. In other words, even if patent holders made sure that a diagnostic test for hereditary haemochromatosis remained available in theory, crucial health information became out of reach and unavailable to many patients, especially the poor and the uninsured, because of the broad patent awarded. Patents on the HFE gene were also awarded in Europe in 2005.[841] Until recently, European laboratories were still performing diagnostic genetic testing with the unpatented tests they had developed for haemochromatosis screening.[842] It will be interesting to follow the consequences the recent patents will have on tests' availability for European patients.

Canavan Disease

A third example of the impact of gene patents on accessibility is the genetic test developed for screening for Canavan disease. Canavan is an inherited, fatal, neurodegenerative disease that predominantly affects Ashkenazi Jewish people. The patent awarded in this case caused one in four US laboratories to cease their screening tests for the disease. As a result of this patent, many laboratories that were already performing some testing activities decided to end their practice because of the very strict royalty and licensing conditions that the patent holder was trying to

[841] Methods and Compositions for Diagnosis and Treatment of Iron Misregulation Diseases, US6849399 B1 (published on February 1rst 2005) and US2005090430 A1 (published on April 28, 2005), online on the EPO website, <http://v3.espacenet.com/family?DB=EPODOC&IDX=US2005090430&F=8&OREQ=0&textdoc=TRUE> (accessed May 19th, 2006).

[842] For example, a genetic test for the two mutations has been developed in the Laboratory of Hematology of the Hôpital St-Eloi in Montpellier and was still being used in practices in March 2005, email exchanges with Dr. Patricia Martinez from Hopital St-Éloi, March 2005; see also P.A Martinez et al. "Simple and Rapid Detection of the Newly Described Mutations in the HLA-H Gene" (1997) 89 *Blood* 1835.

impose.[843] Availability of screening services decreased significantly while costs increased, leaving fewer options for patients. The Canavan gene patent thus impacted the populations around the world in terms of availability of testing and screening products for the patients who needed them. This is especially relevant since the *American College of Obstetricians and Gynaecologists* recommended, in 1998, that **all** Ashkenazi parents be tested for this severe progressive genetic disorder.[844]

As with the haemochromatosis gene patent, before the Canavan patent was granted to the Miami Children's Hospital (MCH), the Canavan Foundation was offering free genetic testing to its patients. Again, the MCH tried to impose very restrictive conditions and high royalty fees on labs wishing to offer the test. This time, however, families of children who had initiated and participated in the research that led to the discovery of the gene, along with the labs that had assisted in collecting tissue samples for research, reacted by filing a lawsuit to challenge MCH's way of exercising its patent rights. [845] Human rights and ethical issues regarding compensatory benefit sharing, justice, and equity were brought before the Court with a specific emphasis on the active participation of patients and their families in research and development activities. Parties reached a confidential settlement in September 2003, allowing a research exception for scientists and institutions interested in research endeavours aimed at finding a cure for Canavan disease. However, although no information on the cost of testing services is available, MCH is entitled to continue licensing its exclusive rights and to collect royalty fees for diagnostic testing. Again, as this test has been recommended for all Ashkenazi parents, limiting its provision to individuals who are able to pay for it will have critical

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[843] L.S Cahill, "Genetics, Commodification, and Social Justice in the Globalisation Era" (2001) 11:3 *Kennedy Institute of Ethics Journal* 221; V. Brower, "Canavan Families Slam Scientists over Test Patent Profits" (December 4, 2000) *Biotechnology Newswtach* 1.

[844] American College of Obstetricians and Gynaecologists, *Screening for Canavan Disease, fact sheet number 212*, November 1998, online on the National Tay-Sach and Allied Diseases website, <http://www.tay-sachs.org/medical.php> (accessed May 19th, 2006).

[845] *Greenberg* v. *Miami Children's Hospital Research Institute Inc* 208 F. Supp. 2d 918 (N.D. Ill. 2002). 121. 793 P.2d 479 (Cal. 1990).

health consequences for an untold number of individuals and will amplify the already huge health gap between the rich and the poor.

These three examples raise important issues about the real impact that patents and license agreements on the one hand, and human rights considerations on the other, can have on the actual **accessibility** of genetic tests and services offered by different labs, and consequently on the standard and quality of medical care available to patients. We have seen that, in some cases, disease gene patents and licensing policies have been used to limit the activities of clinical laboratories and patients' access to diagnostic products, and that human rights have often been of limited help in redressing the situation.[846] However, it is important to mention that since all three examples took place in the context of clinical genetics and relate more specifically to diagnostic tests, the result of our analysis on access to genetics products and services is limited to these areas and spheres of activity.

The issues highlighted in these examples find application in both developed and developing countries where non-communicable diseases affect populations in similar ways.[847] Even though patents on these genes may not yet have been filed in most developing nations, these nations cannot use this knowledge anyway, since they do not have the infrastructure capacity to advance research further, or even to make use of existing genetic technologies.

5.1.3. Accessibility to genetics and countries' internal situation

As previously discussed, access to genetic products can be influenced by applying legal mechanisms, including patents (such as scope, licensing strategies, and the

[846] A. Schissel, J.F. Merz and M.K. Cho, "Survey confirms fears about licensing of genetic tests" (1999) 402 *Nature* 118; J.F. Merz *et al.*, "Disease gene patenting is a bad innovation" (1997) 2 *Molecular Diagnosis* 299; D.J. Willison and S.M. Macleod, *supra* note 6.

[847] Non-communicable diseases have been identified as the leading cause of death in the developing world and are projected to become more and more prevalent in the future: Program in Applied Ethics and Biotechnology and Canadian Program on Genomics and Global Health (University of Toronto Joint Center for Bioethics), *Top 10 Biotechnologies for Improving Health in Developing Countries*, Toronto, 2003, at 59-60; World Health Organization, *Fifty Facts from the World Health Report 1998, Global health situation and trends 1955-2025*, Geneva,, 1998.

patentee's strategy), and by human rights values. However, many other non-legal, country-specific elements (such as physical infrastructure, education levels, and the political situation) can also pose significant hurdles to accessibility in developing countries. Because the focus of this dissertation lies in assessing normative systems with the theoretical concerns of global distributive justice, developing countries' internal political and economic considerations, although very relevant, are beyond the scope of our main analytical focus. However, because these factors are critical to finding a comprehensive solution to global health issues, it appears relevant to discuss them briefly and give a few examples of the role they could play in a multifaceted solution.

One important factor unrelated to patent that influences genetic research and innovation in developing countries is their critical lack of research facilities, infrastructure, and expertise.[848] This indicates very low production of research tools and technologies by and for developing countries.[849] It is nearly impossible for most of them to use, distribute, and administer existing research instruments and technology, never mind genetic products and services that can be licensed or purchased from developed-world patent holders.[850] Indeed, when they exist, most facilities are very poorly equipped and understaffed because of problems related to the brain drain and accessibility to education (basic and higher) in many developing countries.[851] In addition to the lack of equipment and trained personnel, basic physical infrastructure like roads, power supplies, and communications are often deficient.[852] For example,

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[848] L. Bernier, K. Durell & E. R. Gold, *The Impact of DNA Patents on Access to Genetic Technologies and Services: View from Developing Countries*, World Health Organization, Geneva, January 2004, at 31 et ss.

[849] S. P. Marks, "Tying Prometheus Down: The International Law of Human Genetic Manipulation" (2002) 3 *Chi. J. Int'l L.* 115.

[850] J.M. Spectar, "Patent Necessity: Intellectual Property Dilemmas in the Biotech Dominant Treatment Equity for Developing Countries" (2001) 24 *Hous. J. Int'l L* 227.

[851] R.N, Nwabueze, "Ethnopharmacology, Patents and the Politics of Plants' Genetic Resources" (2003) 11 *Cardozo J. Int'l & Comp.* L. 585; T. Kowalski, "International Patent Rights and Biotechnology: Should the United States promote Technology Transfer of Developing Countries?" (2002) 25 *Loy.L.A. Int'l. & Comp. Law Rev.* 41; O. Ogbu, "African Science and Technology Day: Has Africa Surrendered in the Field of Science and Technology?" (2002) *Science and Development in Africa*

[852] For a more complete list of some of the most important infrastructures in a country's development, refer to: K Davies, "Regulatory Treatment of Foreign Direct Investment in Infrastructure and Public

if the basic resources required to offer genetic services and deliver them are insufficient in a given country or region, it can become very difficult (even impossible) to offer this service to the local population, even if it is *available*.

One of the basic resources necessary to implement genetic services is electrical power, as illustrated by the following example. In the late 1980s, the World Health Organisation suggested that community-based studies be launched to remediate the pressing problem of sickle-cell disorder in Africa. One project, involving the use of genetic technologies for prenatal screening for sickle-cell, was undertaken in Lagos, Nigeria. Experienced English medical staff came to Lagos to train African clinicians, but was faced with frequent daily power interruptions. Major waste resulted, as all ongoing tests had to be discarded each time the power failed, and the medical staff was forced to constantly repeat the test with fresh samples. The problem finally forced women who wished to be tested to travel to Europe instead. [853]

Similarly, if no one has been trained to administer and analyse existing genetic test results or offer appropriate genetic counselling in a given territory, their availability to the population can be greatly compromised.[854] Moreover, political instability and corruption can seriously hinder the establishment of efficient policies and actions for socio-economic and scientific development. As Nwabueze clearly explains, "[c]itizens of some developing countries are still caught in the throes of their despotic leaders, who are more concerned with expanding the frontiers of their private economic kingdom than addressing the developmental needs of their countries."[855] Corruption not only paralyses progress and growth, but also contributes to the withdrawal of important international aid and investment, to the extreme

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Utilities and Recent Trends: the OECD Experience", OECD India Investment Roundtable, New Delhi, October 19, 2004, online on the OECD website: <http://www.oecd.org/dataoecd/53/20/33803491.pdf> (accessed June 1st, 2006) at 12.

[853] For more details on this research project, refer to O.O Akinyanju *et al.* "Initiation of Prenatal Diagnosis of Sickle-cell Disorders" (1999) 19 *Prenat. Diagn.* 299; T.A. Adewoled et al. "Application of Polymerase Chain Reaction to the Prenatal Diagnosis of Sickle Cell Anaemia in Nigeria" (1999) 18:3 *WAJM* 160.

[854] L. Heredero, "Comprehensive National Genetic Program in a Developing Country – Cuba" (1992) 28:3 *Birth Defects Original Article Series* 52.

[855] R.N. Nwabueze, *supra* note 851, at 594.

disadvantage of hostage populations.[856] All of these factors contribute to harming the scientific and industrial capacity development required to further innovations and absorb what has been developed in other countries.

Although such factors are not always completely independent from the IP system,[857] they are often related to domestic political and financial instability, issues to be addressed both internally and with external financial and educational input; in some cases in combination with, and, in others, independently of, the normative IP system.[858]

In this section, we have seen that the expansion of international intellectual property rights over genetic material, the application of human rights principles and values to redress abuses, and the presence of other socio-economic and political factors can all have consequences for accessibility in developing countries.[859] We referred to examples from the developed world to illustrate the potential impact that gene patents, and particularly disease-gene patent management, have had in developed nations. Since most of developing nations must rely on research progress made in affluent countries,

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[856] This is an issue in many Indian and African countries. For example, Kenya possesses plenty of natural resources and has great economic potential, but corruption has prevailed in the country for years, presenting major stumbling blocks to the country's economic development. Moreover, Kenya has endured much political instability over the last decade or so, with the end of the single party state in 1992; the subsequent transition phase; and the election, in 2002, of a new government that had promised to fight corruption in every way possible, but who lamentably failed in the task. It does seem that there is still much corruption among high-level officials and members of the Kenyan elite. All of this resulted, at various occasions, in international outcry and withdrawal of financial assistance. For a deeper analysis of the political situation in Kenya and on the topic of corruption more generally, refer to: A. Sen. *Development as Freedom* (New York: Anchor Books, 1999) at 270 et ss.; R. Lewis-Lettington & P. Munyi, *Willingness and Ability to Use TRIPS Flexibilities: A Kenya Case Study,* Department for International Development System Resources Centre, September 2004, at 8; African Studies Center - University Of Pennsylvania, "Kenya: Corruption Fight Stalling" (February 5th 2005) *AfricaFocus Bulletin*, online on the U of Penn website: <http://www.africa.upenn.edu/afrfocus/afrfocus021105.html> (accessed May 18th, 2006).

[857] For example, as previously discussed, intellectual property rights may influence countries' access to crucial research tools for building scientific and technological capacity. On this point: C. Juma and K. Fang, "Bridging the Genetic Divide" in M. Ruse & D. Castle, eds., *Genetically Modified Foods: Debating Biotechnology* (Amherst: Prometheus Press, 2002).

[858] See discussion on the debate regarding the relationship between strong intellectual property rights, and foreign direct investment, foreign and local research into developing countries' diseases, and technology transfer. Chapter III, *supra* note 438.

[859] P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) Introduction, at. 1; J. H. Reichman, *From Free Traders to Fair Followers: Global Competition Under the TRIPS Agreement* (1997) *29 N.Y.U.J. Int'l L. & Pol.* 11, at. 24

they are equally vulnerable to the potential detrimental effects of abusive uses of patents. We have seen that when gene patents play a role in access, much depends on the patentees' strategy, attitude, and agenda, and on opposition from civil society agents, governments, and patient groups. Depending on how they enforce their rights, patentees can improve or hinder actual accessibility of genetic research tools, products, and testing services. As our few examples show, however, the strong private economic agenda often associated with gene patents tends to compromise access in the field of genetic diagnostic testing rather than facilitate it through permissive diffusion strategies. This tendency can be balanced by human rights but, as demonstrated, despite existing remedial mechanisms, the practical legal applications of the human rights system have been limited.[860]

Because the science of genetics is fairly new, complex, and expensive to develop, we did not find genetics-specific examples from the developing world. Though what we have discussed in this section applies to developing countries, it is also important to consider examples from the developing world. This second part of our analysis therefore focusses on issues emerging from the pharmaceutical sector and relating to developing world's access to essential drugs.

5.2 Challenges in Availability and Affordability of Essential Drugs

Much of the existing literature assumes a correlation between the experience of the genetic and pharmaceutical sectors but those two industries are different. Indeed, the later relies a lot more on the exclusionary nature of patent rights and on strict enforcement of legal monopolies than the former.[861] However, even if those two sectors of activity are distinct, they share some similarities, especially with regards to

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[860] S. Leckie. "Violations of Economic, Social and Cultural Rights" in T.C. van Boven, C. Flinterman & I. Westendorp, eds., *The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights — SIM Special No. 20*. Utrecht, 1998; UNAIDS, *Putting Third First: Vaccines, Access to Treatment & the Law*, Barcelona, July 2002, online on the aidslaw website: <http://www.aidslaw.ca/barcelona2002/treatmentpapers.doc> (accessed May 31st, 2006).

[861] L. Bernier, K. Durell & E. R. Gold, *supra* note 848, at 3-5.

issues of equitable access to health by vulnerable populations, as this section demonstrates.[862]

In this section, we will address how both human rights and IP rights have influenced access to essential drugs in the developing world. We will start with a presentation of how those two systems have been working and influencing each other in this context, and then focus on a specific example significant for global health: the accessibility of HIV/AIDS drugs in the developing world.

5.2.1. IP rights, the human right to health and access to essential drugs

As mentioned above, over the last few years in many developing nations the legal aspect of the human right to health has evolved considerably.[863] The inclusion of socio-economic rights like the right to health in many developing countries' constitutions was not an empty gesture. It highlighted the legal obligation to satisfy the most fundamental needs of the most vulnerable by placing real responsibilities on the executive and the judicial powers, "breaking down some of the philosophical and practical barriers that have been raised against the justiciability or enforceability of these rights."[864]

In Latin America, various constitutional norms were established to protect the right to health[865] and the human rights movement grew considerably with the introduction of

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[862] J.H. Barton & E.J. Emmanuel, "The Patents-Based Pharmaceutical Development Process: Rationale, Problems and the Potential Reforms" (2005) 294:16 *The Journal of the American Medical Association* 2075; A.C. Nunnally et al., "Genetic Patent Protection in the Pharmaceutical and Biotechnology Industries" (2005) 8:4 *Community Genetics* 209.

[863] L. Freeman, "Reflection on Emerging Frameworks of Health and Human Rights" in J.M. Mann *et al.*, eds., *Health and Human Rights: A Reader* (New York: Routledge, 1999) 227.

[864] J. Oloka-Onyango, "Reinforcing Marginalised Rights in an Age of Globalisation: International Mechanisms, Non-State Actors and the Struggle for Peoples' Rights in Africa" (2003) 18 *Am. U. Int'l L. Rev.* 851, at 855; see also N. Haysom, "Constitutionalism, Majoritarian Democracy and Socio-Economic Rights" (1992) *8 SAJHR* 451.

[865] Argentina, Law 23.798 of 1990, which makes AIDS a matter of national interest in establishing mechanisms for HIV prevention, diagnosis, and treatment; *Uruguay Presidential Decree of 1997* for the provision of HIV/AIDS drugs to people in need; *Constitution of the Bolivarian Republic of*

amparo suits (a category of constitutional legal constitutional action for the protection of collective human rights which has prevalence over other legal procedures and has to be decided with urgency)[866] brought against various governments to impose compliance with health-related obligations. For example, as a result of an amparo brought on behalf of 3.5 million Argentinians, the court decided that the government had an obligation to manufacture and distribute a vaccine against a serious and often fatal form of fever in that country.[867] In South Africa, in 1996, a new constitution mandated the Human Rights Commission to "promote, monitor and assess the observance of human rights in South Africa."[868] The constitution provides extensive legal protection for socio-economic rights and for health in particular.[869] Indeed, section 27(1) states that "everyone has the right of access to a) health care services including reproductive healthcare" and 27(2) provides that states should take adequate measures to ensure the progressive realisation of the right to health with its available resources. These legislative dispositions have led to important decisions of the South African High and Constitutional Courts concerning the right to health. One was the case *Soobramoney* v. *Minister of Health*,[870] which involved a 41 year-old patient suffering from chronic renal failure and serious heart conditions, who claimed

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Venezuela, Dec. 1999, replacing the 1961 Constitution which considers health a social right and a constituent part of the right to life. For more on these legal instruments, see: M.A. Torres, "The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A Case Study from Venezuela" (2002) 3:1 *Chicago Journal of International Law* 105.

[866] E. Gonzalez Mac Dowell, "Juridical Action for the Protection of Collective Rights and its Legal Impact: A Case Study" (Winter 2002) 30:4 *The Journal of Law, Medicine and Ethics* 644.

[867] Causa No. 31, Viceconte, Mariela Cecilia c/Estado NacionalMinisterio de Salud y Acciôn Social, s/Amparo Ley 16.986. Câmara Nacional en lo Contencioso-Administrativo Federal, Sala IX Jun. 2, 1998 quoted in A.E. Yamin, *supra* note 688. Despite the judgement, however, a motion for compliance was filed a year later to force the government to comply with the ruling, since it had not done so.

[868] J. Klaaren, "A Second Look at the South African Human Rights Commission, Access to Information, and the Promotion of Socioeconomic Rights" (May 2005) 27:2 *Human Rights Quarterly* 539; see also s. 184 (1) & (2) of the South African Constitution and S. Liebenberg, "Violations of Socio-Economic Rights: The Role of the South African Human Rights Commission" in P. Andrews & S. Ellmann, eds., *The Post-Apartheid Constitutions: Perspectives on South Africa's Basic Law* (Johannesburg: Witwatersrand University Press, 2001) 405.

[869] *Constitution of the Republic of South Africa* (adopted May 8, 1996, amended October 11, 1996), online: <http://www.polity.org.za/govdocs/constitution/saconst.html> (accessed May 18th, 2006).; C. Ngwena, "Access to Health Care a Fundamental Right: The Scope and Limits of Section 27 of the Constitution" (2000) 25 *Journal for Juridical Sciences* 1; J. Sarkin, "Health and Human Rights in Post-Apartheid South Africa" (1999) 89 *South African Medical Journal* 1259.

[870] *Soobramoney* v. *Minister of Health*, Constitutional Court of South Africa, 1997 12 BCLR 1696 (CC)

right to long-term dialysis. The Constitutional Court dismissed the appellant's claim on the basis that political and medical authorities were the most competent to make budgetary decisions with their limited resources. Many other amparo suits and claims were introduced in various Latin American states and South Africa for the specific recognition of a collective interest in broad access to antiretroviral medicines as part of the right to health, as we will discuss at greater length below.

Before doing so, however, we need to say a few words about the practical effect of such court decisions. Judicial recognition of specific human rights unfortunately does not ensure compliance with those rights. Turning legal dispositions and decisions into efficient tools that meaningfully address and change the reality of the dispossessed can be complex and very demanding. In reality, the realisation of health rights has been limited by various factors, including enforcement of other legal rights (mainly IP rights) and lack of available resources. [871]

5.2.1.1. IP rights on drugs as an obstacle to the realisation of the human right to health

One of the main elements that can negatively impact access to pharmaceuticals for the realisation of the right to health is the strong enforcement of intellectual property rights. [872] Pharmaceutical companies that file drug patent claims in developing countries are able to prevent other providers from producing and supplying them at a lower price. Drug prices can represent as much as 60% of

[871] L. London, *supra* note 2: J. Oloka-Onyango, *supra* note 864; S. C. Agakwa, "Reclaiming Humanity: Economic, Social, and Cultural Rights as the Cornerstone of African Human Rights" (2002) *5 Yale Hum. Rts. & Dev. L.J.* 177.

[872] It is important to specify that most essential medicines on the WHO list are not patented. However, some drugs that are very important to addressing developing countries' health needs have been patented in recent years. Our discussion will focus on the recently-patented drugs marketed to treat HIV/AIDS, tuberculosis, and malaria. C. Dommen, "Raising Human Rights Concerns in the World Trade Organisation: Actors, Processes and Possible Strategies" (2002) 24 *Human Rights Quarterly* 1; R. Loewenson, "Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPs" (Sept. 2000) 4:7 *Bridges Between Trade & Sustainable Dev.* 3

developing countries' health budgets;[873] brand-name patented drugs normally cost more than generics and are often more expensive in developing countries,[874] rendering them almost always out of reach to uninsured populations.[875]

In filing drug patents in developing countries, patent holders want to ensure that people from these countries will not be in a position to buy their products more cheaply from other sources and to sell those same products back to agents from the developed world at more advantageous conditions. In addition to preventing developing countries from accessing affordable existing medicine for fighting the worst health crisis of the century, patent rights granted and enforced in developing nations can also hinder production of and access to cheaper generic options.[876] In other words, many believe that patents are one of many factors that explain why key patented medicines, often related to serious diseases of high mortality, remain out of reach from more than 40 million people worldwide.[877]

For patent holders in the pharmaceutical sector, there is a logical justification for such a protectionist attitude towards IP rights. As we discussed in the IP chapter, the main argument to justify enforcing strong patents is to argue that, since developing a patentable product often involves huge up-front investments in terms of time and

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[873] D.B. Resnik, "Fair Drug Prices and Patent System" (2004) 12:2 *Health Care Analysis* 91; B-C. Dolmo, "Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example" (2001) 7 *Buff. Hum. Rts. L. Rev.*137, at 151.

[874] D. G. McNeil Jr, "Prices for Medicine are Exorbitant in Africa, Study Says" (June 17th, 2000) *New York Times*

[875] A. R. Chapman, *supra* note 11. To support her point, Chapman refers to the example of tuberculosis, which affects a majority of poor people who cannot afford available treatment priced at US$15 000 per year.

[876] L. Nelsen, "The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries" (January 2003) III:2 *Yale Journal of Health Policy Law and Ethics* 301; G. Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Aldershot: Ashgate, 2003).

[877] J. Borrell & J. Watal, *Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries*, Harvard University Center for International Development Working Paper, Cambridge, May 2002, online on the CID website: <http://www2.cid.harvard.edu/cidwp/092.pdf> (accessed May 18th, 2006); Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign, and Health Gap, *Comment on the Attaran/GillespieWhite and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa*, October 16th, 2001; C. Liu & S. Basu, "Patents and Access: Another Look" (May 11 2004) 23:3 *Health Affairs*, electronic letter published on the Health Affairs Journal website: <http://content.healthaffairs.org/cgi/eletters/23/3/155#112> (accessed May 18th, 2006).

capital, a company needs to recoup some part of this investment to be able to reinvest it in further innovative R&D endeavours. As mentioned at various occasions in the course of this dissertation, there is an ongoing debate on the validity of this argument, given the lack of empirical evidence to support the view that patents encourage or discourage innovation.[878] More specifically, it appears relevant to say a few words on the application of this argument to the pharmaceutical sector, where it needs to be nuanced on many fronts.

As the pharmaceutical industry is known to be extremely profitable and since a very large proportion of its profits end up reinvested in various marketing endeavours in comparison to what is invested in R&D,[879] it is arguable that it would be possible for large pharmaceutical companies to reduce the price of their medicines without having to touch the budget allocated to further R&D.[880] Another industry trend is to dedicate a large portion of R&D (up to 80%) to develop "me too" drugs, which are very similar to existing therapies. The innovative and therapeutic value of these initiatives being questionable, it is hard to defend strong patent rights for their incentive role in creating needed innovation. [881] Moreover, pharmaceutical companies' R&D frequently builds on fundamental public research and is often partly financed through generous governmental tax deductions. With these facts in mind, we can at least ask about the justification, the legitimacy and the existing strength of patent rights systematically held by pharmaceutical companies.[882]

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[878] See discussion on this point in chapter III.

[879] For example, Merck invested 7 346,3 million in marketing vs 4 010,2 million in R&D in 2004. For more figures on this company, see: *Merck 2004 Annual Report, Financial Section*, available online on Merck' website: <http://www.merck.com/finance/annualreport/ar2004/pdf/Merck_2004_AR.pdf> (accessed June 4th, 2006) at 24.

[880] M. Angell, "The Pharmaceutical Industry: To whom is it Accountable?" (2000) 342:25 *New Eng. J. Med.* 1902.

[881] Although marketing initiatives can prove very useful and efficient to generate more capital for further investment, the major issue here is the large proportion of profits allocated to such endeavours in comparison to other activities. J. Robinson, *Prescription Games: Money, Ego, and Power Inside the Global Pharmaceutical Industry* (London: Simon & Schuster, 2001); M. Angell, *La vérité sur les Compagnies Pharmaceutiques* (Montebello: Les Éditions le mieux-être, 2005); J-C St-Onge, *L'envers de la Pilule* (Montréal: Les éditions Écosociété, 2004).

[882] For an enlightening discussion on the pharmaceutical industry, refer to S. Joseph, *supra* note 434, at 432-434.

That being said, IP rights, as we know, can be nuanced with the latitude built into TRIPS and further confirmed by Doha. The latter declaration acknowledges concerns about the effect of patent rights on drug prices, and represents a commitment to essential-drug availability and protection of public health. In a way, Doha established a human rights framework to ensure that the social context of IP rights is properly considered and that health access concerns are treated with appropriate deference when enforcing IP rights. Some argue that Doha's dispositions represent TRIPS' interpretative norms under customary international law, and that they should be given legal value.[883] However, those provisions have so far been implemented with reserve. The United States has openly referred to Doha as a political statement without any legal value, implicitly refusing to consider access to essential drugs a fundamental human right.[884] Also, powerful nations and the transnational pharmaceutical industry have pressured other countries to refrain from taking advantage of compulsory licensing or parallel importation, as well as from going around strict patent rights for producing cheaper drugs.

A clear example of this attitude emerges from the famous South African case which took place before Doha but remains very relevant.[885] Indeed, in 1998, a group of the most powerful pharmaceutical companies decided to sue the South African government for its 1997 *Medicines and Related Substance Control Amendment Act*, which allows parallel imports, compels pharmacists to provide generic versions of off-patent medicine unless specifically requested, and requires a transparent drug pricing system. The pharmaceutical companies consortium argued

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[883] Article 31(3) of the *Vienna Convention on the Law of Treaty* states that when interpreting a treaty, "any subsequent agreement regarding the interpretation or application of the treaty's provisions" should be taken into account. J.T. Gathii, "The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treatis" (2002) 15 Harvard Journal of Law and Technology 292; UNAIDS, *Putting Third First: Vaccines, Access to Treatment & the Law*, Barcelona, July 2002, online on the aidslaw website: <http://www.aidslaw.ca/barcelona2002/treatmentpapers.doc> (accessed June 2nd, 2006).

[884] J.T. Gathii, *ibid.*; USTR Fact Sheet Summarizing Results from WTO Doha Meeting, Nov. 15, 2001, online on the US embassy website: <http://www.usembassy.it/file2001_11/alia/a1111516.htm> (accessed June 3rd, 2006).

[885] J. E. Stiglitz & A. Charlton, *Fair Trade for All, How Trade can Promote Development, supra* note 748.

that the flexibilities enshrined in this act were equivalent to violations of property rights and tried to force developing countries to implement stricter patent protection laws. On the other side, the South African Government argued that their *Act* was not only TRIPS-compliant, but also served the realisation of crucial human rights guaranteed by the constitution. The Consortium ended up dropping the suit after intense public outrage.[886]

Another example relates to the trade dispute filed by the US against Brazil under the WTO's Dispute Settlement body to challenge a Brazilian law allowing the emission of compulsory licenses to local manufacturers when patent holders failed to work granted patents. [887] This legal disposition sought to promote the in-country manufacture of affordable drugs by patent holders and served as a negotiating tool to achieve important price discounts with brand name pharmaceutical companies. The Brazilian strategy led to significant decreases in infection and death rates, and the US ended up withdrawing its complaint, prompted, again, by fervent public protest.[888]

These examples highlight the effect that drug patents owned by developed-nation entities and issued in developing nations can have on developing countries with manufacturing capacities. When strictly enforced, property rights can prevent these countries from relying upon their local industries to develop and sell products at a price that their population and the population of other developing countries would be

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[886] A. Baleta, "Drug Firms Lose Patent Rights Lawsuit Against South Africa's Government" (2001) 357 *Lancet* 1347; P. Sidley, "South African Court Battle Damages Drug Industry's Image" (2001) 322 *BMJ* 635; S. Joseph, *supra* note 434, at 442.

[887] WTO Notification of Mutually Agreed Solution, Brazil - Measures Affecting Patent Protection, WT/DS199/3 (Jan. 9, 2001); for more information on this case, see J.T. Gathii, *supra* note 883; N.A. Bass, "Implications of the TRIPS Agreement for the Developing Countries: Pharmaceutical Patent Laws in Brasil and South Africa in the 21st Century" (2002) 34 *Geo Wash. Int'l L. Rev* 191.

[888] P. Capella, "Brazil Wins HIV Drug Concession From US: Complaint to WTO on Patent Law Withdrawn" (June 26, 2001) *Gardian*, at 18; Office of the United States Trade Representative, U.S. and Brazil to Cooperate on HIV/AIDS and WTO Patent Dispute, press release of June 25, 2001; Brazil, Measures Affecting Patent Protection: Request for the Establishment of a Panel by the United States, WTO Doc. No. WT/DS199/3 (01-0093), 2001.

able to afford.[889] There is a need for governments to take action and control pharmaceutical companies' drug prices without jeopardising further R&D initiatives. In its report on the impact of TRIPS on human rights, the UN High Commissioner for human rights specified that states have a responsibility under international law to prevent non-state entities like big pharmaceutical companies from violating their populations' right to health.[890] Joseph notes that the "[f]ailure to cap Big Pharma's prices may be an example of [states'] culpable omission."[891] In addition to state responsibilities, others propose international mechanisms to address abuses by transnationals. This is a controversial idea.[892] As previously discussed in chapter IV, some argue that transnational corporations are not built to endorse moral causes, that their main purpose is to make profits, and that it would not be reasonable to ask them to spontaneously establish and respect human rights standards.[893] Others, to the contrary, argue that transnationals should bear some responsibility in areas of crucial importance like access to prescription drugs, where ill consumers often represent a "captive market."[894] They have proposed an international system of anti-trust laws and compulsory norms on restrictive business practices.[895] Although is appears morally right to argue that anyone, including transnational corporations, should do all they can to cure people and prevent death, the legal justification of this argument in international law, where states remain the only duty-holders, is less obvious. There are some signs that things could be changing,[896] but as Joseph states,

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[889] L. Nelsen, "The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries" (January 2003) 3:2 *Yale Journal of Health Policy Law and Ethics* 301

[890] *Report of the High Commissioner--The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52d Sess., Provisional Agenda Item 4, par. 45, 27-58, Geneva, 2001, U.N. Doc. E/CN.4/Sub.2/2001/13

[891] S. Joseph, *supra* note 434, at 439.

[892] M. K. Addo, *supra* note 663; M. Ottaway, "Reluctant Missionaries" (July/Aug 2001) *Policy* 44

[893] M. Ottaway, *ibid.*; J. Robinson, *supra* note 881, at 20.

[894] S. Joseph, *supra* note 434.

[895] N. Deepak & J. Court, *Governing Globalization : Issues and Institutions* (Helsinki: United Nations University, 2002)

[896] Sessional working group of the UN Sub-Commission on the Promotion and Protection of Human Rights on the Working Methods and Activities of Transnational Corporations, *Human Rights Principles and Responsibilities for Transnational Corporations and Other Business Enterprises* June 3rd, 2002, UN Doc.E/CN.4/Sub.2/2002/WG.2/WP.1/Add.2.

"[i]nternational law has not yet evolved to the point of holding private actors, such as Big Pharma, responsible for their failure to take action."[897]

5.1.2.2. Available resources as an obstacle to the realisation of the human right to health

Another major problem with constitutionally-entrenched socio-economic rights is that, in addition to conflict with strong IP rights, their enforcement depends also on the resources that a country possesses to address the issue. In other words, the right to health does not guarantee concrete enforcement measures irrespective of available resources according to the decision in *Soobramoney*.[898] Developing nations are often characterised by a severe lack of resources and by important and often contradictory demands on the very limited resources available.[899]

Despite judicial and political decisions ordering the development of health facilities in South Africa, in 2000, one out of five clinics still lacked necessary communication infrastructure, one out of four did not have running water, and one out of ten lacked electricity.[900] This was due to internal factors such as a lack of qualified staff, corrupt officials, and lack of resources or inadequate strategies of resources distribution,[901] as discussed above.

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[897] S. Joseph, *supra* note 434, at 437; see also J.Oloka-Onyango, "Reinforcing Marginalised Rights in an Age of Globalisation: International Mechanisms, Non-State Actors and the Struggle for Peoples' Rights in Africa" (2003) 18 *Am. U. Int'l L. Rev.* 851, at 911.

[898] G.J. Annas, "The Right to Health and the Nevirapine Case in South Africa" (Feb. 20, 2003) 348:8 *N. Engl. J. Med.* 750

[899] J. T. Gathii, "Rights, Patents, Markets and the Global Aids Pandemic" (2002) 14 *Fla. J. Int'l L.* 261; J. Klaaren, *supra* note 868.

[900] D. van Rensburg et al., "Primary Health Care Facilities Survey" in A. Ntuli et al., eds., *South African Health Review 2000* (Durban: Health Systems Trust, 2001) 3-50 survey quoted in L. London,*supra* note 2.

[901] W.O. Oyugi, "Service Provision in Rural Kenya: Who Benefits?" in J. Semboja & O. Therkeldsen, *Service Provision under Stress in East Africa* (Copenhague: Center for Development Research, 1995) 121, at 124 et ss. on the priority that the Kenyan Government awards wealthy citizens living in urban areas compared to those living in rural areas (who often end up neglected with regards to property rights and resources allocation).

When they exist, local funds do not always get distributed in a way that respects the right to health. In Nigeria recently, the government spent $350 million to construct an Olympic Stadium, while the nation's doctors and professors where not receiving their paycheques—a clear example of mismanagement of available funds.[902]

In the face of institutional and economic limits and sometimes doubtful priorities, some have proposed reliance on a minimum core obligation that would be enforced by the Court and could require states to dedicate all of their available resources to the fulfilment of the "minimum essential levels of a right."[903] Such an approach could help justify a focus on individuals' basic health needs and the achievement of a minimum level of health for all. It would complement our ideal proposal in favour of resource distribution to achieve the level of health necessary to benefit from equality of opportunities. Up to now, the Constitutional Court of South Africa has not relied on the concept of minimum core obligation to impose a real, progressive realisation of the right to health with clear indications as to what governments should prioritise.[904]

Now that we have a better idea of the legal context under which drug accessibility issues arise in the developing world, it is relevant to refer to one last practical example demonstrating the intersection of human rights and intellectual property: the accessibility of life-saving HIV/AIDS drugs in the developing world.

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[902] S.A. Agbacka,*supra* note 773; S Udeala, "NLC Faults FG over N38bn Abuja Stadium Contract" (July 19 2001) *VANGUARD* (Lagos) online: <http://www.vanguardngr.com/news/articles/2001/July/19072001/b1190701.htm> (accessed : June 4th, 2006); U.N. Comm. on ESCR, Concluding Observations of the Report of Nigeria, at para. 28, U.N. Doc. E/C.12/1/Add.23 (1998); more generally on funds allocation, see J. T. Gathii, *supra* note 883.

[903] However, this would give considerable power to the judicial, something that would not be compatible with every political system. For more on the minimal core obligation see: D. Bilchitz, "Placing Basic Needs at the Centre of Socio-Economic Rights Jurisprudence" (March 2003) 4:1 *Socio-Economic Rights Project*; S. Liebenberg, "The Right to Social Assistance: The Implications of Grootboom" (2001) 1:7 *S. Afr. J. of Hum. Rts.* 232; J. Klaaren, *supra* note 868.

[904] D. Bilchitz, *ibid.*

5.2.2. Accessibility of HIV/AIDS drugs

This example is very relevant in illustrating the effect of the patent and the human rights systems on health accessibility in developing countries. As Michael Kirby has stated in reference to HIV/AIDS drugs, "although these are not genomic drugs, as such, they illustrate vividly the kinds of developments that will occur as tests and therapies are produced as a result of genomic research."[905]

Over the last 20 years, the HIV virus and AIDS disease have grown in magnitude both in developed and developing countries.[906] In fact, AIDS is still the infectious disease that kills the most people every year, even though many drugs have been developed to slow down the progression of the disease, control the virus, prevent mother-to-foetus transmission, and improve patients' lives. Since 1996, reliable anti-retroviral medicines have been available to control the disease. As an HIV cocktail regimen can cost between US$10 000 and US$15 000 per year, the prognosis for individuals infected with HIV in the developed and in the developing world is very different.[907] In a developing nation, a person infected with HIV and left untreated will likely die within 2 years of the onset of full-blown AIDS; in the western world, HIV/AIDS is a serious and chronic disease that can be controlled with anti-retroviral therapy for a lifetime. The difference is, quite literally, life and death. Indeed, as it appears from the statistics, although the disease's progression has been appreciably controlled in industrialised countries (which represent a huge market for HIV/AIDS drugs), the situation is still critical in developing nations, where the pandemic kills millions each year. Poverty is the main indicator of vulnerability to HIV.[908] For

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[905] M. Kirby, *supra* 477.

[906] In fact, according to UNAIDS, in 2004, there were approximately 40 million of people infected with HIV/AIDS worldwide, 26 million in Sub-Saharan Africa and 7 million in East and South East Asia. Between 1981 and 2003, AIDS killed about 20 million of people worldwide. In 2004 alone, more than 3 million died from the disease. This obviously has had (and is expected to continue to have) tremendous impact on the most affected countries, especially in terms of labour forces and economic potential. For more details and figures, refer to: UNAIDS/ WHO, *Aids Epidemic Update*, Geneva, December 2004.

[907] L. C. Fentiman, "AIDS as a Chronic Illness: A Cautionary Tale for the End of the Twentieth Century" (1998) 61 *Alb. L. Rev.* 989.

[908] G. Stine, *AIDS Update 2000* (Upper Saddle River, N.J.: Prentice Hall, 2000) at 11.

example, about 70% of the world's HIV-positive adults and 80% of the world's HIV-positive children live in Sub-Saharan Africa; 95% of all HIV-positive people live in less-affluent nations.[909]

Some have tried to explain problems with accessibility to HIV/AIDS drugs by cultural differences, arguing that some populations' cultural values are incompatible with strict compliance with complex anti-retroviral cocktails and a precise dosing schedule.[910] However, studies have clearly refuted this argument, showing successful use of anti-retroviral regimens in Haiti, Sub-Saharan Africa, and Brazil, where successful prevention and treatment strategies have been put in place.[911]

Despite sporadic initiatives by pharmaceutical companies to provide patented HIV medicines to some developing nations at a fraction of the price (and sometimes even for free), access remains very limited. It has been argued that such initiatives are inadequate for establishing any form of sustainable global health strategy, and that they are used more as a public relations and marketing exercise than anything else.[912]

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[909] The situation is so critical in some parts of the world that some mothers infected with HIV/AIDS are forced to choose between breastfeeding their newborn babies (exposing them to the disease) or bottle-feeding with contaminated water (exposing them to other dangerous infections). For more facts on the epidemic, see: P.G. Harris & P. Siplon, "International Obligation and Human Health: Evolving Policy Responses to HIV/AIDS" (2001) 15:2 *Ethics and International Affairs* 1; G. Stine, *ibid*; R.P. Petchesky, "Rights and Needs: Rethinking the Connections in Debates over Reproductive and Sexual Rights" (2000) 4:2 *Health and Human Rights* 17; K. Siverstein, "Millions for Viagra, Pennies for Diseases of the Poor" (19 July 1999) *The Nation* 13.

[910] For a detailed explanation of this argument see: P. Marshall and B. Koenig, "Accounting for Culture in a Globalized Bioethics" (Summer 2004) 32:2 *The Journal of Law, Medicine and Ethics* 252.

[911] J. Mukherjee, "HIV-1 Care in Resource-Poor Settings: A View from Haiti" (2003) 362 *Lancet* 994; P. Farmer et al., "Community-Based Approaches to HIV Treatment in Resource-Poor Settings" (August 4, 2001) 358:9279 *Lancet* 404; A. D. Harries et al., "Preventing Antiretroviral Anarchy in Sub-Saharan Africa" (August 4, 2001) 358: 9279 *Lancet* 410; for more on the critic of the cultural argument see: P.G. Harris & P. Siplon, *supra* note 909; P. Farmer, "On Suffering and Social Violence: A View from Below" in A. Kleinman, V. Das & M. Lock, eds., *Social Suffering* (Berkeley: University of California Press, 1997) 278.

[912] This is due, in part, to the strict conditions attached to the agreements, to their precariousness, and to the type of discounts (which are generally not competitive with what generic companies can offer). For more on these agreements, see: S. Joseph, *supra* note 434; B. Brubaker, "The Limits of $100 Million; Epidemic's Complexities Curb Impact of Bristol-Myers's Initiative" (Dec. 29, 2000) *Wash. Post*, at A1; Oxfam, *Generic Competition, Prices and Access to Medicines: The Case of Antiretrovirals in Uganda,* Briefing Paper 26, 10 July 2002, online on the Oxfam website: <http://www.oxfam.org.uk/what_we_do/issues/health/bp26_generic.htm> (accessed May 30th, 2006).

The widespread lack of access to affordable medicine is thus the main reason proposed to explain the critical situation. This shortage of available and affordable HIV/AIDS drugs can be explained by several important factors.

5.2.2.1. Human rights and accessibility to HIV/AIDS drugs

Access to medication is important for the progressive realisation of the human right to health, and there have been a number of initiatives to try and secure better access to HIV/AIDS drugs.[913] To this effect, "[s]tates are called upon to pursue policies which would promote the availability, accessibility and affordability for all without discrimination of scientifically appropriate and good quality pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS."[914]

Human right arguments have been crucial for framing the reactions of South American and South African governments and activists to the HIV/AIDS crisis.[915] They have allowed the identification of common and collective interests needed for an adequate and sensitive response to the HIV/AIDS epidemic.[916] For example, in Latin America, strong advocacy and legal action have been undertaken. This has brought a number of nations in the region to acknowledge the right to health, as well as to antiretroviral drug therapy, through court rulings and administrative decisions on health policy.[917] For example, in Argentina, after three years of legal proceedings,

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[913] For example, see: UN Commission on Human Right, *Access to Medication in the Context of Pandemics such as HIV/AIDS* Resolution 2001/33, Geneva, 23 April 2001, UN Doc. E/2001/ 23-E/CN.4/2001/i67; World Health Assembly, *HIV/AIDS: Confronting the Epidemic*, Resolution WHA 53:14, Geneva, 2000; UNHCHR and UNAIDS, *HIV/AIDS and Human Rights: International Guidelines*, New York and Geneva: UN, 1998, UN Publication no. HR/PUB/98/ 1.

[914] WHO, "25 Questions on Health and Human Rights" (July 2002) 1 *Health and Human Rights Publication Series*, online on the WHO website, <http://www.who.int/hhr/NEW37871OMSOK.pdf> (accessed June 2nd, 2006), question 22, at 25; S. Joseph, *supra* note 434, at 441-442.

[915] L. London, *supra* note 2; S. Harrison & M. Qose, "Health Legislation" in A. Ntuli, ed., *South African Health Review 1998* (Durban: Health Systems Trust, 1999) 17.

[916] J.M. Mann, "Human Rights and AIDS: The Future of the Pandemic", in J. M. Mann et als., eds., *Health and Human Rights* (New York: Routledge, 1999) c. 15.

[917] E. Gonzalez Mac Dowell, "Juridical action for the protection of collective rights and its legal impact: A case study" (Winter 2002) 30:4 *The Journal of Law Medicine and Ethics* 644

the Supreme Court released an important decision in 2000, guaranteeing access to HIV treatment and rejecting the argument that the judiciary should refrain from intruding in the executive competence to make budgetary decisions.[918] Also, in *Bermudez et al* v. *Ministerio de Sanidad y Asistencia Social*,[919] the Venezuela Supreme Court reaffirmed that the right to health includes access to anti-retrovirals for those in need. The Court ordered the Minister to find money to ensure an adequate supply of these therapies and of drugs to cover associated infections, and to undertake research on HIV/AIDS for better treatment and prevention of the disease. Instead of limiting the effect of its decision to the petitioners, the Court went as far as extending it to all patients in need.

In South Africa, following strong activism from NGOs, the right to access anti-retroviral therapies was also included in the right to health and acknowledged by the courts. The recent decision of the Constitutional Court in *Health* v. *Treatment Action Campaign*[920] provides an interesting example. While the manufacturer of Nevirapine (an anti-retroviral drug that greatly reduces the risk of mother-to-child HIV transmission[921]) had agreed to provide it for free to the South African government for a period of five years, the government adopted a policy that restricted its availability to only 18 research centers involved in a pilot study. On July 5th, 2002, the Constitutional Court affirmed a Trial Court's decision [922] and ruled that the

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[918] *XXX* v. *Ministry of Health*, Supreme Court of Argentina, June 1, 2000 as cited in E. Gonzalez Mac Dowell, *ibid.*, at 646. Despite this decision, however, HIV drug-delivery ceased 1½ years later, and a new decision was rendered in 2002 to order the Ministry of Health to continue distributing treatment to people in need (Civil Federal Court decision of April 26, 2002); see also M. Bianco et al., *Human Rights and Access to Treatment for HIV/AIDS in Argentina* (Buenos Aires: FEIM/ LACCASO, 1999) online: <http://www.laccaso.org/pdfs/argeng.pdf > (accessed May 29th, 2006), at.15.

[919] *Bermudez et al* v *Ministerio de Sanidad y Asistencia Social*, 15 July 1999, Supreme Court of Justice of Venezuela, Case No. 15.789, Decision No. 916; for more details on this case, see UNAIDS, *Putting Third First: Vaccines, Access to Treatment & the Law*, Barcelona, July 2002, online on the website of AIDSLAW:
<http://www.aidslaw.ca/barcelona2002/treatmentpapers.doc> (accessed May 28th, 2006), at 33-34.

[920] 2002 (5) SALR 721 (CC)

[921] L.A. Guay et als. "Intrapartum and Neonatal Single-Dose Nevirapine Compared with Zidovudine for Prevention of Mother-to-Child Transmission of HIV-1 in Kampala, Uganda: HIVNET 012 Randomised Trial" (1999) 354 *lancet* 795; B. Hirschel & P. Francioli, "Progress and Problems in the Fight Against AIDS" (1998) 338 *New Eng. J. Med.* 906; E. M. Mckenna, "The Mandatory Testing of Newborns for HIV: Too Much, Too Little, Too Late" (1997) 13 *N.Y.L. Sch. J. Hum. Rts.* 307.

[922] *Treatment Action Campaign* v. *Minister of Health, High Court of South Africa*, Transvaal Provincial Div., 2002 (4) BCL 356M, Dec. 12, 2001.

government's policy decision was unreasonable and violated women's and children's right to health (s. 27 & 28 of the constitution). The Court ordered that Nevirapine be distributed broadly and without delay in the public health institutions where counselling and testing services are available.[923]

In all these cases, governments moved slowly in implementing the court orders. Although recognised in many important legal documents,[924] socio-economic human rights of poor individuals infected with HIV are not always given the priority they deserve. As discussed in the human rights chapter, many obstacles stand in the way of efficient implementation of those rights. In some cases, like the Nevirapine situation, lack of drug accessibility is not caused by strong IP rights, but by government laxity; by its failure to take the right to health seriously; and by a shortage of human and infrastructure resources necessary for wide dispensation of available life-saving drugs.[925] In other cases, IP is one factor that influences HIV-drug affordability and the realisation of the human right to health.

5.2.2.2. IP rights and accessibility of HIV/AIDS drugs

There are a growing number of patents in areas connected to fundamental needs.[926] Because most of the existing HIV/AIDS medicines are patented in numerous

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[923] In fact, the court ordered the government to perform four specific actions detailed in G.J. Annas, "The Right to Health and the Nevirapine Case in South Africa" (Feb. 20, 2003) 348:8 *N. Engl. J. Med.* 750.

[924] For example, see United Nations General Assembly, 26th Special Session, *Declaration of Commitment on HIV/AIDS, A/Res/S-26/2*, June 27, 2001; UNAIDS, *The African Consensus and Plan of Action: Leadership to Overcome HIV/AIDS*, December 7, 2000; see also L. London, *supra* note 2; G.J. Annas, "The Impact of Health Policies on Human Rights: AIDS and TB Control" in J.M. Mann et al., eds., *Health and Human Rights: A Reader* (New York: Routledge, 1999) 374.

[925] For example, the South African government has always been very reluctant to qualify HIV as a high health priority, even expressing doubts about the very safety of Neverapine. The government went so far as to request a revision of the drug approval by the Medicines Control Council. For more on this, see: A.S. Baleta, "Africa Soaks up Pressure to Change HIV/AIDS policy" (2002) *Lancet* 360; see also D. Bilchitz, "South Africa: Right to Health and Access to HIV/AIDS Drug Treatment" (2003) 1:3 *International Journal of Constitutional Law* 524.

[926] Commission on Human Rights, *Access to Medication in the Context of Pandemics such as HIV/AIDS, Resolution 2001/33*, in Report on the 57th Session, 19 March-27 April 2001, UN Doc. E/2001/ 23-E/CN.4/2001/i67.

developed and developing countries, their prices are affected by licensing fees that can have direct negative impacts on drug affordability and on the production of cheaper generic options. Many researchers have analysed the effects of patents on the costs of HIV/AIDS drugs. Some have found that market exclusivity greatly increases the price of patented products and that, while patents seem to promote availability of HIV/AIDS drugs to patients who can pay for them, they also hinder access for the ones who cannot afford to pay high prices.[927] Other researchers, analysing the cost of ten essential drugs in eight countries, observed that the cost of HIV/AIDS drug is as much as 82% cheaper in countries with access to generic versions of the unpatented drugs.[928] The price of fluconazole, for example, a drug used to treat HIV/AIDS-infected patients, costs $20 a day in Kenya (where it is patented); the generic version produced in Thailand (and *unavailable* in the Kenyan market) would cost $0.70 a day.[929] Similarly, many generic medicine combinations can be produced for approximately $500 per year, but are not widely *available* to patients from developing nations because of patents on drugs like 3TC, AZT, and Nevirapine.[930]

A more encouraging (but unique) example is the Brazilian program of using generic drugs to deliver affordable and reliable treatment to the population. This initiative succeeded in considerably reducing HIV infections and AIDS deaths, and lowering costs for hospitalisation and medical care.[931] This was made possible because of Brazil's strong manufacturing capacity and its 1996 patent law, stipulating that medicines commercialised before May 14, 1997 would remain off-patent in the country. Because of the way it handled the AIDS crisis in producing generic anti-retrovirals locally, Brazil became a model in the fight against this epidemic. This is,

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[927] J. Borrell & J. Watal, *supra* note 877.
[928] C. Perez-Casas et al, *HIV/AIDS Medicines Pricing Report. Setting Objectives: is there a Political Will?*, Médecins Sans Frontières, July 6, 2000; C. Perez-Casas et al, *Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries, Campaign for Access to Essential Medicines*, Médecins Sans Frontières, October 5, 2001; H. E. Kettler & C. Collins, *supra* note 438.
[929] V. Hoffman, "Health Groups Say Poor Nations Need Access to Generic Drugs" (27 November 1999) *Boston Globe,* at A 15; D.G. Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32 at 154.
[930] Consumer Project on Technology *et al.*, *supra* note 877.
[931] UNDP, *Millennium Development Goals: A compact among nations to end human poverty,* Human Development Report 2003 (New York: Oxford University Press, 2003), at 158-160; S. Buckley, *Brazil Becomes Model in Fight Against AIDS*, (Sept. 17, 2000) *Wash Post* A22.

however, a partial victory; Brazil cannot use this same strategy to produce generic versions of new, potentially more efficient and reliable products commercialised since May 1997.

It is important to repeat, at this point, that the view that patents play an important role in hindering access to affordable important life-saving HIV/AIDS drugs is not universal. In fact, some scholars (and most transnational pharmaceutical companies) argue that patents are not the cause of inequitable access to essential medicines, and that the problem originates instead from poverty and too little spending on health care.[932] Some also believe that even if prices might increase with patent protection, this is a necessary, temporary consequence to promoting innovation and scientific progress, and to fund further R&D.[933] Others believe that accessibility of HIV drugs is more an issue of social welfare policy than a question of IP rights, and that it is governments' responsibility to provide these drugs to their population. This is a weak argument, as it does not take the governments' economic capacities into account and implicitly demands that the public sector unconditionally subsidise private pharmaceutical companies'

[932] The accessibility to AIDS treatment in India, where even massive generic production of low-cost AIDS therapy has not permitted the drugs to reach the majority of the Indian population is often cited to support this view. So does a study conducted in 53 African nations, which found that 15 HIV drugs were not patented in most of these countries. This study was severely criticised, as it did not include several important combinations of patented AIDS drugs. For more on this, see: International Federation of Pharmaceutical Manufacturer Associations, *TRIPS, Pharmaceuticals, and Developing Countries: Implications for Health Care Access, Drug Quality, and Drug Development*, Geneva, 2000; International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, Washington, D.C., 2000; A. Attaran, "How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?" (March-April 2004) 23:3 *Health Affairs* 155; A. Attaran & L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" (October 17, 2001) 286:15 *Journal of the American Medical Association* 1886; L. Gillespie-White, "What did Doha accomplish?" November 19, 2001, International Intellectual Property Institute, online on the IPRs online website, <http://www.iprsonline.org/resources/health.htm> (accessed May 20th,2006).

[933] However, this argument is not very convincing in the case of HIV/AIDS drugs. In fact, as the most affected developing nations represent less than 1% of the global drug market, lowering prices would not have significant effects on drug companies' profits and further innovation. Moreover, in an international health emergency situation like the HIV/AIDS epidemic, the issue should not be prioritising tomorrow's lives over today's lives. The strategy of the most affluent aims instead at preventing subsequent parallel importation from lower-price markets to more affluent markets. C. Barry & K. Raworth, *supra* note 294; H.E. Bale, "The Conflict Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals" (1998) 1:4 *Journal of International Economic Law* 637; D. B. Resnik, *supra* note 354.

activities and profits rather than controlling them.[934] In other words, this argument removes all sense of responsibility from the private sector, while "the state is put in the bizarre circumstance of providing financial assistance to people who cannot afford medicines because the state granted the firm a monopoly on the production of the medicine."[935] Another argument proposed is that the patent system allows an appropriate level of flexibility to address and solve important access issues when necessary. This last idea requires more development.

As discussed above, there is some flexibility built into TRIPS, the Doha Declaration, and the August 30, 2003 decision of the WTO member states, and these mechanisms could allow developing countries to take a stand and work around critical HIV/AIDS drug-access problems towards realisation of the human right to health.[936] With those tools and possibilities at their disposal, one could expect developing nations, especially those most severely affected by the HIV/AIDS epidemic, to do more to limit the negative effects that patents can have on availability and affordability of essential drugs. It seems that these nations would simply need to declare a national health emergency, grant licenses to local manufacturers for the production of life-

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[934] For an interesting discussion on this point, see: R. L. Ostergard, Jr., "Intellectual Property: A Universal Human Right?" *supra* note 379, at 169-170.

[935] *Idem*, at 170.

[936] Although we have already discussed some of these normative dispositions under 3.3.2.2, it appears relevant to repeat some of them here, in relation to the specific problem of access to HIV/AIDS drugs. Art. 27(3) a) of TRIPS stipulates that governments can decide to exclude some pharmaceuticals from patent protection if it appears essential for the protection of public health. Compulsory licensing is authorised by art. 31 of TRIPS, which allows governments to grant limited authorisation to use the object of a patent without the patent holder's consent under strict conditions, including national emergency and other circumstances of extreme urgency. Moreover, art. 6 of TRIPS and par. 5 d) of the Doha Declaration leave it to the member states to decide how they wish to apply the principle of exhaustion of rights within their territory. This choice can have important consequences on affordability, and could allow less affluent countries to access essential health-related products like HIV/AIDS drugs that they wouldn't otherwise be able to afford (on their domestic market). Furthermore, par. 4 of the Doha Declaration specifically states that TRIPS should not prevent states from taking steps to protect public health and should be interpreted and implemented so as to allow member states to promote access to medicines for all. Par. 5 (3) also specifies that every country should be entitled to decide what constitutes a national health emergency, including those related to HIV/AIDS, malaria, and other epidemics. Finally, the August 30, 2003 decision allows exportation of products made under compulsory licenses to countries who do not have sufficient manufacturing and production capacity, and who need help dealing with serious public health problems. This requires amending TRIPS, something that was decided by the WHO members on December 6, 2005, when they agreed to transform the August 2003 waiver into a permanent amendment to TRIPS. For more details on this decision, refer to: WTO, Amendment to the TRIPS Agreement, Decision of 6 December 2005, Geneva, WT/L/641, December 8, 2005).

saving generic medicines at a fraction of the price, and adopt a broad strategy of parallel importation.[937] However, this has not been happening for economic and political reasons highlighted at many occasions in the course of this dissertation. It is safe to say that the most affluent countries have instead often hindered developing nations' efforts to address the HIV/AIDS epidemic with the resources they have, in the most economically efficient way.[938]

Consequently, regardless of the seriousness of the global health crisis resulting from HIV/AIDS and in spite of the existing theoretical normative flexibility, it is not surprising that "apparently no African country has issued a compulsory license for any medicine."[939] Indeed, we saw that the South African government has even been sued by private pharmaceutical firms for enacting legislation allowing compulsory licensing and parallel imports, an example which is characteristic of the attitude of the most affluent states towards less-developed states' socio-economic development.[940] Even with the enactment of Doha, the real value of such flexibility has been principally in its potential as a negotiating tool. In other words, "[t]he practical value of the existence of compulsory license provisions in the Patent Law is that the threat of its use usually induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished."[941] This is at the heart of a global system that accepts and even

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[937] D.G. Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32, at 141-166.
[938] P.G. Harris & P. Siplon, *supra* note 909.
[939] J. Love, "Access to Medicine and Compliance with WHO TRIPS Accord" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 74, at 87.
[940] S.A. Agbacka, *supra* note 773: see also H. Guisse, *The Realization of Economic, Social and Cultural Rights: Final Report on the Question of the Impunity of Perpetrators of Human Rights Violations*, 1997, U.N. Doc. E/CN.4/Sub.2/1997/8.
[941] S. Ladas, *Patents, Trademarks and Related Rights- National and International Protection* (Cambridge: Harvard University Press, 1975) at 427. Despite a forced reticence by developing countries toward legal flexibility, we have observed a growing number of initiatives by generic companies and civil society groups over the last few years to compel pharmaceutical companies to license their exclusive rights on brand name ARVs drugs. For example, Cipla-Medpro (a joint venture between an Indian generic company and its South African partner) and the NGO Treatment Action Campaign (TAC) filed a complaint before the South African Competition Commission in June, 2002 to protest the attitude of GlaxoSmithKline (GSK) and other brand-name pharmaceutical companies. They argued that these drug companies were charging excessively for their patented products and were abusing their dominant position at a time where cooperation was key in the fight against the worst health crisis ever encountered. With this initiative, Cipla-Medpro wanted to obtain a compulsory

encourages major access inequalities in key sectors influencing health, life, and death—even at a time when the worst pandemic in history is ravaging a whole continent.

To conclude, it is important to mention that, again, many factors unrelated to patents are likely to influence accessibility of HIV/AIDS treatments. As we have seen, some of these issues relate to nations' international and domestic financial resources, the physical infrastructure in place,[942] and the prevailing political climate. Moreover, the growing number of AIDS orphans in developing countries is another factor influencing national stability. Most will unfortunately end up lacking the "formal education, parental role modelling, or significant skills development" necessary for satisfactory professional and personal development.[943] Judicial cases for enforcing human rights also clearly highlight the limits of relying on legal tools for addressing a complex health tragedy like the HIV/AIDS epidemic at times when amasingly high poverty rates, illiteracy, and widespread ignorance still prevail. As we have discussed throughout this dissertation, global health issues need to be addressed through a comprehensive

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license to market ARVs at a fraction of the price charged by brand-name pharmas. In December 2004, in exchange for the withdrawal of the complaint, GSK agreed to grant licenses to Cipla-Medpro and other generic drug companies for the importation and sale of generic ARVs in South Africa. For more on this case, see: S.A. Singham, "Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry" (2000) 26 *Brook. J. Int'l L.* 363; J. T. Gathii, "Construing Intellectual Property Rights and Competition Policy Consistency with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers" (2001) 53 *Fla. L. Rev.* 727, at 769; UNAIDS, *supra* note 860; *GSK Grants License to Cipla in Accordance with Competition Commission Settlement* (December 14, 2004) TAC Electronic Newsletter online on the TAC website: <http://www.tac.org.za/> (accessed on June 4th, 2006); More generally on contractual licenses see: F-K Beier, "Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law" (1999) 30:3 *International Review of Industrial Property and Copyright Law* 251; C. Correa, *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*, South Center, Geneva, October 2000, online on the netamericas website <http://www.netamericas.net/Researchpapers/Documents/Ccorrea/Ccorrea1.pdf> (accessed June 2nd, 2006).

[942] However, while the importance of infrastructure is not questioned, it has been demonstrated that many HIV-related technical interventions, like testing and treatment services, can be performed in infrastructure-poor environments. Better HIV-drug accessibility can also be used as a tool to improve and extend infrastructure. For an enlightening discussion on this point, refer to L. London, *supra* note 2; R. Loewenson & A. Whiteside, United Nations Development Programme, HN/AIDS: Implications for Poverty Reduction (New York: United Nations Development Programme, 2001); P.G. Harris & P. Siplon, *supra* note 909.

[943] P.G. Harris & P. Siplon, *supra* note 909; S. Joseph, *supra* note 434, at 433.

strategy that should include education, nutrition, prevention, capacity-building, and knowledge-transfer initiatives.[944]

Regardless of who or what is to blame for affordability and availability problems in developing countries, Cooper Ramo's shocking statement remains prescient: "[w]hat's going on in Africa right now is a crime. When the history of our times is written, future generations will be astonished that we watched the death of 40 million people—at least half of which we could have prevented—and did nothing."[945] There are, however, signs that things are slowly changing. In this respect, it appears relevant to say a few words on an international initiative undertaken to address neglected diseases affecting the most-vulnerable and less-affluent of the world: the Global Fund to fight AIDS, Tuberculosis and Malaria. This fund is an independent public-private partnership between governments, international organisations, companies, activists, and communities seeking to raising money and improve resources available to eradicate these diseases. This fund was launched by the G8 in January 2002, following a forceful call by Kofi Annan. It represents an original approach to health funding, as it operates through a grant application system that can serve different purposes, including the production and delivery of drugs, training programs, and prevention campaigns. After an encouraging start, the fund now seems to be in a critical position in terms of funding commitments from its partners, something that, unfortunately, highlights the inherent weakness of such a voluntary, charitable initiative. Depending on the future success rate of this endeavour, this scheme "could challenge the economic orthodoxy which deems that profits and therefore patents are necessary to foster useful R&D."[946] It will be interesting to follow the progress made in fighting these diseases in the next few years.

The last two sections sought to give us a better, more concrete idea about the practical role that intellectual property and human rights can play in terms of accessibility of

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[944] K.M. De Cock, D. Mbori-Ngacha & E. Marum, "Shadow on the Continent: Public Health and HIV/AIDS in Africa in the 21st century" (2002) 360 *Lancet* 67.
[945] J.C. Ramo "The Real price for Fighting AIDS" (July 9, 2001) *Time Magazine* at 5.
[946] S. Joseph, *supra* note 434, at 435.

genetic research and essential drugs in the developing world. We realised that existing legal mechanisms to ensure more equitable distribution of health-related resources are applied inconsistently, not always in the best interest of the most vulnerable people they are meant to protect. The next section provides a brief analysis of the intersection of intellectual property and human rights in health.

5.3 Analysis of the Intersection Between IP and Human Rights in Health

> *However useful saying "that's my right" is in extracting things from the state, it is not good for extracting things from the economy, unless you are a property holder.*[947]

Implementing a human right to health and to scientific benefits can obviously impose limits on the realisation of other rights, like the right to private property. Related to this topic, Chapman says that "many libertarian theorists interpret the provision of a right to health or health care through public financing as amounting to an unwarranted seizure of private property and an intrusion on a property owner's freedom to dispose of his own goods."[948] The liberal tradition is grounded in the importance of private property, which can conflict with the realisation of economic and social rights.[949]

The UDHR recognises the right to property (arts. 17 and 27), and the ICESCR acknowledges a right 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)). Theoretically elevating intellectual property to the rank of a human

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[947] D. Kennedy, *supra* note 598, at 117.
[948] A. R. Chapman, "Conceptualizing the Right to Health", *supra* note 683.
[949] R. Nozick, *supra* note 71; C.B. Macpherson, *Democratic Theory: Essays in Retrieval* (Oxford: Clarendon Press, 1973); E. O'Keefe & A. Scott-Samuel, *supra* note 651.

right has not attracted much attention, and when it did, there was some scepticism.[950] Conceiving IP as a human right means balancing inventors' rights with the positive impact that IP should have on the public in terms of useful innovation and disclosure. As we have seen in previous chapters, IP rights however protect the economic interest of inventors first and foremost in practice.

Private property rights, protected by an independent normative system, are aggressively defended and implemented by powerful economic agents. Some, like Pettersmann, adopt a liberal and individual perspective on trade and property rights, arguing for unrestrained questing for economic benefit through total individual economic liberty.[951] This position presupposes that everyone is in a position to pursue his individual interests through economic means, and ignores the destructive consequences that such rights can have on the vulnerable and less-affluent.[952]

There is an ongoing debate on the scope that should be granted to property and intellectual property rights, especially when they affect the realisation of other basic health rights, such as access to drugs.[953] These two types of rights can conflict, and this can engender serious consequences for the less-affluent individuals, as illustrated by the practical examples presented above. In the face of competing rights such as,

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[950] R. L. Ostergard, Jr., "Intellectual Property: A Universal Human Right?", *supra* note 379. at 175-176; P. Cullet, *supra* note 449, at 145-147.

[951] E.-U. Petersmann, "National Constitutions and International Economic Law", *supra* note 532; E.-U. Petersmann, "How to Constitutionalize International Law and Foreign Policy for the Benefit of Civil Society?" (1998) 20 *Michigan Journal of International Law* 1; E.-U. Petersmann, "The WTO Constitution and Human Rights", *supra* note 532.

[952] A persuasive example of the priority often awarded to private property can be found in the South African constitution, which institutionalises the right to property while simultaneously reducing the possibility of important land reform that could help building a more equitable society: T. Evans, "Universal Human Rights", *supra* note 605: M. Mutua, *supra* note 645, at 151; more generally on the effect of private property rights on other rights, refer to J. Donnelly, "The Social Construction of International Human Rights" in T. Dunne & N. J. Wheeler, eds, *Human Rights in Global Politics* (Cambridge: Cambridge University Press, 1999) 71; S. Picciotto, "Defending the Public Interest in TRIPS and WTO" in P. Drahos & R. Mayne, eds., *Global Intellectual Property Rights, Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) 224, at 236.

[953] C. Krause, "The Right to Property" in A. Eide et als., eds., *Economic, Social and Cultural Rights: A Texbook* (Maartinus Nijhoff, 2nd ed., 2001) at 191-192; P. Cullet, *supra* note 449: see also the UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights in Development Policy, supra* note 47, which states that the scope of IP protection should never interfere with the realisation of the most fundamental human rights.

for example, inventors' intellectual property rights on the one side, and patients' human right to health when they cannot afford patented health goods and services on the other, treaty law asks that states attempt to reconcile all their international obligations.[954] Our theoretical framework for global distributive justice in health demands that we first pay special attention to bringing people to a certain health level where they can profit from available opportunities and have a chance to build a good life. Protecting access to health with access to screening and therapeutic tools can be compatible with property rights protection, if the latter is viewed as having a strong social role to play and are implemented accordingly.[955] Some refer to this as a human rights approach to IP, which would be geared toward the importance of the common good in the evaluation and application of science. This vision necessarily implies a broad interpretation and application of TRIPS' flexibilities and asks for a better and more explicit recognition of people's right to enjoy the benefits of science and right to health in IP rights enforcement, which is somewhat unlikely in the current political and economic context.[956]

In reality, the very architecture of international policy-making in intellectual property revolves around trade officials. Health, labour, and welfare ministers are not invited to WTO or IMF negotiation sessions, even if their sectors of activity are often directly and profoundly affected by the decisions made in those fora.[957] The interests at stake and the meaning of things are not the same in the trade and human rights arenas. Therefore, when we deal with issues likely to have major repercussions in both sectors, conflicting interests should be represented and voiced.[958] As the normative IP system can affect many sectors of activity and can profoundly impact the realisation of vital human rights (including accessibility to health and health care), it appears unacceptable that this system be shaped by trade officials only.

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[954] *Convention on the Law of Treaties*, Vienna, May 23, 1969, art. 26.
[955] C. Krause, *supra* note 953; H. Shue, *Basic Rights, supra* note 245.
[956] As discussed in the last chapter, although these objectives are not completely incompatible with the overall purpose and philosophy of IP rights, the politics and economics of IP do not generally allow the implementation of a strong social vision of IP. P. Cullet, *supra* note 449.
[957] On this topic, see J. E. Stiglitz, *Globalisation and its Discontents*, *supra* note 152
[958] F. Abbott, "The Enduring Enigma of TRIPs" (Dec. 1998) 1 *Journal of International Economic Law* 506.

To this effect, many propositions have been put forward to ensure better protection of the indivisibility of all human rights, particularly socio-economic human rights, against the forces of neo-liberal globalisation and private property. Indeed, the ICESCR Committee has issued many interpretative statements giving direction on how to interpret the covenant in relation to IP issues.[959] One of the most important for us remains the *2000 General Comment 14 on the Right to the Highest Attainable Standard of Health.*[960] It covers the provision of essential drugs and is not opposed to a broad interpretation of the covenant so as to ensure access to patented drugs, even if it implies possible violation of TRIPS. In 2001, the Committee acknowledged a potential conflict between the ICESCR and TRIPS and specified that "any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, [...] is inconsistent with the legally binding obligations of the State party."[961] Many similar initiatives and resolutions have been undertaken and adopted.[962] These proposals can be characterised as "soft law" and will likely remain non-binding on state parties. They could, however, serve as tools for developing countries in the course of further TRIPS negotiations or in dealing bilateral and multilateral agreements, for example.[963]

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[959] M. Craven, *The International Covenant on Economic, Social and Cultural Rights: A Perspective on its Development* (Oxford: Clarendon Press, 1995).

[960] Committee on ESCR, *General Comment No 14*, *supra* note 658.

[961] Committee on Economic, Social and Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*; *Statement on Human Rights and Intellectual Property*, Geneva, December 14, 2001, E/C.12/2001/15, par.12; see also United Nations Sub-Commission on Human Rights, *Intellectual property and human rights, Resolution 2001/21*, Geneva, 2001, UN Doc. E/CN.4/Sub.2/RES/2001/21, par. 3 & 5.

[962] For example, the UN Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property Rights and Human Rights,* Geneva, 2000, E/CN.4/Sub.2/2000/7; Economic and Social Council Committee on Human Rights, *Economic and Social Council Resolution (ESCOR) res. 2000/7 on Intellectual Property Rights and Human Rights*, 52d Sess., Geneva, 2000, U.N. Doc. E/CN.4/Sub.2/2000/L.20; *Report of the High Commissioner--The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 52d Sess., Provisional Agenda Item 4, paras. 10-15, 27-58, Geneva, 2001, U.N. Doc. E/CN.4/Sub.2/2001/13 (2001); J. O. Onyango & D. Udagama, *Globalization and Its Impact on the Full Enjoyment of Human Rights*, U.N. ESCOR Comm'n on Hum. Rts., 53d Sess., Provisional Agenda Item 4, paras. 19-34, Geneva, 2001, U.N. Doc. E/CN.4/Sub.2/2001/10 (2001).

[963] L. R. Helfer, *supra* note 574, at 49-52.

Other important initiatives for better human rights protection emerge from civil society, grassroots, and activist movements, which, over the last decade, have become increasingly organised, articulate, and powerful. They have been the source of various highly-publicised initiatives and campaigns for better human rights protection, including the national and international battles for affordable HIV/AIDS drugs and well-orchestrated resistance to international institution and big pharmaceutical companies' actions.[964] For example, human rights activists lobbied for the consideration of the health needs of the most vulnerable at the 2001 ministerial meeting in Doha.[965] In this case, however, most developing nations unfortunately remained "spectators in the negotiations leading to the adoption of the Doha Ministerial Declaration."[966]

Nevertheless, the important place that property and intellectual property rights occupy both on the national and international scenes, the powerful interests they serve, and the fact that they remain for the most part unsupervised, continue to have negative consequences on the implementation and realisation of human rights.[967] As Rittich states, "where hard and soft strategies are deployed at the same time in respect of the same field or issue, or where hard rights are available to advance the interests of one of the parties involved in a dispute, while the other relies on soft norms to further its case," it is impossible to expect the same normative efficiency from the two systems.[968] Despite such disparity, some argue that, since human rights and intellectual property rights norms are based on the same moral principles, respecting them simultaneously should naturally lead to improving individual welfare worldwide.[969] We have seen, however, that the reality is different. There is great tension between those two systems both in terms of philosophy and concrete

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[964] B. Rajagopal, *supra* note 797; B. Gellman, *An Unequal Calculus of Life and Death; As Millions Perished in Pandemic, Firms Debated Access to Drugs; Players in the Debate Over Drug Availability and Pricing* (Dec. 27, 2000) *Wash. Post*, at A1.

[965] A.R. Chapman, "The Human Rights Implications of Intellectual Property Protection", *supra* note 687, at 881.

[966] B. S. Chimni, *supra* note 664, at 20; See also F. Jawara & A. Kwa, *Behind the Scenes at The WTO : The Real World of International Trade Negotiations* (London ; New York : Zed Books, 2003).

[967] C. Krause, *supra* note 953.

[968] K. Rittich, "The Future of Law and Development", *supra* note 667, at 240.

[969] E-U. Petersmann, "The WTO Constitution and Human Rights" *supra* note 532.

application. The connection between the two arises less in terms of how they can complement each other, and more in terms of how one negatively impacts on the other.[970]

This tension can be explained by that fact that, above all, states rely on IP tools to improve their economic competitive advantages on the global scene. [971] This economic focus results in a considerable advantage for the most powerful and wealthy agents, like major transnational corporations, instead of protecting individual and community access to crucial knowledge and products.[972] This focus appears indefensible, at least in the field of drug development and genetic diagnostic testing, where, to say the least, the level and innovative quality of R&D are not optimal. In other words, despite the fact that the WTO preamble refers to concepts of sustainable development and improved living standards, most of its supporters believe that the global trade system is independent from the system of public international law and is meant to address freedom of trade, not inequities between countries and individuals, equitable distribution, or protection of the most vulnerable.[973]

As discussed throughout the dissertation, the broader global order under which these two normative systems evolve plays an important role in the situation just described. Many factors–including paternalistic western attitudes and policies, colonialism, the interests of the most powerful agents (defended by international monetary institutions through structural-adjustment programs), the burdensome debt loads of developing countries, the priority of efficiency vs equity, and major bargaining power differences—all play an important role in preserving the current

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[970] C. Dommen, *supra* note, 872, at 40-45.
[971] A. R. Chapman, " The Human Rights Implications of Intellectual Property Protection", *supra* note 687.
[972] S. Shulman, *Owning the Future*, (Boston: Houghton Mifflin, 1999); Keith Aoki, "The Stakes of Intellectual Property Law" in D. Kairys, *The Politics of Law: A Progressive Critique* (New York: Basic Books, 1998) at 271.
[973] General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX, 4 T.I.A.S. 669, 55 U.N.T.S. 262; C. Dommen, *supra* note 872, at 46; J. L. Dunoff, "The Death of the Trade Regime" (1999) 10 *Eur. J. Int'l L.* 733; J. T. Gathii, *supra* note 883, at 302-303; on the opposite view that the WTO must be analysed in a public international law context, see: D. Palmeter & P. C. Mavriodis, "The WTO Legal System: Sources of Law" (1998) 92 Am. J. Int'L L. 398.

situation.[974] This broad, neo-liberal framework is rarely questioned or analysed properly, and "[v]iolations of the right to health—whether caused by poverty-related conditions or by lack of access to health care—continue to be invisible, accepted as part of the natural order of things."[975] However, as Mandela pointed out:

> The unavailability of food, jobs, water and shelter, education, health care and a healthy environment is not a preordained result of the forces of nature or the product of a curse of the deities. [...I]t is the consequence of decisions which men and women take or refuse to take, all of whom will not hesitate to pledge their devoted support for the Universal Declaration of Human Rights.[976]

It is difficult to admit that freedom of trade can overwhelm crucial human needs and that the system in place does not guarantee access to basic health necessities to those in need.[977] An effective human rights approach requires that we analyse, question, and criticise the very economic power constructions that create, accept, and even endorse patterns of poverty and ill-health.[978] Achieving goals related to the right to health will not be possible without major changes in the capitalist world economy. Therefore, "[u]nless human-rights advocates provide an effective intellectual and organisational counterweight to economic interests, the intellectual property landscape will be reshaped in the years ahead without adequate consideration of the impact on human rights."[979]

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[974] We refer the reader to the relevant sections of the previous chapters for further discussion on this issue, as well as to enlightening discussions by T.W. Pogge, *World Poverty and Human Rights*, *supra* note 284; C.R. Beitz, *Political Theory and International Relations*, *supra* note 64; C. Thomas, "International Financial Institutions and Social and Economic Human Rights: An Exploration" in T. Evans, ed., *Human Rights Fifty Years On: A Reappraisal* (Manchester: Manchester University Press, 1998) 165; P.G. Harris & P. Siplon, *supra* note 909.

[975] A.E. Yamin, *supra* note 688; see also G. A. Cohen, "Capitalism, the Proletarian and Freedom" in A. Ryan, ed., *The Idea of Freedom* (New York: Oxford University Press, 1982) at 14 quoted in C. Barry & K. Raworth, *supra* note 294.

[976] N. Mandela, *Address at the 53rd United nations General Assembly*, New York, 21 September 1998 quoted in M. Heywood & D. Altman, "Confronting AIDS: Human Rights, Law and Social Transformation" (2000) 5:1 *Health and Human Rights* 149.

[977] R. L. Ostergard, Jr., "Intellectual Property: A Universal Human Right?", *supra* note 379, at 170.

[978] A.E. Yamin, *supra* note 688.

[979] A. R. Chapman, "The Human Rights Implications of Intellectual Property Protection", *supra* note 687, at 15.

Conclusion

This last chapter provided examples of how genes (mostly disease genes) and pharmaceutical patents have hindered accessibility to research tools and therapeutic and diagnostic products and services. Since little information is available on the level of gene patenting in developing nations, it is difficult to measure their actual effects on accessibility. We thus used analogies with genetics cases having arisen in developed nations and with accessibility in the pharmaceutical sector. We have seen that access to health and genetics can be influenced by the functioning of the patent and the human rights systems. This brief analysis demonstrates that global health needs, which are not expressed by purchasing power on the market, are often not taken into consideration by those frameworks.[980] For example, the normative exceptions to strong patent rights are often of very limited practical utility because of the numerous and burdensome conditions to be met, and because of the pressure exercised by the most affluent on the less powerful. Moreover, the system entitles patent-holders to adopt a stringent proprietarianist attitude in relation to the object of their rights, even in cases where it can influence access to essentials and satisfaction of individuals' basic needs and human rights.

The examples presented in this section mainly referred to access to disease genes and essential drugs, and this brief reflection does not allow us to make any general conclusions regarding the effect of patents and human rights on the overall availability and affordability of genetic benefits in developing nations. At present, there is no clear evidence that these systems have had such an impact. However, with the way the actual IP and human rights systems have been working lately, we can safely conclude that extensive patent rights, licensing strategies, and human rights enforcement

[980] This ability will depend on various factors. For example, some countries, like Canada, provide universal health insurance for certain products and services; many countries do not. Depending on whether the patented product is covered by an insurance program, each individual may have to assume health-related costs. D.G Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32, at 25-38.

problems refered to in this dissertation will not be resolved easily. As long as the global capitalist system and its neo-liberal institutions allow and endorse such attitudes, there is a definite possibility that the IP normative system will continue to negatively influence availability and affordability of genetics, and that human rights will be of very limited help in redressing situations where individuals' health and their chance to realise their full potential is in jeopardy.

This last chapter concludes the second part of our dissertation, which has been dedicated to the assessment of the normative systems of intellectual property rights and human rights, with both the benchmarks established in our theoretical framework and a few practical examples. At the very beginning of this dissertation, we presented evidence that benefits arising from genetic science have real potential for improving global health. In the first part, we argued that justice demands a broad redistribution of the benefits of genetics. We defended the equal and universal consideration of every individual's basic health needs to further a broader ideal of equal opportunity for all on the global scene. The analysis of the last three chapters reveals that the two main normative international systems meant to govern global access to scientific innovation and knowledge as well as distribution in health and genetic technology do not operate to advance equitable distributive justice ideals in global health. Our analysis has brought to light the magnitude of the gap between the normative expression of universal ideals of justice, equality, and solidarity, and the real limits imposed by the global world order's politics and economics.

As they currently function, the IP and human rights systems, taken both alone and together, do not allow adequate consideration of human welfare concerns. Despite the numerous positive law mechanisms in place, the philosophy and politics underlying these legal schemes hinder genetic-benefit redistribution and therefore prevent the realisation of global distributive justice ideals to broaden access to common health standards. This, however, does not mean that these normative systems should be completely abolished or replaced. They have definite potential, both individually and in concert, to contribute to global health improvement and allow individuals to

profit from available opportunities. However, significant changes will have to occur in order to find some balance in applying these normative standards.

Establishing detailed solutions and practical policy options is beyond the scope of this dissertation. In conclusion, however, we will say a few words about avenues that could be explored further, to set the basis for further discussion.

Conclusion

> *The primacy of human rights over trade liberalization is consistent with the trade regime on its own terms. The institutions that are the official guardians of trade law pose formidable barriers to the proper and full realization of this insight.*[981]

As significant progress is being made in the field of human genetics, physicians, researchers and governments increasingly recognise that genetic technology, research tools, and therapeutic and preventive services are crucial for the improvement of global health. In particular, there is significant evidence that genetics will play an increasing role in medicine and public health in the coming years, and that it could consequently also have far-reaching impact on the health of developing countries' populations. However, less affluent countries often do not have the financial, technological, and human resources to take advantage of these potential benefits and tailor them to their specific health care needs. Even with an increasing, globally accessible body of scientific and technological knowledge and constant medical progress and discoveries, the condition of human health in many developing countries continues to decline.[982] Disparity in access to products and services arising from genetics is an important issue for the contemporary international policy agenda, and a specific challenge is to find ways to harness genetic knowledge so that it can contribute to global health equity through collaborative efforts. This topic has recently attracted a great deal of attention in many fora, especially in light of the widely-used concept of genetic-benefit sharing. Beyond outrage and intuitive feelings of injustice, however, the debate surrounding the global health and genetics divide

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[981] R. Howse & M. Mutua, *Protecting Human Rights in a Global Economy Challenges for the World Trade Organization*, Montréal, 2000, online on the website of Law and Democracy, <http://www.ichrdd.ca/english/commdoc/publications/globalization/wtoRightsGlob.html> (accessed May 28th, 2006)

[982] C. Juma & L. Yee-Cheong, "Reinventing Global Health: the Role of Science, Technology and Innovation" (March 19th, 2005) 365 *The Lancet* 1105.

needs to be brought one step further, through a deep analysis of the theoretical, legal, normative, socio-economic, and political factors involved in global inequalities.

This dissertation contributes to the debate about what has been called the genetics divide. In the face of the existing powerful market-oriented distribution mechanisms and the conceptual and normative weaknesses of the notion of compensatory benefit sharing, we adopted a different lens through which to analyse and reinvent the concept in relation to global health equity. We focussed on a global way of envisioning benefit sharing to realise distributive justice in health. To this end, we based our reasoning on the idea that justice demands the protection of the most vulnerable individuals to ensure that they benefit from equality of opportunities, an essential element for achieving justice.

The theoretical framework we built covers many different aspects. We first established that an acceptable conception of justice in health should necessarily transcend boundaries. Indeed, while groups and communities are certainly very important units of consideration in many spheres of activity, we determined that we should deal with basic health and genetic needs using individuals as the ultimate unit of moral concern. This discussion resulted in the adoption of a cosmopolitan framework based on a global scheme of cooperation as the basis of our analysis. This global lens established a reference for assessing institutions that could be involved in the distribution of genetic benefits.

Following the establishment of our parameters of reference, we worked on a thorough analysis of the specificity of health to justify the elaboration of a particular framework of distributive justice in this area. Building on the work of Daniels and Rawls, this exercise highlighted the crucial importance of health and genetics for normal functioning, and the need to ensure a fair distribution of goods and services in this field because of the role normal functioning plays in individuals' ability to profit from available opportunities. We then saw the links between ill health, lack of access to genetics, and a reduced range of opportunities and realised, even more, the specific

and universal importance of health. This framework provided us a basis for equal consideration of every person's health, for requiring equality of opportunities and, consequently, for the use of distributive justice schemes to solve avoidable health inequalities and encourage equitable access to the benefits arising from genetics. In other words, our theoretical analysis led us to adopt normative landmarks linked to needs in our assessment of the distribution of benefits arising from genetics rather than continuing to rely on market-based distributive mechanisms.

Following this theoretical analysis, we moved to the second goal of this thesis: assessing the compatibility of two important international legal systems concerned with distribution issues – intellectual property law and human rights law – with our framing principles. Our investigation of the underlying philosophy, principles, structure and operation of these two legal frameworks led us to several conclusions. First, we realised that, although the intellectual property and the human right systems incorporate positive law dispositions relating to human welfare, knowledge diffusion and access, equity, and justice, neither system operates to advance equitable distributive justice ideals in terms of global health. We are faced with the conclusion that both structures, though quite different in their underlying rationales, are nevertheless similar in that they are both driven by powerful interests and market considerations in what we know as the global economy. In other words, although the content of both the international intellectual property and the human rights systems show strong potential for global health improvement, their tacit focus on market efficiency and their tolerance of significant economic and health inequalities represent important obstacles to achieving real access to genetics by people in need. The practical examples discussed in the last chapter confirmed this understanding.

Our work offers a significant contribution to the evaluation and analysis of this situation, beginning with the widely-used notion of benefit sharing, and questioning and restructuring it in such a way as to address and prevent a genetics divide. Doing so, we have produced strong and original normative landmarks that can be used to

justify relying on a cosmopolitan approach to global justice based on health needs and opportunities in the face of major social, political, economic and legal pressure resulting from commercialisation of the fast growing field of genetics. Our overall analysis resulted, however, in the identification of a clear gap between the framework we constructed to give theoretical relevance to global benefit sharing obligations and the legal and political constraints that the application of two major and influential legal systems impose on global benefit sharing. Indeed, we realised that as actually implemented, neither intellectual property nor international human rights guarantee that the benefits of health-related genetics research will be distributed equitably. For each legal system, we faced two kinds of deficit. First, we identified inherent legal (procedural and structural) problems that can impair the realisation of equitable distribution of genetic benefits. Second, we confronted broad, subtle, and major socio-economic and political problems affecting the functioning of the global order.

These findings represent the groundwork needed to initiate policy discussions and to eventually undertake concrete changes to achieve an international redistribution of resources emerging from genetics, and likely for other promising technologies with potential for global health improvement. With this grounding, we can begin to consider whether there exists any short and middle-term policy solutions that we could implement within the actual global architecture. More generally, we can start to think about how to approach the greater challenge of limiting hegemonic forces and powers that lie at the basis of this same global architecture to allow global distributive justice in health. Although establishing detailed solutions and practical policy options is not the aim of this work, by way of conclusion to this thesis, we will, however, say a few words about tensions that would need to be resolved and avenues that could be explored further in the short and longer term, to lay some foundation for further discussion.

Policy options to explore within the existing global structure

Policy makers could have an important role to play in the redistribution of the resources emerging from genetics in terms of global health equity. Indeed, some of the access and justice issues highlighted in this dissertation can be addressed by adapting existing legal structures using built-in flexibilities and proposing changes to the systems. The literature has proposed various means to decrease and eliminate the existing health gap between developed and developing countries. We will briefly address some of these.

Concerning the human rights system, alternative measures could be established within the existing legal structure to address the poor level of enforcement and justiciability of socio-economic rights. For example, one author has proposed a "concerted and integrated approach"[983] under which socio-economic human rights could be indirectly enforced though the application of civil and political human rights, or be considered as a specific social or ethical dimension of those same civil and political rights, given the clear link existing between the two types of rights and the better justiciability of the latter.[984] This strategy would only emphasise and give concrete expression to the already well-recognised principles of indivisibility and inter-relatedness of rights. Another way of envisioning socio-economic rights implementation has been to argue for their progressive realisation through a "minimum threshold approach." This approach would justify compelling governments to defend their priorities and require that they provide the minimum level of enjoyment of the whole range of basic human rights before prioritising any sector of economic activity.[985] Such an approach could be more effective with the

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[983] S.A. Agbacka, *supra* note 773.

[984] As was done by the European Court of Human Rights in *Airey* v. *Ireland*, *supra* note 703, which enforced the right to legal aid through the right to a fair trial and by the European Commission on Human Rights in *Tavares* v. *France*, App. No. 16593/90, Eur. Comm'n H.R. Dec. & Rep. (Sept. 12, 1991) which enforced the right to health through the right to life; on the topic, see also C. Scott & P. Macklem, "Constitutional Ropes of Sand or Justiciable Guarantees? Social Rights in a New South African Constitution" (1992) 141 *U. Pa. L. Rev.* 1 at 29.

[985] A. Bard-Anders et al., "Assessing Human Rights Performance in Developing Countries: The Case for a Minimal Threshold Approach to Economic and Social Rights" in A. Bard-Anders & E. Asbjorn, eds., *Human Rights in Developing Countries* (Copenhagen: Akademisk Forlag, 1988) at 333.; S.A.Agbacka, *supra* note 773

establishment of specific indicators against which we could assess compliance with a minimum level of socio-economic rights.[986]

In terms of changing the patent system, patent pools have been proposed as a response to the potential negative effects of patents on fundamental research and access to technology. A patent pool arises when patent-holders mutually agree to license their patents to each other and to third parties. It has been suggested that the application of patent pools in the area of diagnostic genetics may work to provide greater access to genetics technology and to encourage collaboration between different agents involved in this sphere of activity who share the same goal of developing accurate, safe, and reliable testing methods for given polygenic diseases. However, industry may be reluctant to share their patents via a pool, preferring instead to pursue their research alone with the hope of bigger financial returns.[987] To solve this dilemma and encourage the formation of patent pools in genetics, inventive and attractive licensing and financial redistribution schemes could be set up to encourage industry to appreciate and acknowledge the financial and social advantages of a patent pools.[988] Nevertheless, many other challenges remain to the feasibility of patent pools in genetics. More research and a more thorough analysis than cannot be offered here would be needed to assess whether, in the end, patent pools offer any real hope of addressing access concerns.

Innovative licensing strategies could also play an important role in securing access to genetics by developing countries.[989] Indeed, when licensing fees become prohibitive in terms of affordability of innovations, developing countries should think about other modes of securing access to patented technologies. As discussed briefly in the course

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[986] P. Hunt, *Interim Report of the Special Rapporteur of the Commission of Human Rights on the Right of Everyone to Enjoy the Highest Attainable Standard of Health*, 58th Sess., Agenda Item 117(c). A/58/427, 10 Oct. 2003.
[987] A.K. Rai, *supra* note 422.
[988] T.J. Ebersole, M. C. Guthrie & J. A. Goldstein, "Patent Pools as a Solution to the Licensing Problems of Diagnostic Genetics" (Jan. 2005) 17:1 *Intellectual Property & Technology Law Journal* 6, at 11.
[989] L. Nelsen, "The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries" (January 2003) III:2 *Yale Journal of Health Policy Law and Ethics* 301.

of this dissertation, one solution is to allow compulsory licensing within national patent systems, as permitted by TRIPS under the heading not only of "national emergency or other circumstances of extreme urgency" but also of "public non-commercial use" (art.31 TRIPS).[990] Some are of the view that these last-resort restrictions are very limiting and suggest that the scope of compulsory licenses should be extended to help provide access to genetic tools and technologies for prevention purposes, for example.[991] We instead believe that the problem is not with the rights themselves but with how some countries are afraid to use and enforce them out of fear of retaliation from the most powerful countries. Another solution would be for governments to use mechanisms to encourage different industry sectors to agree on consistent and uniform advantageous licensing practices when dealing with developing nations. Such an agreement could create "ethical business leadership" while helping countries to meet their international cooperation obligations and would likely not affect private profits substantially.[992] Apart from licensing, other mechanisms exist in IP law to facilitate access and are also widely debated and discussed on the international scene.[993]

In addition to these system-specific initiatives, more effort could be expended to better ensure compatibility and connection between human rights and intellectual property rights. The gap that makes them evolve on separate tracks could be bridged, at least partially, using different strategies, such as working towards a more organised

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[990] E. R. Gold & D. Lam, "Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing" (2003) 6 *The Journal of World Intellectual Property* 5. The WTO's General Council adopted a decision in August 30th, 2003 in Cancun, which allows countries without manufacturing capacity to also use compulsory licensing for importation rather than production.

[991] C. M Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries,* Working Paper for the Center for Advanced Studies at the University of Buenos Aires, Argentina.

[992] A. Attaran & L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?, *supra* note 932.

[993] We are referring, for example, to differential pricing and price control depending on the market and the consumers' ability to pay, imposing local working of patented products following their introduction in a given market, allowing R&D of generic products before the patent expires with Bolar provision, and allowing parallel imports of patented products. For an extensive discussion on those mechanisms, refer to H. E. Kettler & C. Collins, *supra* note 438; J. Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement* (Oxford: Blackwell Publishers, 2000); J.H. Barton, *Differentiated Pricing of Patented Products, Commission on Macroeconomics and Health Working Paper Series*, Paper No. WG4:2, July 2001.

and concerted action and strategy from different branches of the civil society; improving the dialogue between policy makers and governmental officials of the two sectors on the national and international scene; and focussing on the social role of IP rights, on their compatibility with human rights and on their related capacity to protect access to a certain level of health in priority. For example, in response to the major normative and political obstacles they face with TRIPS' application, some developing countries, assisted by international NGOs and intergovernmental organizations, are now trying to further their interests in other fora, adopting strategies of regime-shifting. These initiatives aim to expand IP lawmaking in other regimes like biodiversity, public health, and human rights to address the social aim of IP and challenge and revise some of TRIPS' problematic dispositions and associated practices.[994] This can result in conflicting and contradictory legal obligations, and the results will depend on the nature of the emerging documents, binding or non–binding; their enforcement mechanisms; and the authority, mandate, and resources of the organisation in charge of implementing them.

As well as legal mechanisms, new types of business strategies and partnerships could also be explored and adopted to complement the human rights and the intellectual property rights systems. For example, in reaction to global health inequalities induced by market forces, some have proposed reliance on new ways to finance R&D in genetics, especially for neglected conditions, involving key players though public private partnerships (PPP).[995] As an alternative to PPP, some have instead proposed a

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[994] L. R. Helfer, *supra* note 574.

[995] Such a strategy aims to get funds from the private sector to further R&D for global health issues with the ultimate purpose of providing affordable and adapted goods to populations from the developing world. To this end, IP arrangements have to be negotiated creatively to ensure that private companies have enough commercial incentive to invest and that IP can also be used as a tool in the pursuit of social objectives. Such an initiative has taken place in many spheres, including malaria, tuberculosis, and AIDS research with the Global Fund to fight AIDS, Tuberculosis and Malaria. They can achieve rapid and quality results and crucial social goals but can also be perceived negatively by some companies who are not willing to take the risk of being limited in the way they can use IP rights. Up to now, results achieved by PPP have been mitigated. For more on PPP, see: E. Ziemba, *Public-Private Partnerships of Projects Development: Financial, Scientific and Managerial Issues as Challenges for the Future*, CIPIH Research Report, Geneva, 2005, online on the WHO website: <http://www.who.int/intellectualproperty/studies/Ziemba.pdf> (accessed May 21, 2006); H. Thorsteinsdottir et al. "Genomics, a Global Public Good?" (2003) 361 *Lancet* 891, at 892; H. E.

mandatory global *need tax* mechanism, which would be applicable to the profits of private agents in certain high-profile spheres of activity and subsequently redirected toward the needs of developing countries.[996] Another option is a *Global Resources Dividend*, requiring agents who exploit natural resources to compensate those who do not have the opportunity to make use and profit from the same resources.[997] Another possibility would be to establish an international regime overseeing the pursuit of research and development activities and the distribution of benefits in the area of human genetics.[998] Instead of being exclusively driven by IP law, this system could be a stand-alone mechanism and be viewed both as an alternative and a complement to the present regime.[999] An additional area where attention could be focussed is the improvement of public, government, media, and health professional awareness of the medical potential of genetics, the functioning of the IP system, and important international negotiations on complex technological and normative issues. This could take the form of a global network of different agents involved in the field with a strong presence of people from developing countries and the civil society.[1000]

Kettler & C. Collins, *supra* note 438 at 26; P. Trouiller et als., "Drug Development for neglected Diseases: A deficient Market and a Public-Health Policy Failure" (June 2002) 359 :9324 *Lancet* 2188.

[996] D.G Richards, *Intellectual Property Rights and Global Capitalism, supra* note 32, at,141; L. Doyal & I. Gough, *supra* note 92.

[997] T. Pogge, "Severe Poverty as a Violation of Negative Duties", *supra* note 278; T.W. Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms*, *supra* note 159; T.W. Pogge, "A Global Resources Dividend", *supra* note 331 in D. Crocker & T. Linden, eds., *Ethics of Consumption* (Totowa, NJ: Roman and Littlefield, 1999) 501; T. Hayward, "Thomas Pogge's Global Resources Dividend: A Critique and an Alternative" (2005) 2:3 *Journal of Moral Philosophy* 317.

[998] It could follow the distribution model established in the recent International Treaty on Plant Genetic Resources for Food and Agriculture FAO, International Treaty on Plant Genetic Resources for Food and Agriculture, *supra* note 43. To this end, an international organisation could be in charge of the regime, collecting royalty fees from the use of the human genetic pool and setting up redistribution mechanisms on the basis of the impact of inventions on global health, for example. For more on what those systems could look like, refer to: T.W. Pogge, *supra* note 3; A. Motoc, *Specific Human Rights Issues, Universal Declaration on the Human Genome and Human Rights*, UN Economic and Social Council, Geneva, 2002, doc.E/CN.4/sub.2/2002/37, par. 13-15; WHO, Genetics, genomics, *supra* note 19.

[999] For example, it could include terms consistent with section 67 of TRIPS, which provides a basis for cooperation between affluent and less affluent countries while concurrently ensuring transfer of a portion of patent royalty fees to the researchers involved.

[1000] It could be similar to the latest regional initiative of the New Partnership for Africa's Development (NEPAD) or the *Global Genomics Initiative* proposed by the Joint Centre for Bioethics recently. For more information on these, see NEPAD and African Institute for Capacity Development (AICAD), *Memorandum of Understanding to collaborate on Capacity Development and Poverty Reduction in Africa*, Kenya, November 4th, 2005; and Joint Center for Bioethics, *Genomics and World Health*, Toronto, 2004, at 42-44.

This being said, even if some negative consequences of socio-economic and health inequalities could theoretically be addressed through human rights law and intellectual property law built-in flexibilities and complementary policy and business strategies, it has become clear, in the course of the thesis, that neither system is currently working very effectively in equitably distributing benefits. Socio-economic rights are often perceived as "feel good window dressing" rather than real, enforceable norms,[1001] and IP flexibilities are frequently of very limited practical utility. This is not a problem, however, with the systems per se, but is instead symptomatic of the larger, troubling economic and political global reality analysed in the dissertation.

Indeed, the patent system is intended, in part, to provide incentive for innovation, disclosure of invention, and, ultimately, increase public knowledge. IP law is not static, and if we go back to its roots and emphasise its role in greater knowledge diffusion and access, it can contribute to improving the social good. In fact, the basis of the global trade system was established as part of a broader objective of global peace and security following the World War II. This is clearly evident from art. XX of the GATT on the primary importance of protecting public morals and human life, and from the Preamble of the *Agreement Establishing the WTO*, which states that the purpose of the system is not free trade at all costs, but also "allowing for the optimal use of the world's resources in accordance with the objective of sustainable development."[1002] As suggested by May, the public access and social utility aspects of IP should therefore be emphasised and elevated to the rank of primary consideration, while relegating the private characteristics to the status of privilege.[1003] Similarly, the human rights system aims to address, limit, and solve different types of inequalities with the ultimate ideal of attaining universal respect for human beings' freedom, dignity, and equality. It is therefore important to emphasise, again, that equity and access problems are not created by the systems of IP rights and human

[1001] M. Darrow & T. Amparo, "Power, Capture and Conflict: A Call for Human Rights Accountability in Develoment Cooperation" (May 2005) 27:2 *Human Rights Quarterly* 471, at 479.
[1002] *Marrakesh Agreement Establishing the World Trade Organization*, Geneva, April 15, 1994.
[1003] C. May, "Unacceptable Costs: The Consequences of Making Knowledge Property in a Global Society" (2002) 16:2 *Global Society* 123.

rights per se, but partly by how they are manipulated by external agents driven by powerful economic and political interests.

Policy changes and isolated business strategies like those just addressed could certainly tackle problems arising with the application of human right and IP law and improve global access to health and genetic benefits temporarily. However, limits to access and obstacles to distributive justice in health are bigger than intellectual property and human rights law and policy. In fact, we have been faced, at many occasions in the course of this dissertation, with the limits of analysing legal processes independently of other social, political, and economical factors. Even if clear legal dispositions or court orders aiming at improving individual health through better access exist, their practical and real impact often depends on broader political and economic factors and struggles which originate in the very construction and functioning of the global order under which normative systems evolve.

Broader long-term and inclusive options

Actions outside of the system of rights, at the level of global governance and international architecture, will be needed if we are to expect any significant, inclusive, and sustainable solutions to limit hegemonic forces, to include the most vulnerable and change the way human rights and intellectual property principles are translated into reality. Institutional changes of many kinds can be envisioned and new influential actors of the global political picture, like international non-governmental organisations and transnational corporations, need to be involved.

We will need to reflect on establishing innovative strategies to give more space and authority to developing nations in international institutions.[1004] This is an important challenge, due to the tremendous financial control that some powerful states operate on the policy positions, priorities, and initiatives of those institutions. As Richards

[1004] A. Kwa, Power Politics in the WTO, Focus on the Global South (second edition), January 2003, online on the Focus on the Global South website, <http://www.focusweb.org/publications/Books/power-politics-in-the-WTO.pdf> (accessed April 11, 2006); B. S. Chimni, *supra* note 664; J.E. Stiglitz, Globalization and its Discontents, *supra* note 152, at 225.

states, "insofar then as nation-state governments themselves are dominated by global capitalist interests, the difficulties of creating and financing transnational regulatory agencies that are autonomous of these same interests are magnified."[1005] To this end, attention could therefore be focussed on the role and capacity of NGOs to influence the behaviour of the most powerful agents of the world and to change their established dynamic. At many occasions, NGOs of various regions and different social sectors have had a positive social impact through public awareness initiatives and widely-publicied opposition to human rights violations and injustices committed by the world's most powerful stakeholders.[1006] Their capacity to "investigate, expose and shame"[1007] is their main strength. Unfortunately, the concrete results of their actions are often limited, given their restricted resources to further their social and political agenda and to network with other similar groups to establish concerted actions and have a voice in the international dialogue.

Also, in the face of the immense and growing economic power of transnational corporations in this same global picture, another avenue could be to increase corporate social responsibility. Some oppose additional responsitiblities, arguing that the first duty of transnational corporations (TNCs) is to make profit for their shareholders' benefit, while respecting the law of the states in which they operate.[1008]

However, the perception and the role of TNCs is gradually changing. Indeed, they are more and more regarded as social organisations with social duties towards their employees, the environment, and the society at large. TNCs themselves seem to be inclined toward some social role, as most of them are now voluntarily adopting corporate codes of ethical conduct. Given this changing reality, insisting on TNCs' accountability for human rights violations and persisting inequities could contribute to gradually changing the actual global architecture and its troubling focus on the

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[1005] D. G Richards, *supra* note 380, c. 6, at 147.
[1006] For an interesting overview of some successful NGO actions and strategies, refer to R. Khan, "The Anti-Globalization Portests: Side-show of Global Governance, or Law-Making in the Streets?" *supra* note 797.
[1007] K. Roth, "Defending Economic, Social and Cultural Rights: Practical Issues Faced by an International Human Rights Organization" (2004) 26 *Human Right Quarterly* 63, at 67.
[1008] P. T. Muchlinski, "Human Rights and Multinationals : Is There a Problem?" (2001) 77:1 *International Affairs* 31.

needs of its more powerful and wealthy agents.[1009] One strategy could be to insit on the market value of a positive public image and on the effect that respect for human rights could have on a company's economic value.

Again, however, such reforms have to arise from a real and shared conviction that global health gaps and human rights deficits should be eliminated in priority, even if it means direct and coordinated contributions, changes in the distribution of benefits, and opportunity costs for the most affluent. It has to gain support from governments, corporations, and the public at large. In the actual global order, resolving the inequitable power distribution arising in the social, economic, and political arenas appears very challenging, since the most affluent are almost always the most powerful politically.

The current patterns of inequality created by the tremendous influence of powerful states and TNCs on the global order are neither natural nor unavoidable, but are the result of political choices driven by powerful socio-economic concerns for which no one seems to be held accountable. As highlighted by Howse and Mutua, the United Nations, WTO, and international financial institutions are actually in place and represent the institutional foundation needed to arrive at some agreement on complex issues touching on human rights, economics, and trade. These organisations are not incompatible with one another and could work in a collaborative way instead of evolving independently and inconsistently, as they often do. Institutional evolution, more accountability for non-state actors, and a broader perspective on trade law's implications are needed if we expect to bridge the gap existing between human rights and economic institutions. Such reorganisation will likely only happen through a reallocation of political authority, a very complex and long-term global project.

[1009] One example of such a proposal is the UN Global Compact discussed previously, where corporations agree to promote human rights in their spheres of activity. For a comprehensive discussion on the social responsibility of TNCs, refer to J. E. Parkinson, *Corporate Power and Responsibility* (Oxford: Clarendon Press, 1993); J. Dine, *The Governance of Corporate Groups* (Cambridge: Cambridge University Press, 2000); B. S. Chimni, *supra* note 664, P.T. Muchlinski, *Multinational Enterprises and the Law* (Oxford: Blackwell Publishers, 1995) at 93-95; UNCTAD, *The Social Responsibility of Transnational Corporations* (New York and Geneva: United Nations, 1999).

Some, inspired by the recent successful grassroots environmental movement, suggest starting with a re-evaluation and valorisation of the public realm to rationalise restrictions on property rights.[1010] In any case, a sense of the common interest in health has to develop across different and disparate groups to move toward global distributive justice in health.

Agents from civil society and leaders from developing world governmental agencies are already in place, trying to coordinate their work to this end against inequalities and in furtherance of justice in distribution and access. They need to be empowered if we want them to effectively contribute to breaking the current health inequality cycle.[1011] To this end, coalitions and strategic alliances between countries and organisations with the same distributive justice vision need to be established, and important reforms have to be envisioned. This can build on the ethical vision and international social purposes slowly spreading as a result of globalisation, what has been referred to as the "social dimensions of globalization."[1012] Such a strategy has not been very successful on the international scene up to now because of widespread resistance from some affluent nations to renouncing any of their sovereignty in favour of a more equitable global negotiation process. In response to this international deficit, countries and organisations with similar problems and visions could aim to form strong alliances at the regional level, for example, as a way to become less isolated, stronger, and more coordinated in their opposition to the commodification of health and genetics. This could be a first step in the process of gradually reforming the hegemonic international order to make it more accountable in the long-term, not just in the health and genetic sphere, but in many other areas where technological

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[1010] C. May, "Unacceptable Costs: The Consequences of Making Knowledge Property in a Global Society" (2002) 16:2 *Global Society* 123, at 144; J. Boyle, "A Politics of Intellectual Property: Environmentalism for the Net?'' (1997) 47:1 *Duke Law Journal* 89.

[1011] M. Darrow & A. Tomas, *supra* note 1001; F. Fukuyama, *End of History and the Last Man* (New York: Free Press, 1992); M. Mandelbaum, *The Ideas that Conquered the World* (New York: Public Affairs, 2002); F. Zakaria, *The Future of Freedom* (New York: Norton, 2003).

[1012] J.A.Ocampo, "Rethinking the Development Agenda" (2002) 26:3 *Cambridge Journal of Economics* 393; J. Martin, *Globalization and Development: A Latin American and Caribbean Perspective* (Palo Alto: Stanford University Press, 2003).

development is likely to give rise to socio-economic inequalities and exclusions due to powerful market demands.[1013]

More research and analysis should be invested in exploring such a strategy further, especially on how alternative political forces could be used and manipulated differently to ensure some sort of social control over knowledge, products and services access and distribution. For example, it will be interesting to study how existing political and social powers both from the developed and the developing world could mobilise, build a consensus and join together in their action to influence the international distributive scheme. Also, strategies will be needed to translate the cosmopolitan notion of global citizenship and the widespread refusal of health inequalities in the global dialogue and make them strong enough to resist market liberalisation and national political forces. More generally, it will be essential to continue thinking about the most equitable and realistic way to envision a redistribution of authority, governance and related institutional reforms at the global level.

Bridging the genetics divide requires more than an injection of money into innovative research projects and products relevant for the needs of developing countries. In this dissertation, our approach has been focused principally on the normative responses and deficit in approaching the genetics divide but we have quickly realised that a broader vision is required if we want to tackle the major issues of health inequalities. Achieving justice in health and more equitable distribution of the benefits emerging from genetics to further human life and health improvement is of public interest and is within our capacity. It requires collective action towards building functioning innovation systems in developing countries and addressing local deficits including education, scientific capacity building, infrastructure improvement, corruption eradication. Ultimately, it mostly requires questioning the established global order

[1013] For more on what has been called "open regionalism," refer to J. A. Ocampo, "Globalization, Development and Democracy" (2005) 5:3 *Items and Issues*, online on the website of Yale Global, <http://yaleglobal.yale.edu/about/pdfs/ocampo.pdf> (accessed June 2nd, 2006).

and working towards reducing and eliminating persisting social inequalities using national and global political and economical forces into place in a different way.

As a global community with resources, knowledge and technology to reduce and even eliminate the majority of existing global health issues, we have a responsibility to act to prevent radical inequalities.

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Glossary of Acronyms

AIDS: Acquired Immunodeficiency Syndrome

CBD: Convention on Biological Diversity

CIPP: Center for Intellectual Property Policy

CF: Cystic Fibrosis

EMBO: European Molecular Biology Organization

ESC: European Social Charter

ESTs: Expressed Sequence Tags

FAO: Food and Agriculture Organization

FTAs: Free-Trade Agreements

FTAAs: Free Trade Areas of the Americas

GATT: General Agreement on Tariffs and Trade

GCP: Guidelines for Good Clinical Practice

GNP: Gross National Product

HGP: Human Genome Project

HUGO: Human Genome Organization

IBC: International Committee on Bioethics

ICCPR: International Covenant on Civil and Political Rights

ICESCR: International Covenant on Economic, Social and Cultural Rights

ICH: International Conference on Harmonisation

IFIs: International Financial Institutions

Int J Hum Rights: International Journal of Human Rights

Int'l L.: International Law

IMF: International Monetary Fund

IP: Intellectual Property

IPRs: Intellectual Property Rights

ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture

MDGs: Millennium Development Goals

MRC: Medical Research Council

R&D: Research & Development

SNPs: Single Nucleotide Polymorphisms

TNCs: Transnational Corporations

TCC: Transnational Capitalist Class

TRIPS: Trade Related Aspects of Intellectual Property

UDHR: Universal Declaration of Human Rights

UN: United Nations

UNICEF: United Nations Children's Fund

UNESCO: United Nations Educational, Scientific and Cultural Organization

WHO: World Health Organization

WIPO: World Intellectual Property Organization

WMA: World Medical Association

WTO: World Trade Organization