A (Bio)Ethical Intellectual Property Framework for Vaccines

Maushumi Bhattacharjee

Faculty of Law and Biomedical Ethics Unit

McGill University, Montreal

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"Racism is not only when black people or brown people cannot breathe because of police violence. Racism is when black people, brown people, people of color take their last breath because of policy violence... when they are denied lifesaving, pandemic-ending medicines because they live in majority-black countries, brown countries, when they can't access care or education because debt is choking them. What would you call that? That's racism."

- Winnie Byanyima, UNAIDS Executive Director during a session titled 'The Journey Towards Racial Equity' at the World Economic Forum's annual meeting in Davos, Switzerland on 24th May 2022.

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English

Abstract

This thesis examines and addresses the global health concern of inequitable distribution of vaccines created by intellectual property laws through a bioethical lens. The existing legal framework of Intellectual Property Rights and their protection under the TRIPS agreement produce barriers to access to vaccines in a pandemic, especially in lower- and middle-income countries. For the first time, India and South Africa have proposed a temporary waiver of TRIPS obligations to address the inequities in the supply of vaccines in the Covid-19 pandemic. Some developed countries and proponents of intellectual property rights oppose the waiver claiming that intellectual property rights are essential for vaccine innovation and that the TRIPS agreement provides enough flexibility to developing and low-income countries to increase their vaccine production. As traditional approaches based on the theoretical framework of human rights have failed to uphold people's right to health against the intellectual property rights of pharmaceutical companies, this thesis attempts to evaluate the problem by conducting a bioethical enquiry into intellectual property rights in vaccines. Drawing from literature stating the importance of bioethical analysis of laws and global health policies, this thesis applies theoretical arguments based on feminist ethics and ethics of care to evaluate the justification of maintaining intellectual property rights in vaccines, despite its limiting effects on vaccine access across the world. Finally, the thesis claims to provide an ethical alternative to the intellectual property framework in vaccines based on the core features of feminist ethics and ethics of care theories.

Français

Résumé

Cette thèse vise à aborder et examiner le problème de la distribution inéquitable des vaccins dans un contexte global engendrée par les lois de propriété intellectuelle à travers l'optique de la bioéthique. Le cadre légal actuel des Droits de Propriété Intellectuelle et leur protection sous l'accord ADPIC (TRIPS) font obstable à l'accès aux vaccins en cours de pandémie, en particulier chez les pays en voie de développement. Pour la première fois, l'Inde et l'Afrique du Sud ont proposé un abandon temporaire des obligations de l'ADPIC afin d'adresser les inéquités en lien avec l'approvisionnement de vaccins durant la pandémie de Covid-19, ce auquel les pays développés et les partisans des droits de propriété intellectuelles s'opposent, arguant que ces droits sont essentiels à l'innovation, l'accord de l'ADPIC fournissant suffisamment de flexibilité aux pays en voie de développement pour augmenter leur propre production de vaccins. Considérant que les approches traditionnelles basées sur le cadre théorique des droits humains échouent à soutenir le droit individuel à la santé contre les droits de propriété intellectuelle des compagnies pharmaceutiques, cette thèse aspire à évaluer cette problèmatique en menant une enquête bioéthique à travers les droits de propriété intellectuelle dans le domaine des vaccins. Partant d'une littérature affirmant l'importance de l'analyse bioéthique des lois et des politiques de santé globale, cette thèse s'appuie sur des arguments théoriques basés sur la théorie féministe et l'éthique du care afin d'examiner la justification derrière le maintien des droits de propriété intellectuelle en regard aux vaccins, malgré ces effets limitants sur l'accès aux vaccins à travers le monde. Enfin, cette thèse soutient apporter une alternative éthique au cadre de la propriété intellectuelle pour les vaccins, se basant sur les valeurs centrales des théories féministes et de l'éthique du care.

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INTRODUCTION

The Covid-19 pandemic has created a global situation of unprecedented stress on healthcare systems. Availability of a global vaccine is the most economic and efficient way to counter the disruption caused by infectious disease pandemics such as Covid-19, as the early provision of vaccine shots to the population reduces the spread of infections, thereby reducing the mortality rates.[1] It has been observed in previous pandemics and epidemics that developing or low-middle income countries (LMICs) are generally at a disadvantage in obtaining sufficient amounts of vaccines for their populations as compared to developed or high-income countries. A similar trend has been followed in the current Covid-19 pandemic.[2] Developed countries hoarded and secured more than enough vaccines for their population from the few companies manufacturing the safest Covid-19 vaccines in the world.[3] On the other hand, developing countries have been dependent on local research and development of vaccines or have been at the mercy of licensing agreements with these few pharma companies due to their monopoly in the international vaccine market and lack of suitable competitors in the local market.[4] In 2009, during the H1N1 pandemic, developed countries showcased a similar kind of 'vaccine nationalism' by pre-acquiring and hoarding maximum manufacturing capacity through legal contracts, while poor nations in Africa and South Asia continued to suffer from to lack of availability of vaccines.[5] Consequently, as of August 2022, while most developed countries have vaccinated a majority of their populations with two doses, only a quarter of the population of developing and low-income countries has received the first dose of the Covid-19 vaccine.[6]

Only a few multi-national private pharmaceutical companies have created a monopoly in the international market for Covid-19 vaccines by securing Intellectual Property[7] rights to prevent access to their vaccine technologies and know-how, thereby restricting other companies from manufacturing those vaccines.[8] This monopoly is aided by the World Trade Organization

[1] *See* Mark Eccleston-Turner, The Economic Theory of Patent Protection and Pandemic Influenza Vaccines: Do Patents Really Incentivize Innovation in the Field, 2 AM. J.L. & MED. 572 (2016), at 584-585, at 577.
[2] *Ibid.*
[3] *See* Ana Santos Rutschman, The Reemergence of Vaccine Nationalism (July 3, 2020). Georgetown Journal of International Affairs, Forthcoming, Saint Louis U. Legal Studies Research Paper No. 2020-16.
[4] *Ibid.*
[5] *Ibid.*
[6] Hannah Ritchie et al, "Coronavirus Pandemic (COVID-19)" (2020) Our World in Data, online: <https://ourworldindata.org/covid-vaccinations>.
[7] Hereinafter referred as IP.
[8] *Ibid.*

(WTO)'s TRIPS[9] agreement, a multilateral agreement between countries aimed at ensuring uniform protection of IP rights, including patents and other forms of IP in vaccine technologies across the globe. This pandemic is not the first instance when the TRIPS agreement has been criticized for promoting and protecting the private sector's interests over public health interests while undermining the people's right to health across the globe. The argument that patent laws create legal barriers to access essential medication, especially in low-income and developing countries, has been supported with substantial empirical evidence, and ignorance of such an argument can continue to claim the lives of several people across the globe.[10] The HIV pandemic of South Africa in the late 90s brought forth disastrous consequences of the TRIPS agreement on public health. The Doha Declaration of 2002[11] was adopted to counter these consequences of the TRIPS agreement by encouraging countries to use flexibilities within TRIPS to increase access to essential medicines for protecting and promoting public health. However, these flexibilities have not been useful in addressing barriers to accessing Covid-19 vaccines in developing countries.

To enable fast and equitable distribution of Covid-19 vaccines, India and South Africa proposed a temporary waiver of TRIPS obligations of protecting IP rights in vaccines and other essential Covid19 related products before the WTO.[12] The TRIPS waiver proposal received tremendous support from most developing countries, the WHO civil society members, and other international organizations. However, many developed countries and the private sector continue to argue that protecting IP rights is essential to fostering innovation in vaccine technologies. WIPO and WTO also state that IP laws should not be considered a hindrance to access because of TRIPS flexibilities which were highlighted in the Doha Declaration, such as "compulsory licensing" that allows the governments of developing countries to compel pharma companies to grant licenses to the local generic manufacturers for making vaccines or other

[9] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS or TRIPS Agreement].
[10] *See* OECD (2007) Matthew Herder and E. Richard Gold, *Intellectual Property Issues in Biotechnology: Health and Industry,* "The Bioeconomy to 2030: Designing a Policy Agenda" Paris, 2008, The Innovation Partnership, pg 6.
[11] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].
[12] WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19 Communication From India And South Africa (2 October 2020),* WTO Doc: IP/C/W/669.

medical products available to the people at affordable prices.[13] On the other hand, supporters of the TRIPS waiver point out that since vaccines are complex biological molecules, they cannot be easily developed by generic manufacturers. The licensing process and generic vaccine development are so complicated and lengthy, it ultimately raises the price of generic vaccines as well.[14] Scholars have also pointed out that most of the research and development for Covid-19 vaccines is publicly funded through governments and that pharma companies are doubling their profits by claiming IP rights in vaccine technologies.[15]

Invoking the established international framework of the human right to health to counter the enforcement of IP rights of pharma companies has been unsuccessful in this pandemic. Recently, the WHO Director-General and a UN human rights expert referred to the inequity in global vaccine distribution between the global north and global south as "vaccine apartheid" and urged the WTO to adopt the TRIPS waiver.[16] The UN expert stated that denying a comprehensive TRIPS waiver will violate the "human rights principles of racial equality and non-discrimination" as the vaccine apartheid has caused immense harm to racially marginalised people in the global south.[17] It has been over two years since the Covid-19 pandemic struck the world and almost two years since India and South Africa proposed the TRIPS waiver, yet the WTO has not adopted the waiver in totality. Global health and human rights scholars and activists have cited systemic and structural racism as reasons behind forcing developing countries to protect foreign IP over protecting the right to health of their people.[18] Global health scholars note that growing dependence on the private sector for healthcare is one of the root causes of vast health disparities between the rich and poor population. They claim that the TRIPS agreement enables the private sector to further these disparities between wealthy and low-middle income nations.[19]

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[13] Francis Gurry, *Intellectual property, innovation, access and COVID-19*, WIPO MAGAZINE (June, 2020), pg 8-10; Chris Garrison *Background Paper for WHO Workshop: Intellectual Property Rights and Vaccines in Developing Countries,* WORLD HEALTH ORGANIZATION (Apr. 13, 2004), http://www.who.int/intellectualproperty/events/en/Backgroundpaper.pdf [http://perma.cc/BM4J-TUPM].
[14] *Supra* note 1.
[15] *See* Matthew Herder, E Richard Gold & Srinivas Murthy, "University Technology Transfer Has Failed to Improve Access to Global Health Products during the COVID-19 Pandemic" (2022) 17:4 Healthc Policy 15–25.
[16] "UN expert urges States to end 'vaccine apartheid'", online: *OHCHR* <https://www.ohchr.org/en/press-releases/2022/06/un-expert-urges-states-end-vaccine-apartheid>.
[17] *Ibid.*
[18] Simar Singh Bajaj, Lwando Maki & Fatima Cody Stanford, "Vaccine apartheid: global cooperation and equity" (2022) 399:10334 The Lancet 1452–1453.
[19] Vanessa S Lanziotti et al, "Vaccine apartheid: This is not the way to end the pandemic" (2022) 58:2 Journal of Paediatrics and Child Health 228–231.

Seeing as how the current IP framework poses grave concerns for infectious disease pandemics in the present and future, establishing a more sustainable IP model beyond the TRIPS agreement seems inevitable. In this context, I explore the field of bioethics to find solutions to address the thesis problem. Bioethics is an interdisciplinary field with a diverse theoretical framework constituting several moral theories used for solving ethical issues within the healthcare field. Considering that the global vaccine distribution inequity caused by the current IP framework for vaccines is a major global health issue, I sought to analyse this problem through a bioethical lens. Bioethical discourse within the sphere of IP has been restricted to the discussion of morality and ethics of patent laws when applied to biotechnological inventions, for example, gene patenting or patenting of microorganisms. Scholars state that in applying patent laws to biotechnological inventions in pharmaceutical and healthcare industries, the focus of law must change from commercial profiteering to the availability of essential medical inventions, such as vaccines, to every human in the world.[20] Therefore, in this thesis I focus on the need to discuss the consequences of IP laws on vaccine distribution within the bioethical realm. The aim of this thesis is to find ethical and sustainable solutions to the thesis problem thorough a bioethical enquiry into IP framework for vaccines.

[20] *See Ana Santos Rutschman, supra* note 3.

STRUCTURE, METHOD, AND LITERATURE REVIEW

This thesis is divided into three parts. In the first part I explain how I will analyse IP laws through a bioethical lens for determining whether there can be a (bio)ethical IP framework for vaccines. To explain that, I will first address the question of why I choose to use a bioethical analysis or enquiry, and then describe what constitutes a bioethical analysis and how I aim to apply it to the research problem. In the second part I will provide a critical analysis of the flexibilities within TRIPS agreement to show that they are not appropriate measures to ensure fair and equitable distribution of Covid-19 vaccines in the world. In the third part, I discuss how and why feminist ethics and ethics of care are the most suitable theoretical frameworks within bioethics to solve this problem. Finally, through a feminist ethics and ethics of care analysis of IP laws I discuss whether there can be an alternative legal and ethical framework beyond the TRIPS agreement for innovation in vaccines.

1. PART 1: Why a Different Approach? Why Bioethics?

Scholars, lawyers, and activists have used different approaches to analyse the current framework of IP laws within the TRIPS agreement and deliberate upon the conflict between IP rights and public health interests. Many scholars have challenged the enforcement of IP rights by invoking the human right to health. Yet, the TRIPS agreement has sustained these challenges and continues to exist as the most comprehensive and multilateral agreement that binds members of WTO to maintain certain minimum standards for the protection of various forms of IP. Therefore, it is crucial to understand what made the TRIPS agreement a concrete primary legislation for enforcement of IP rights across the globe.

In the first chapter of part one, I will reflect on the political history of TRIPS agreement by heavily referencing critical literature on the topic by Susan Sell and Christopher May. By throwing light on the political history of TRIPS agreement I tend to establish that TRIPS was formulated to further the economic interests of the mostly Western-based private sector. I will refer to contemporary literature that advances concepts of colonialism or imperialism to advance by discussing the fact that TRIPS was entirely based on western philosophy of legal norms surrounding knowledge and property rights. I will supplement that discussion with Morin and Gold's analysis of various causal mechanisms such as coercion, emulation etc. that caused the legal transplantation of IP Laws of developed countries into developing countries

despite their asymmetrical interests. Further, I will discuss how the discourse on the conflict between protecting IP rights and the human right to health has been largely unsuccessful in delivering any sustainable solutions for mitigating the negative effects of TRIPS on public health.

In the second chapter I aim to explain why a bioethical analysis of IP laws, in the context of vaccines, could provide better and more sustainable solutions. I start by giving a brief introduction to the field of bioethics and how it has developed over the years to address ethical issues that affect global health. I will then discuss how bioethics is different from human right by discussing the conflict between the two fields that sprouted among scholars after the Universal Declaration on Bioethics and Human Rights was adopted by UNESCO. Finally, I address the relation between bioethics and law and how bioethics can provide a framework to ethically analyse legislations or develop health policies that promote ethical goals.

2. PART 2: TRIPS Flexibilities vs TRIPS Waiver

I begin by discussing the significance of the Doha Declaration in providing recognition to the interests of developing and least developed countries (LDCs) with respect to protection of public health. I then define the flexibilities within TRIPS agreement which were highlighted in the declaration and discuss how these flexibilities have been utilized by developing countries. Following that, I advance my argument that none of these flexibilities are effective when applied to vaccine technologies and have failed in ensuring equitable access to vaccines in low- and middle-income countries (LMICs). Furthermore, I discuss the existing COVID-19 vaccine landscape and challenges in accessing COVID-19 vaccine technologies, despite there being numerous voluntary and public sector initiatives. Towards the end I present the alternative of TRIPS waiver and briefly discuss the challenges in its implementation.

I refer to Turner's work on the economic theory of patent laws when applied to vaccines in pandemics to discuss that patents do not incentivize innovation in vaccine technologies and only promote unequitable distribution of vaccines during a pandemic. To establish this argument, I also give examples of Hepatitis-B, Ebola and H1N1 vaccine case studies. I discuss the TRIPS waiver proposed by India and South Africa in detail by referring to several authors who have critically assessed the waiver in recent past. I also throw light on how the private sector has utilized the TRIPS agreement and other legal instruments to create barriers to access

vaccine technologies and know-how. Finally, while I acknowledge TRIPS waiver as the need of the hour, I conclude that a more sustainable and ethical legal framework for IP in vaccines needs to be established to promote ethical goals for securing global health in future epidemics or pandemics.

3. PART 3: A Bioethical Enquiry into IP Laws

In the third part, I briefly describe the various theoretical frameworks within bioethics and explain why feminist ethics and ethics of care are best suited to analyse IP laws. Drawing from a plethora of works by scholars in the field of feminist ethics and ethics of care such as Virginia Held, Rita Manning, Sara Ruddick, Annette Baier, etc. I describe the opposition to traditional philosophical theories that are generally used to justify IP. Further, I analyse the works of feminist scholars who have written extensively on how fundamental values of ethics of care theory can be utilised in creating caring policies for international development and global health. I identify the relevant propositions from this literature and apply them towards suggesting an alternate "caring" framework for IP in vaccines. I support my suggestions by referring to scholarly work on feminist interpretations of IP, such as Mala Pollack's paper representing a "feminist public domain". Finally, I suggest and describe how open science can be a "caring" alternative framework to IP for innovation in vaccine technologies.

PART I: WHY A DIFFERENT APPROACH? WHY BIOETHICS?

CHAPTER I. THE "ACTUAL" MAKING OF TRIPS AGREEMENT

The key objective behind the launch of United Nations Conference on Trade and Development (UNCTAD) in 1964, and the subsequent establishment of World Trade Organization, was to ensure that world trade was carried out in a way that did not disproportionately disadvantage the developing and least-developed countries.[21] This objective has been expressly recognized as a critical underlying principle of international trade in the preamble of WTO.[22] This overreaching principle is also binding on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which was negotiated during the Uruguay Round (1986-1994), of the General Agreement on Tariffs and Trade (GATT). In 2015, 20 years after the signing of TRIPS agreement, the WTO published a book, *The Making of the TRIPS Agreement*, containing the personal accounts of key negotiators from signatory countries who participated in the Uruguay round of TRIPS negotiations.[23] Given that none of the personal accounts included anyone from the African group of countries, I supplemented the analysis with a communication from Government of Nigeria in August 1991[24] as a representative of the Government of African Unity (OAU).[25]

The Nigerian communication voiced some significant concerns of African negotiators during the Uruguay Rounds. The communication reflected the deteriorating condition of African trade in developed country markets, which were increasingly protectionist, and the mounting pressure from the African external debt crisis on African countries. The representatives of OAU stated that African negotiators participated at various steps of the negotiation process and had raised several concerns on issues such as access conditions for products of interest to African countries and the inadequate treatment of the development dimension in the new areas of trade-

[21] *See* United Nations Conference on Trade and Development, ed, *The History of UNCTAD, 1964-1984* (New York: United Nations, 1985); Craig VanGrasstek, *The history and future of the World Trade Organization* (Geneva, Switzerland: World Trade Organization, 2013).
[22] *See* Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [WTO or Marrakesh Agreement]; The 2nd paragraph of clause 1.1 of the Preamble to the WTO agreement: *"The Parties to this Agreement recognize that there is a need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth of international trade commensurate with the needs of their economic development"*.
[23] Jayashree Watal, Antony Taubman & World Trade Organization, eds, *The making of the TRIPS Agreement: personal insights from the Uruguay Round negotiations* (Geneva, Switzerland: World Trade Organization, 2015).
[24] GATT, Trade Negotiation Committee, *Communication from Nigeria* (dated 28th August, 1991), GATT doc TNC/W/86, online: https://docs.wto.org/gattdocs/q/UR/TNC/W86.PDF.
[25] *Ibid*; The communication was made by the Government of Nigeria in the form of a declaration titled, "Declaration of the Heads of State and Government of the Organization of African Unity on the Uruguay Round of Multilateral Trade Negotiations" and was addressed to the Uruguay Round Participants.

related aspects of intellectual property rights.[26] None of their concerns were addressed until the very last stage of TRIPS negotiations, and yet they were being subjected to demands for reciprocity on several issues. They further reiterated that, "the ability of African countries to influence the course of the negotiations has further been impaired by the lack of adequate transparency in the negotiating process"[27]. Towards the end, the representatives of OAU voiced their demands for "unimpeded transfer of technology and to provide for national capacity building in all sectors of critical importance."[28] Notably, none of the key negotiators included in *The Making of the TRIPS Agreement* spoke to any of these issues nor to the effect of the agreement on African nations.

While it is clear that the interests of African group of countries were largely ignored during the negotiations, it is important to discuss what brought these countries to the table to participate in these negotiations in the first place. WTO's account of the process behind signing of the TRIPS agreement is a narration of a story about grand negotiations between developed and developing countries involving compromises from both sides, as they worked towards the fruition of an allegedly common objective: enacting an international agreement on protection of IP rights. This story, however, fails to discuss the political history, economic coercion, and the effective agency of private sector actors behind the push towards harmonized global adoption of an enforceable global IP regime. Susan Sell, in her account of history of the TRIPS agreement, unravels the role played by the Intellectual Property Committee (IPC), a small group of private corporates in driving international political actors and nation states towards establishing a protectionist global IP agreement that is based on the IP laws of highly industrialized and developed countries.[29] This small twelve-member group of chief executive officers of mostly US-based companies in pharmaceutical, software, and entertainment industries, were the key player in gathering support internationally for stronger protection of IP rights across the globe.[30]

1.1. Enhanced Role of the Private Sector in Gathering International Momentum for a "Global" IP Agreement

[26] *Ibid.*
[27] *Ibid,* para 5.
[28] *Ibid,* para 7.
[29] Susan K Sell et al, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge, UNITED KINGDOM: Cambridge University Press, 2003).
[30] *Ibid, See* Chapter 2: Structure, Agents, and Institutions at pg30.

Due to the increased sale of counterfeit and "pirated" products in many developing countries, western IP holders were not able to collect rents on the sale of products those countries. This was the key factor driving IPC's concerted efforts for a global IP agreement.[31] These private actors from different industries realized that the old system of IP protection was not adequate to sufficiently extend their IP rights internationally, and so they mobilized their resources to redefine the existing structure through highly effective international political lobbying.[32] The 12 individuals representing the different affected industries organizing themselves into IPC formed a group of corporate agents with well-articulated interests and strategies for achieving the desired change in structure.[33] IPC aimed for a multilateral global IP agreement to protect their interests internationally. Initially they began by garnering support domestically within the US.[34] With increasing market power and the status of US economy internationally, IPC realized that the US government can be their strong ally in improving their competitive position.[35] They used US government pressure to force foreign governments in increasing protection of IP within their local legislation.[36] IPC was instrumental in forming other lobbying organizations with similar objectives such as International Intellectual Property Alliance (IPA) and Pharmaceutical Research and Manufacturers of America (PhRMA), and they vigorously worked towards changing the US trade laws to strengthen protection of US-based IP abroad.[37]

IP activists received immense support from United States Trade Representative (USTR) and were successful in legitimising "insufficient foreign IP protection" as a significant barrier to international trade, thereby linking IP to trade.[38] This gave them the opportunity to push for amendments in trade laws such as the Trade and Tariff Act and Special 301 of Trade Act of 1974 to target the countries that failed in providing what they viewed as adequate protection to US-based IP.[39] The Special 301 process allows US government to pressure foreign governments in making changes to their local policies if they inadequately protected their IP.[40] The Special 301 allows private sector actors to make complaints to USTR for investigation into

[31] *Ibid.*
[32] Susan K. Sell, "Trips and the Access to Medicines Campaign" (2001) 20:3 Wis Int'l LJ 481.
[33] *Ibid.*
[34] *Supra* note 29, see Chapter 5: The Intellectual Property Committee and transnational mobilization, 96-120.
[35] *Ibid.*
[36] *Ibid.*
[37] *Ibid.*
[38] *Ibid.*
[39] *Supra* note 32 at 492.
[40] *Ibid.*

foreign country's actions of not providing adequate protection as per US standards.[41] If the USTR decides to investigate, then it will first consult with the reported foreign country's government to solve the issue, and then advise the US government accordingly on whether to impose trade sanctions against the foreign government.[42] The USTR also conducts an annual review of the status of global intellectual property rights protection and enforcement and releases a list of countries that are on a "watch list" for not providing adequate protection to IP.[43] Further, the USTR maintains another review mechanism called the GSP review. GSP or generalized system of preferences provides tax free treatment for several products when imported to any of the designated developing countries.[44] One of the criteria for a country to earn such trade privileges with the US is whether it maintains a standard of IP protections that closely matches the US standard for IP protection.[45]

The World Intellectual Property Organization (WIPO), which was the original forum governing international protection of IP, was more concerned with providing support to developing countries in IP related matters and lacked a mechanism for enforcing IP protection.[46] WIPO's functioning did not cater to the IPC's agenda of extending stringent IP protection to developing countries through a global IP agreement.[47] Thus, IPC lobbied for US government support in promoting a multilateral and international IP agreement through GATT.[48] IPC started gaining support transnationally by convincing its counterparts in Europe and Japan to join forces resulting in a multinational coalition of private sector with the common goal of furthering a global IP policy that favoured their interests in the global market.[49] The IPC members also held key positions in Advisory Committee for Trade Negotiations (ACTN), a forum for businesspeople to share their views on trade and policy. Through ACTN, these private sector IP activists had access to high quality policymaking resource persons who helped frame the proposal and the base draft for the multilateral and global IP agreement that best suited their interests.[50] They formed a task force specifically focused on getting the US

[41] *Ibid.*
[42] *Ibid*.
[43] *Ibid.*
[44] "Generalized System of Preferences (GSP)", online: *United States Trade Representative* <http://ustr.gov/issue-areas/trade-development/preference-programs/generalized-system-preference-gsp>.
[45] *Supra* note 32 at 495.
[46] *Supra* note 32 at 486.
[47] *Ibid.*
[48] *Ibid.*
[49] *Supra* note 32 at 487.
[50] *Ibid.*

government to include intellectual property issues in the Uruguay round of negotiations in 1986.[51] Interestingly, Edmund Pratt, founding member of the IPC, CEO of Pfizer, and the chairman of ACTN was appointed as an advisor to the U.S. Official Delegation at the Uruguay Round.[52] IPC and their European, Canadian and Japanese counterparts (the multi-national coalition) came to a consensus over a trilateral IP agreement with three main components, that is, "a) a code of minimum standards for copyrights, patents, trademarks, and appellation of origin issues b) an enforcement mechanism; and c) a dispute settlement mechanism".[53] They lobbied to get their respective nation's governments to support the trilateral agreement at the Uruguay rounds. The US government then used its enormous market power and coercive economic policies of trade sanctions in the Uruguay rounds to force governments of developing nations to adopt and enforce stricter IP policies.

After the signing of TRIPS agreement, most countries did not adopt the minimum standards of IP protection as defined under TRIPS, immediately. The private sector had systematically designed a "post-TRIPS implementation strategy".[54] The strategy was to not overburden the WTO dispute settlement mechanism by filing several complaints under TRIPS, but instead to use the USTR Special 300 and GSP mechanisms to ensure that the developing countries were implementing TRIPS standards for IP protection within their national laws.[55] To minimise the use of flexibilities within TRIPS agreement, the US also entered into bilateral Free Trade Agreements (FTAs) with several countries that ensured that contracting nations adopted IP rules that closely matched the level of IP protection in the US, which was well beyond what was required under the TRIPS agreement.[56] Many countries signed these FTAs for availing the trade benefits and access to US market which was promised through mechanisms such as GSP in return for stricter IP protection.[57] The IPC and TRIPS advocates also used a multi-level strategy to ensure TRIPS implementation in developing countries by strategically using WIPO's Patent Agenda.[58] WIPO's Patent Agenda's focus was to "develop a universal patent, a fully globalized and harmonized patent regime, building on the international application

[51] *Ibid.*
[52] *Ibid.*
[53] *Supra* note 32 at 489.
[54] *Supra* note 32 at 493.
[55] *Ibid.*
[56] Susan K Sell, "TRIPS: Fifteen years later" (2011) 18:2 Journal of Intellectual Property Law, 6.
[57] *Ibid, see also* Susan K Sell, "TRIPS was never enough: Vertical forum shifting, FTAs, ACTA, and TPP" (2010) 18 J Intell Prop L 447.
[58] *Ibid,* at 7.

procedure already existing under the Patent Cooperation Treaty"[59]. Most of WIPO's funds also came from the PCT which was heavily used by the same companies that were members of the IPC and many other companies that belonged to similar industries as the IPC members.[60]

1.2. "Globe = West?": An IP Framework ONLY for the Western World

To understand what propelled the IPC to the forefront of global trade regulations and allowed it to exercise immense influence transnationally by lobbying its way from domestic politics to international politics, one must critically examine the historical context that made these 12 individuals so powerful at that time.[61] The larger forces including the relentless growth of global capitalism and technology brought enormous industrial expansion. Private actors owning businesses in key areas of this industrialised economy also held a great deal of transnational capital power. Their power in global trade was compounded as they had support from the politically and economically powerful states in the West that controlled the global market.[62] As the Western "free-market" ideology dominated global markets, the private actors united in their agency using the existing structure of global capitalism to devise international trade rules that favored them. However, they had to get the governments of developing countries with very different economic, social, and cultural interests to follow the Western laws.[63] Through unified efforts and resources, the IPC was able to convince their powerful state allies to use their economic might and coerce the developing nations to accept their trade policies.

Based on the literature of "policy diffusion", Morin and Gold identify the causal mechanisms for legal transplantation in cases where the "adopter" country and the "originator" country have asymmetrical interests.[64] Legal transplantation is a process wherein a country adopts a rule which originates in and is formulated for a foreign country into its legal system.[65] Due to power

[59] Christopher May, *The World Intellectual Property Organisation: resurgence and the development agenda* (London: Routledge, 2007).
[60] *Supra* note 32 at 519.
[61] *See* Christopher May & Susan K Sell, eds, *Intellectual Property Rights: A Critical History* (Boulder: Lynne Rienner Publishers, 2022), 15-43.
[62] *Ibid.*
[63] *Ibid.*
[64] Jean-Frédéric Morin & Edward Richard Gold, "An Integrated Model of Legal Transplantation: The Diffusion of Intellectual Property Law in Developing Countries" (2014) 58:4 Int Stud Q 781–792.
[65] *Ibid,* at 782.

imbalance between countries, powerful countries will strongly require for their rules to be followed in foreign countries and may use certain mechanisms to diffuse their rules globally.[66] Birnhack, describes such legal transplants as "brute transplants" and compares it with colonialism as "colonialism was often such a brute transplant, where the colonizer applied its own foreign law in the domestic scene".[67] In the case of intellectual property protection, developed countries such as the US which are mostly creators of IP have stricter IP protection rules, whereas developing countries generally import the IP from developed countries and benefit by maintaining lower standards of IP protection. Yet, the developing countries agreed to sign the TRIPS agreement which obligates them to raise their standard of IP protection to a level that is closer to that of the US. Economically powerful countries such as the US, used the mechanism of coercion through instruments such as Special 301 and GSP review to start the process of legal transplantation of IP laws in developing countries.[68] Then they used the mechanism of contractualization through bilateral FTAs to get more and more countries to adopt their IP rules. Morin and Gold also identify socialisation as a causal mechanism that helped in legal transplantation of US-based IP rules.[69] Apart from "training in US-based IP standards" provided by USTR in the form of technical assistance, one other instrument for socialisation is the population of students studying in the US, that is, foreign students who "absorb more general normative principles underpinning the IP system, such as individualism, rationalism, liberalism and modernism" and take these foreign values back home to integrate into local social circles.[70] Thus, through coercion, contractualization and socialization mechanisms US has legal transplanted its IP rules into other developing countries despite their interests conflicting with that of US.

Rahmatian describes TRIPS as a device of modern economic – neocolonialism.[71] He explains the concept of economic "imperialism" or "colonialism" as being "exercised by corporations, and the governmental agencies under influence, backed by legal instruments".[72] These multinational corporations were and are typically based in the West and backed by Western

[66] *Ibid.*
[67] *See* Michael Birnhack, "A Post-Colonial Framework for Researching Intellectual Property History" in *Handbook of Intellectual Property Research* (Oxford University Press, 2021) 260.
[68] *Supra* note 64 at 782-783.
[69] *Ibid.*
[70] *Supra* note 64 at 786.
[71] *See* Andreas Rahmatian, "Neo-Colonial Aspects of Global Intellectual Property Protection" (2009) 12:1 The Journal of World Intellectual Property 40–74.
[72] *Ibid.*

governments.[73] Modern neo-colonialism is entirely driven by "economic success". Globalization of IP rights also involved extending the Western concepts of property rights to intangible or intellectual property, thereby granting owners of intellectual property powers to enforce their exclusive rights against other persons.[74] Rahmatian explains that in the colonial era, informal empires were created through property rights and their guaranteed legal protection in dependent colonies, just like how TRIPS obligates developing nations to provide guaranteed legal protection to intellectual property of developed countries.[75] TRIPS forces non-Western countries to adopt the Western IP regime irrespective of whether such a regime is well-suited for their economic, social, and cultural needs. This is achieved by the minimum standards of IP protection that are comprehensively described in the TRIPS agreement along with the principle of "national treatment" which ensures that countries will treat imported goods the same way as they treat their own, in terms of IP protection.[76]

The surge in global capitalism, the influence of private actors in international politics compounded by the economic power held by developed countries which led TRIPS to be a success also changed the perception of IP rights universally as being the same as "natural rights" in property.[77] This perception, however, was a product of coercive economics and politics and was incongruent with the history that considered IP rights to be privileges. The way IPC framed issues while proposing for stricter global IP framework is also a significant factor behind convincing the governments to consider IP protection as a critical aspect of international trade.[78] By referring to intellectual property as intellectual property "rights" during the TRIPS negotiations, the IPC was successful in shifting the historical perception of IP as "privileges" being *granted* by the sovereign, to "rights" that the sovereign has an *obligation to uphold*.[79] When the discourse surrounding justification of IP rights is largely based on philosophies underlying knowledge and property, one misses out on the political factors such as economic neo-colonialism, imperialism, and global capitalism, that have systematically led to the exclusion of the world other than the West from this discourse.[80] The

[73] Here, I am referring to the 12 multinational corporations that formed the IPC.
[74] *Supra* note 71.
[75] *Ibid.*
[76] *Ibid*; Article 3 of TRIPS agreement defines the principle of national treatment as "forbidding discrimination between a Member's own nationals and the nationals of other Members".
[77] *Supra* note 61.
[78] *Sell, Supra* note 32 at 490-91.
[79] *Ibid.*
[80] *See Christopher May and Susan Sell, Supra* note 61 at 203-219 (Forgetting History is not an Option).

TRIPS agreement is heavily based on the Western ideas and concepts that justify the protection of IP by creating property rights in knowledge and information. Knowledge and information are essentially public goods that have "common usage" and a "shared social existence".[81] Many scholars have pointed out that IP rights restrict the use of knowledge and information by creating the "fiction of scarcity" where there is none. This is because, unlike tangible property, knowledge or information are intangible and non-rivalrous public goods, meaning their use by one person does not restrict other people from using the same.[82] The narrative that IP rights must be protected since they drive innovation by rewarding the efforts of innovators is largely based on the Western philosophical foundations of utilitarianism and deontology. Such narratives of IP's sole purpose being "rewarding the individual innovator" do not take into account the fact that knowledge and information are the "common heritage" of people, and by extending private ownership laws to IP leads to commodification of this common heritage for economic profits.[83]

1.3. TRIPS and Public Health

Including IP within the rights discourse led to an inevitable conflict between protecting private rights and the public good, especially problematizing the effect of TRIPS agreement on public health. In this section I will discuss how the HIV pandemic in South Africa in the late 90s brought the world's attention to this conflict between protecting the IP rights of big pharma and preserving public health by allowing enhanced access to life-saving HIV drugs. Developing countries were soon realising the consequences of signing the TRIPS agreement, especially in public health, as countries in Africa paid the cost of being a signatory to TRIPS with lives of thousands of people who died in the HIV/AIDS pandemic. Despite big pharma being the major actors in TRIPS negotiations, World Health Organization (WHO) or even the health ministers of countries who participated in negotiations did not raise any concerns regarding effects of TRIPS on access to essential medicines. If the TRIPS agreement was framed as a public health issue instead of a trade issue, it would not have been the great success that the representatives of WTO members claim it to be in *The Making of TRIPS Agreement.*[84]

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[81] *See* Rajshree Chandra, *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Rights* (Oxford University Press, 2010), 3-20, DOI: 10.1093/acprof:oso/9780198065579.001.0001.
[82] *Ibid.*
[83] *Ibid.*
[84] *Sell, Supra* note 32 at 490-91.

The opposition to the TRIPS agreement heightened only after its signing in 1995, as international civil society organizations such as Oxfam and Medicins-Sans-Frontiers (Doctors Without Borders) spoke extensively against the actions of pharma companies that were imposing their patent rights and limiting the access to HIV anti-retroviral drugs, thereby killing millions of people in South Africa. As the realization that these new and stricter IP laws which were a result of the TRIPS agreement were restricting access to essential drugs and causing deaths of millions was spreading through the globe, the developing countries who were members of WTO demanded solutions for the public health crisis created by TRIPS. Finally, a meeting was arranged in Doha between the WTO members with the agenda being to address the apprehensions of developing countries with respect to TRIPS and public health. The African group of countries, which had the least representation in the Uruguay rounds, were the drivers of negotiations among the WTO members in Doha. The meeting in Doha was arranged right after the legal war between the big pharma and South African government, over the Medicines Act passed by the parliament under Nelson Mandela's governance in 1997.[85] The anti-retroviral drugs, anti-fungal and anti-bacterial drugs that played an essential role in fighting the HIV virus, HIV related tuberculosis and other sexually transmitted diseases were extremely expensive and protected by patents owned by the big pharma companies such as Pfizer, Bayer etc.[86] In their efforts to win the battle against the raging HIV epidemic that had killed over 4 million Africans, the government of South Africa enacted the Medicines Act. The Medicines Act allowed them to increase the access to essential HIV drugs through certain provisions that limited the extent of patent protection under the Patents Act 1978.[87] Subsequently, the pharmaceutical giants sued the South African government by bringing forth a constitutional challenge stating that the Medicines Act violated their constitutional right of right to property.

Post the signing of TRIPS agreement, the South African Patent Act of 1978 was amended in 1997 to be fully compliant with the TRIPS agreement and provided high level of protection to

[85] Ruth May, *"South Africa vs. the Drug Giants A Challenge to Affordable Medicines"(*2001), Oxfam GB at 1, online:<https://policy-practice.oxfam.org/resources/south-africa-vs-the-drug-giants-a-challenge-to-affordable-medicines-620381/>.
[86] *Ibid,* at 2. There were 39 companies that filed a case against the government of South Africa including GlaxoSmithKline, Merck and Co, Bristol-Myers Squibb, Roche, and Boehringer Ingelheim, Pfizer, Novartis, etc.
[87] *Ibid,* at 5.

patents and patented drugs.[88] However, in 1997 South Africa also passed the Medicines Act which gave the government rights to override patent protection of drugs on grounds of protecting public health.[89] The provisions enabling parallel importing, issue of compulsory licenses and use of generic medicines were the key controversial features of this Act were actually drafted in a manner that brought forth a flexible interpretation of the TRIPS agreement, in contrast to the stringent interpretation of the agreement which was preferred by the big pharma.[90] These provisions were:

i. Parallel Imports – Medicines Act allowed the South African government to import patented drugs that were available at a lower cost in other countries without prior authorization from the patent owner. This was not covered under the South Africa's Patents Act and was not specifically addressed under TRIPS agreement.
ii. Compulsory License – The Act gave powers to the health minister instead of the commissioner of patents to grant compulsory licenses, which would help the government in fast-tracking the process during national emergencies.
iii. Use of generic medicines – The Act provided for measures that ensured the dispensation of low-costing generic medicines instead of branded patented medicines in pharmacies.

Despite the abovementioned provisions being TRIPS compliant, the interpretation by the South African government which was reflective of their intention to protect public health was criticized by the US and EU to the extent that US threatened South Africa with serious trade sanctions, such as adding South Africa to their "Special 301" list.[91] The resulting tensions surrounding the conflicts between patent protection of pharmaceuticals and access to essential medicines pushed the African group and other developing countries to seek clarification

[88] *Ibid.*
[89] *Ibid,* at 4; "Section 15 c of the Medicines Act stated: The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may – (a) notwithstanding anything to the contrary in the Patents Act 1978 (Act no 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent; (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported; (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)."
[90] *Ibid.*
[91] *See page 14-15 of this chapter. (*The Special 301 Report is prepared annually by the Office of the United States Trade Representative (USTR) that identifies trade barriers to United States companies and products due to the intellectual property laws, such as copyright, patents and trademarks, in other countries.)

through a formal declaration by WTO members on the provisions of TRIPS and whether it hindered with their rights to ensure protection of public health.[92] The US and EU countries were strictly against any such declaration as they were concerned that a declaration which allowed an interpretation of TRIPS that diluted protection of patent protection of medicines on grounds of public health concerns would severely affect the economic interests of their pharmaceutical companies.[93] The US and EU were of the view that protection of intellectual property rights of the pharmaceutical companies was of paramount importance in fostering innovation in industry by providing innovators with exclusive rights.[94] The meeting in Doha concluded in the Doha Declaration being adopted in 2001 which provided the developing countries an assurance that they are allowed to use flexibilities within the TRIPS agreement to protect and preserve public health, without any fear of trade sanctions from developed countries. Part II of this thesis discusses these TRIPS flexibilities in context of access to Covid-19 vaccines.

1.4. IP Rights vs Human Right to Health

For the longest time, scholars have vigorously debated the issue of intellectual property rights restricting access to essential medicines or vaccines and have lengthily described the conflict between intellectual property rights and the human right to health. The definition of an "international human right to health" is found in the Universal Declaration of Human Rights (UDHR)[95] and International Covenant on Economic, Social and Cultural Rights (ICESCR).[96] While the UDHR[97] confirms the health of all individuals to be a fundamental human right based on the inalienable right to life, ICESCR[98] gives a more comprehensive definition explaining the role of the state in taking affirmative action towards ensuring that individuals or citizens can enjoy the "highest attainable standard of physical and mental health." Article 2 of ICESCR promulgates the principle of progressive realization, which means that individual state governments must make maximum use of their available resources to fully realize the right to health of individuals. Many scholars argue that such an interpretation of the human right to

[92] *Supra* note 85.
[93] *Ibid.*
[94] *Ibid.*
[95] Universal Declaration of Human Rights, G.A. Res. 217A, U.N. GAOR, 3d Sess., art. 3, U.N. Doc. A/810 (1948) [hereinafter UDHR]
[96] International Covenant on Economic, Social and Cultural Rights, opened for signature Dec. 16, 1966, art. 12.1, 993 U.N.T.S. 3, 8 (entered into force Jan. 3, 1976) [hereinafter ICESCR]
[97] UDHR, art. 25(1).
[98] ICESCR, art 12.

health contradicts its universality and uniformity due the vast inequities in economic resources across the globe.[99] It becomes colossally difficult for the state governments of developing countries to protect the right to health of their people when stringent IP laws limit the availability of resources, such as essential drugs and vaccines.

Some scholars have debated whether intellectual property rights can be given the status of "rights" or whether they can be recognized as "human rights", while other scholars argue that they are more suited to be described as "privileges". Intellectual property rights are recognized as property rights in intangible property. Property rights are often acknowledged as core civil rights or natural rights that are parallel to and equally important as the right to life and liberty.[100] ICESCR and UDHR also have, in a way, defined intellectual property rights. Article 15(c) of the ICESCR recognizes the right of everyone "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author", and Article 27(2) of the UDHR states that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

While some scholars and the World Intellectual Property Organization (WIPO) use the provisions of ICESCR and UDHR to justify the status of intellectual property rights as human rights, other scholars focus on the statement adopted by the Committee on Economic, Social and Cultural Rights in 2001.[101] This statement clarified the meaning and purpose of Article 15(c), just after the South African government was sued jointly by several pharmaceutical companies for violating their human right in intellectual property by not providing adequate protection to their patents in essential HIV medicines.[102] The Committee concluded in its statement that, "any intellectual property regime that makes it more difficult for a State to comply with its core obligations about health, food, education [...] is inconsistent with the legally binding obligations of the State party".[103] The statement reiterates an established principle of human rights: the enjoyment of one human right cannot be allowed if it negatively

[99] *See* Benjamin Mason Meier, "The Highest Attainable Standard: Advancing a Collective Human Right to Public Health" (2005) 37:1 Colum Hum Rts L Rev 101.
[100] Hans Morten Haugen, "Intellectual Property - Rights or Privileges?" (2005) 8:4 Journal of World Intellectual Property 445 at 58.
[101] *Ibid* at 451. See also, Committee on Economic, Social and Cultural Rights, *Statement on Human Rights and Intellectual Property*, E/C.12/2001/15 (2001).
[102] *Ibid.*
[103] *Ibid.*

affects the enjoyment of other basic human rights. The Committee also clarified that the wording of Article 15(c) is more inclined towards maintaining a balance between protecting the moral and economic interests of the authors by recognizing them as legitimate human rights only under specific conditions.[104] Patents provide inventors with exclusive monopoly rights and economic privileges for a specific period, allowing them to exploit their inventions commercially. However, patents do not fit under the exact definitions of either rights or privileges.[105] Scholars suggest that their functioning involves imparting patent holders with powers that allow them to define how they wish to exercise their rights. They have the power to license their rights, or to decide whether the use of their inventions is to be commercial or non-commercial, or to restrict others from the use of their invention legally.[106] Patent holders must have legal and financial capacities to exercise these powers. Since there is substantial involvement of powers in the functioning of patents, the threat of abuse of such powers from increasing reliance on patents must be addressed.[107] Despite scholars and international organizations having explicitly and comprehensively elaborated on why intellectual property rights cannot be given the same status as human rights, most multi-national pharmaceutical companies continue to argue otherwise. For example, Pfizer recently claimed their intellectual property rights as human rights in response to a drive for the grant of a compulsory license on Pfizer's COVID-19 antiviral in The Dominican Republic, which would allow the sale of generic copies of the drug at a much lower cost, without the company's permission.[108]

1.5. A Different Approach

As discussed in previous sections, the TRIPS agreement is a result of coercive international politics orchestrated by a group of private actors based in developed countries. The theoretical justification for IP rights and their protection within the TRIPS agreement is primarily based

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[104] *Ibid.*
[105] *Ibid*; Haugen explains why patents are neither rights or privileges. Patents are not rights because, a) they are granted by public authority and can only be granted if the meet he eligibility criteria, b) state is not responsible to enforce patents but the patent-holder is, c) they are subjected to the limitations of public interest and d) patent holder does not have full ownership, but only economic rights to exploit the innovation. Patents are not privileges because traditionally privileges allowed people to do what was restricted to the rest, and patents are not exactly that. However, some say that property rights aren't called privileges but rights because "privileges" doesn't have a nice ring to it.
[106] *Ibid,* at 456.
[107] *Ibid.*
[108] Zoey Becker, "Betrayal of Public Trust: Pfizer under fire for resisting Paxlovid compulary license" (April 21 2022), online: *Fierce Pharma* <https://www.fiercepharma.com/>; Pfizer signed a voluntary license with the medicine patent pool, but The Dominican Republic is not part of that license.

on Western philosophy of knowledge and property rights. Enforcing this Western IP framework uniformly across countries with different economic, social, and cultural interests is a form of imperialism or economic neo-colonialism. It is clear from the description of the political history of TRIPS agreement that TRIPS as a trade policy administered by WTO was not drafted to further the economic development of developing countries. Rather, it was drafted to protect the economic interests of West-based private sector by ensuring that Western standards of IP protection were being followed in the developing world as well.

To address the consequences of TRIPS on public health, the Doha Declaration officially provided clarification that developing countries could use the TRIPS flexibilities to the maximum to ensure access to essential medicines without the fear of trade sanctions from developed countries. However, if these flexibilities worked then the equitable access to Covid-19 vaccines shouldn't have been a problem. Part 2 of this thesis will discuss how TRIPS flexibilities have failed to ensure equitable global distribution of Covid-19 vaccines, and whether the alternative of a waiver of TRIPS obligations for developing countries is a better solution. Part 2 also shows how private companies have managed to use the TRIPS agreement and the present IP framework to their benefit and have ensured that their IP rights in new vaccine technologies continue to be protected across the globe. The human right to health is downplayed yet again as the private sector backed by the developed countries' governments have continued to resist and restrict the efforts of developing countries in adopting mechanisms that dilute protection of IP rights by ensuring greater access to vaccines. The US and EU countries continue to argue that stricter IP protection in vaccine technologies is essential for fostering innovation and development of Covid-19 vaccines. Part 2 will also discuss how this argument which forms the "economic rationale or theory of IP rights" fails in the context of vaccines in infectious disease pandemics.

The discussion in the sections above follows the basic argument made by most scholars that a "one size fit all" approach to intellectual property is not suitable or appropriate for all countries. The Covid-19 pandemic seems to be the second unfortunate public health crisis after the South Africa's HIV pandemic that has brought waves of solidarity among developing countries to revive the access campaign against the highly protectionist IP regime. However, IP protection in vaccine technologies presents a far more complex problem and finding solutions within the current IP framework no longer seems like an option. South Africa and India's proposal for a waiver of TRIPS obligations to increase access to Covid-19 vaccines is a temporary solution

literally outside of the TRIPS agreement. Further, it is also clear that using the rights discourse wherein the "private rights in IP" are put up against "human right to health" or "right to promote public health" which helped the developing countries Thus, Part 2 of the thesis will establish that there aren't any solutions within the TRIPS agreement to address the inequitable distribution of Covid-19 vaccines caused by protection of IP rights of pharma companies. Further, while invoking the right to promote public health and human right to health gave developing countries a win in the form of Doha Declaration, the Covid-19 pandemic has intensified the need to find solutions that are beyond TRIPS flexibilities and the traditional Western discourse of public good or human rights vs private rights.

With this backdrop, it is important to explore alternate interdisciplinary frameworks to address this global health concern. The next section will introduce one such alternative - the field of bioethics and the process of a bioethical enquiry into intellectual property policy restricting the availability of vaccines.

CHAPTER 2. BIOETHICAL FRAMEWORKS FOR SOLVING GLOBAL HEALTH CONCERNS

2.1. Brief Introduction to Bioethics

Bioethics should not be confused with medical ethics. Medical ethics is primarily based on the Hippocratic literature. It can be described as ethics for the medical profession that governed the doctor-patient relationship and focused on highlighting the behaviors that made a good doctor. Bioethics came after medical ethics.[109] From the 1960s, the world saw unparalleled advancement in health technologies and medicine, which brought forth novel ethical issues in biomedical sciences, clinical medicine, and healthcare. Ethical issues related to genetics, artificial reproductive technologies, abortion, organ transplants, and clinical research involving human subjects were central to the field of bioethics and influenced its foundation.[110] Apart from the advances in biomedical sciences and technologies, another growing concern was the

[109] Bonnie Steinbock, "Introduction" in *ed, The Oxford Handbook of Bioethics* (New York: Oxford University Press, 2007) 1 at 2.
[110] Daniel Callahan, "Bioethics and Policy—A History" (21 September 2015), online: *The Hastings Center* <https://www.thehastingscenter.org/>, [https://www.thehastingscenter.org/briefingbook/bioethics-and-policy-a-history/].

power exercised by clinicians and scientists, which affected the quality of patient care.[111] Patients' rights and the ethical issues involved in medical decision-making became a significant aspect of bioethical discourse. In its development, bioethics has transformed into a critical and contemplative field of enquiry and has evolved beyond professional ethics governing the clinical profession. However, medical ethics is still considered a part of the broader bioethics field, despite their starkly different methodology and approach.[112]

The second world war raised numerous horrifying instances involving the use of human subjects for clinical or medical research, raising critical ethical concerns. One of the war crimes which was tried in the infamous Nuremberg Trials, was the crime against prisoners of war who were abused in unethical biomedical clinical trials. In late 1940s, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.[113] It became the prototype of many later codes that intended to assure that research involving human subjects would be carried out in an ethical manner. However, the code's impact was inadequate to curtail significant forms of unethical research on humans, as shocking cases of patients being injected with live cancer cells or viruses without their consent, continued to surface. Horrifyingly unethical Tuskegee trials in which researchers aimed to determine the historical natural causes of syphilis on untreated black patients, showcased the grim reality of colonialism and racism in medical research from 1930s till 1970s.[114] In 1974, the US government established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to provide regulations to protect the rights of human subjects in clinical research.[115] The Commission developed several recommendations that resulted in the Belmont Report which aimed to identify the broad underlying ethical principles that would govern the protection of human subjects in clinical trials, and would act as a basic set of guidelines for all health practitioners, providers, citizens etc. The report later became crucial in the creation of major principles of bioethics, that is, respect for persons' autonomy, beneficence, and justice.[116]

[111] *Ibid.*
[112] *See* Helga Kuhse & Peter Singer, "What Is Bioethics? A Historical Introduction" in Helga Kuhse & Peter Singer, eds, *A Companion to Bioethics* (Oxford, UK: Wiley-Blackwell, 2009) 1.
[113] *Steinbock, supra* note 109.
[114] *Ibid* at 7.
[115] *Ibid.*
[116] *Ibid.*

With just about 60 years having passed since its inception, bioethics is a young field of study. As bioethics was growing into a separate field during the late 60s, its development was influenced by a plethora of socio-political changes in the West such as the civil rights movement, the Vietnam war, nuclear weapons, and the revival of feminism which drove the debate on abortion rights.[117] The publication of John Rawls's *A Theory of Justice* had a significant impact on American philosophers. It filled them with a new sense of confidence and showed them that there could be a rational approach to ethics that produced actual results applicable to practical problems. As a result, philosophers in the United States began to take interest in normative and applied ethics for analysis of not just moral but practical issues such as euthanasia, abortion, capital punishment, allocation of scarce medical resources and so on.[118] Since many of these practical issues were related to biomedical sciences and healthcare, this undertaking of the philosophers led to the formation of bioethics as a critical discipline.

2.2. Bioethics as Global Health Ethics

Despite great advancement in health and medical technologies, inequity in the state of global health continues to persist. Inequitable state of health across the globe is a result of a wide range of economic, social, environmental, and political factors. Neo-liberal economic policies have led to the widening of disparities in wealth among high-income and low-income or low-middle income countries.[119] Environmental degradation through industrialization and globalization, emergence of a large range of infectious diseases that affect populations at large, neo-colonialism, racism, misogyny, gender-based violence, armed conflicts, religious wars, and so on continue to impair the state of global health.[120] Scientific and medical research has been largely focused towards finding cures for diseases that mostly affect developed countries, thereby showcasing the colonial nature of research in the field of medicine. The benefits of new advances in health technologies and medicine are predominantly available to people living in the developed countries.[121] Communicable diseases such as malaria, tuberculosis, HIV, and Ebola continue to take many lives in low-income countries where nascent public health systems

[117] *Steinbock, supra* note 109 at 3.
[118] *Ibid,* at 4.
[119] *See* Solomon Benatar, Abdallah S Daar & Peter A Singer, "Global health ethics: the rationale for mutual caring" in Solomon Benatar & Gillian Brock, eds, *Global Health and Global Health Ethics*, 1st ed (Cambridge University Press, 2011) 129-140.
[120] *Ibid.*
[121] *Ibid.*

are insufficient to provide adequate healthcare.[122] Extreme poverty and its dehumanizing effects have been largely ignored, and despite leaps of development in science and technology, more than half of the world's population continues to suffer due to poor healthcare.[123] The social implications of advances in health technologies need to be considered, since it is crucial to deliberate on why already verified drugs and vaccines or the multitudes of amassed scientific knowledge have not been used to improve health across the globe.

Bioethics has developed into a field that provides ethical principles and frameworks to address such abovementioned grave global health concerns. Bioethics has been an interdisciplinary field since its inception. Scholars and professionals belonging to several disciplines, such as theology, sociology, philosophy, religion, medicine, biology, politics, and law, have contributed to its theoretical foundation and construction of its methodology.[124] Drawing from its multi-disciplinary establishment, bioethics has started to extend from impacting micro-level doctor-patient relations to meso-level healthcare institutions and macro-level international relations.[125] The need for exemplary shifts towards extending ethical discourse to global health issues at the institutional and policy levels is more evident now than it has ever been. The international community needs to be continually informed of their ethical obligations to preserve the dignity of all humankind, and to empower social justice and welfare by improving global health. Since most of the development of the bioethics field has primarily been in the west, bioethicists have been starkly criticized for ignoring the bioethical literature and ethical concerns of countries other than the west.[126] Bioethicists have also been criticized for eliminating dialogue on issues surrounding the continued effects of racism and colonialism from bioethical discourse.[127] Some scholars have also commented strongly on the "whiteness" of bioethics to elaborate how bioethics has restricted its discourse to issues that primarily affect the West, such as ethical issues concerning the latest biomedical technologies, whereas more

[122] *See* Michael J Selgelid, "Justice, infectious diseases and globalization" in Solomon Benatar & Gillian Brock, eds, *Global Health and Global Health Ethics*, 1st ed (Cambridge University Press, 2011) 89.
[123] *See* Norman Daniels, "International health inequalities and global justice: toward a middle ground" in Solomon Benatar & Gillian Brock, eds, *Global Health and Global Health Ethics*, 1st ed (Cambridge University Press, 2011) 97.
[124] *See* Ana Iltis, "Look Who's Talking: The Interdisciplinarity of Bioethics and the Implications for Bioethics Education" (2006) 31:6 The Journal of Medicine and Philosophy 629–641.
[125] *Supra* note 119.
[126] *See* Catherine Myser, "Differences from Somewhere: The Normativity of Whiteness in Bioethics in the United States" (2003) 3:2 The American Journal of Bioethics 1–11.
[127] *Ibid*; See also Derek Ayeh, "Bioethical Silence and Black Lives" in Osagie K Obasogie & Marcy Darnovsky, eds, "11. Bioethical Silence and Black Lives" in *Beyond Bioethics* (University of California Press, 2019) 128.

social and immediate issues of poverty and health disparities continue to be ignored.[128] WIPO's consultation draft on IP and bioethics principally talks about the morality and ethics of patenting certain new technologies such as gene patenting, etc.[129] There has been no adequate response on issues of IP and access to medicines/vaccines until very recently. However, the role of bioethics in creating ethical global health policies continues to expand, especially in recent times.

The Covid-19 pandemic has roaringly brought forth existing health disparities and has raised the curtain on the poor state of health systems across the globe. Bioethics scholars have spoken up and published scholarly articles, commentaries, and news reports about a plethora of ethical concerns that have continued to materialize form the very onset of this pandemic. From ethical issues surrounding fast-tracked clinical trials for covid-19 vaccines, access to vital resources, overburdened health systems, mask mandates, compulsory vaccination and so on, bioethicists have provided their inputs and conducted ethical enquiries into global pandemic policies.[130] Bioethics is now global; thus, global health ethics can be called a significant sub-field of interdisciplinary bioethics. Heath and ethics can provide a framework of values and principles for health policies that can be developed, promoted, and diversified across cultures globally. Furthermore, bioethics can influence global policies to promote the idea of a holistic model for human flourishing that is not limited to economic development and can stimulate the peaceful use of scientific knowledge for the betterment of all human life. Thus, reflecting on its growing global nature and interdisciplinary framework, bioethics can provide an ethical solution to the global health concern of IP laws restricting access to vaccines.

2.3. Bioethics and Human Rights Discourse

As many issues in Bioethics are closely associated with human life and health, there is often a crossover between Bioethics and Human Rights discourses wherein many bioethical concerns are addressed through the established international framework of human rights. However, it is necessary to clarify the differences between these two discourses, as their methodology for

[128] *Supra* note 126.
[129] *Intellectual property and bioethics: an overview* (Geneva: World Intellectual Property Organization, 2007).
[130] *See* Amy L McGuire et al, "Ethical Challenges Arising in the COVID-19 Pandemic: An Overview from the Association of Bioethics Program Directors (ABPD) Task Force" (2020) 20:7 The American Journal of Bioethics 15–27; Zamina Mithani, Jane Cooper & J Wesley Boyd, "Race, Power, and COVID-19: A Call for Advocacy within Bioethics" (2021) 21:2 The American Journal of Bioethics 11–18.

solving issues varies significantly. In this section, I discuss how bioethics is a better and more appropriate discipline than human rights to address the problem of IP rights and access to vaccines.

In 2006, United Nations Educational, Scientific and Cultural Organization (UNESCO) released a declaration called the UNESCO declaration on Bioethics and Human Rights[131], which spurred discussion among bioethicists about the exact purpose of the declaration.[132] The lack of clarity as to what the declaration sets out to achieve led scholars to explore the relation between Bioethics and Human Rights.[133] While many blame the drafting of the declaration for the controversy, some pointed out striking differences between bioethics and human rights. Ashcroft's comment on the matter, "what this debate demonstrates is that rather than the Declaration bringing bioethics and human rights discourses and practitioners together, it in fact forced them to confront their differences"[134] is an appropriate description of the controversy. Ashcroft and Andorno[135] have discussed the ideological and political critiques on the declaration. One of the criticisms is that the declaration gives a narrow interpretation of human rights, without considering economic and social inequalities, or unequal wealth distribution across the globe, and that there is no representation of the poor.[136] However, other declarations on human rights can also be subjected to a similar criticism. Another criticism highlights the lack of legal force or an enforcement mechanism within the declaration. Again, all declarations on human rights such as UDHR, ICCPR or ICESCR are not legally binding on nations. It is also crucial to question the lack of involvement of WHO in drafting this declaration. It is unclear if the declaration sought to address the lack of laws or legal guidelines for doing bioethics, and it also fails to clarify how bioethics is positioned with respect to human rights laws. The declaration also makes it frustrating to understand if it intends to incorporate bioethical principles into human rights, so that they can be used for addressing larger global issues, or if it intends to make human rights as the dominant language for doing bioethics.[137]

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[131] Universal Declaration on Bioethics and Human Rights, UNESCO, 2006.
[132] *See* Richard Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights" in Michael Freeman, *Law and Bioethics* (Oxford University Press, 2008), 31-53 DOI: 10.1093/acprof:oso/9780199545520.001.0001.
[133] *Ibid,* at 33-35.
[134] *Ibid.*
[135] *See* R Andorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics" (2009) 34:3 Journal of Medicine and Philosophy 223–240.
[136] *Ibid.*
[137] See *Ashcroft and Andorno, supra* note 132 and 135.

Bioethical frameworks are different from human rights in their application. Human Rights may focus more on individual demands and preferences than the entire community or society, whereas bioethics tends to focus on health and welfare of the global majority.[138] Bioethicists are neutral in giving importance to Civil - Political or Economic, Social and Cultural Rights. Bioethicists do not see Human Rights as a means through which to provide solutions for bioethical inquiries.[139] Still, because of the vast and global discourse surrounding human rights, they use human rights as a platform to further bioethical concerns, which could potentially encourage Human Rights advocates, lawyers etc. to entertain such bioethical issues globally.[140] Bioethicists look to Human Rights as a way of broadening the platform for bioethical concerns such as public health, access to medicines, global health inequity, reproductive rights etc.[141] Though when complex issues are blanketed under an overreaching term of "right to health", more specific bioethical concerns are left unaddressed. Bioethicists therefore claim that Human Rights impose universal solutions over far more complex and local problems and do not fit well for specific bioethical concerns.[142] Another issue with Human Rights is that they are too flexible, which does not lead to practicably acceptable solutions. Therefore, Bioethicists may apply human rights in raising the right issues before the world but not solving them.[143]

In the previous section, I discussed the conflict between intellectual property laws and the human right to health and concluded that despite there being a strong and established international framework for human rights, intellectual property rights of pharmaceutical companies have prevailed over the right to health of individuals. As mentioned above, bioethics does not use rights as guiding moral concepts to solve bioethical concerns, but rather focuses on moral theories that provide a foundation for human rights, such as deontology, utilitarianism, virtue ethics, etc. While bioethical principles do focus on preserving the dignity of all humans, they are equally motivated towards securing social justice for all, rather than putting the basic liberties and rights of individuals on a pedestal. Thus, a bioethical enquiry into intellectual property laws that restrict access to vaccines can provide solutions that are focused towards improving global health.

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[138] *Ibid.*
[139] *Ibid.*
[140] *Ibid.*
[141] *Ibid.*
[142] *Ibid.*
[143] *Ibid.*

2.4. Bioethics and Law

Ethics and Laws differ in their purpose. While ethics is a process of determining what is good and bad with the aim of promoting the good, laws have a narrower scope and are aimed towards ensuring that common interests of society are fulfilled. Most laws can be enforced in a society by means of penalties or punishments.[144] Owing to law's characteristic of being more action oriented, many scholars have elaborated on how bioethics can use laws as action tools to enforce bioethical principles, and to solve bioethical concerns in practice.[145] The role of law in bioethics is clearly defined as an enforcement tool.[146] However, it will be wrong to ignore the work that bioethics does for laws, especially health laws. Health law is a field of law that has been greatly used to address bioethical concerns.

There are several examples of bioethics and laws working together for better health policies. Principles of bioethics have been used to regulate clinical trials and to ensure the safety and autonomy of human subjects who participate in such trials.[147] Bioethics has used legal tools to encourage patient-centered care in the medical community by advocating for patients' rights.[148] Laws and policies surrounding reproductive rights and artificial reproductive techniques have been heavily guided by bioethical discourse and the advice of national ethics committees. Bioethicists have had a major role to play in the development of laws related to end-of-life care, such as, the recent legislation called Medical Assistance in Dying (MAiD) in Canada.[149] While most scholars have noted how bioethicists use laws as tools, many scholars have also criticized the role of law in doing bioethics. Laws tend to focus more on rules and procedures, which impedes achievement of the goal of bioethics which is "moral reflection" or to find out what is good and promote it. Nevertheless, bioethics and law are interdependent, and the role of bioethics in health policy needs to be more systematized and standardized.[150] As Susan Wolf states, instead of solely focusing on a "top-down" approach wherein bioethical principles are translated into legal practice, a "bottom-up" approach for examining "when has law done a

[144] *See* Susan M Wolf, "Law & Bioethics: From Values to Violence" (2004) 32:2 J Law Med Ethics 293–306.
[145] *See* Zachary E Shapiro, "Bioethics in the law" (2017) 47:1 Hastings Center Report, online: <https://onlinelibrary.wiley.com/doi/10.1002/hast.662>.
[146] *Ibid.*
[147] *See* C E Schneider, "Bioethics in the language of the law" (1994) 24:4 Hastings Cent Rep 16–22.
[148] *Ibid.*
[149] Shelley Tremain, "Bioethics (and) MAID in Canada" (3 February 2020), online(blog): *Bioethical Philosophy* < https://biopoliticalphilosophy.com/>.
[150] *See Wolf, supra* note 144.

good job and when a bad one, what kind of law has succeeded in addressing what problems"[151] is essential for a better collaboration between bioethics and law. Developing "bioethics of law" would require questioning "whether law is being used in the pursuit of ethical goals".[152]

Intellectual property laws do not prima facie fall under the domain of health laws. However, patents and other forms of intellectual property rights are deeply interwoven within drugs and pharmaceutical policies. Furthermore, intellectual property laws affect access to medicines and vaccines across the globe causing a global health concern, and so they should be treated as a component of global health policy. My goal is to apply a bottom-up approach and use bioethical principles, approaches, or moral theories to investigate whether intellectual property laws are ethical, and whether they promote good, in context of access to vaccines.

CONCLUSION

In Chapter I, I discussed the Western normativity underlying IP framework within the TRIPS agreement which is a result of a political history involving coercion and manipulation used by developed countries against developing countries. Since then, the TRIPS agreement has come into conflicts with matters of public health and the rights discourse led to a debate between protecting IP rights vs protecting right to promote public health or human rights to health. However, neither of these discourses have solved the debate and the Covid-19 pandemic has revealed that IP rights continue to be protected at the cost of public health and human right to health of several people in developing countries. Therefore, I proposed bioethics as a framework to address this problem, as bioethics provides a broad, flexible and an interdisciplinary approach to counter the normativity and rigidity of laws and human rights discourses. In Part III of the thesis, I will give a brief description of the various theoretical approaches of doing bioethics and identify the approach that is best suited to solve my research problem. Through this "bottom-up" bioethical enquiry into IP laws I aim to find solutions beyond the current legal framework of IP protection that promote ethical goals of global health.

As stated before, the Part II of this thesis will critically examine the solutions provided in the Doha Declaration for the disastrous consequences of TRIPS agreement on public health. I will analyze whether the flexibilities within TRIPS agreement which were reinforced by the Doha

[151] *Ibid* at 295.
[152] *Ibid.*

Declaration can ensure equitable distribution of Covid-19 vaccines across the globe. Part II will compare the TRIPS flexibilities with the TRIPS waiver proposed by India and South Africa, to analyze which of them can lead to fast and immediate distribution of Covid-19 vaccines in developing and low-income countries.

PART II: TRIPS FLEXIBILITIES AND TRIPS WAIVER

CHAPTER I. DEFINING TRIPS FLEXIBILITIES

1.1. Doha Declaration

The Doha Declaration of 2001 is hailed to be a win for developing countries against the pharmaceutical industry, as it ensures that no signatory of TRIPS agreement is prevented from enacting policies directed towards protection of public health interest. Even though developed countries maintained their stand on the importance of providing stringent patent protection to pharmaceutical products for growth of industry, the evidence showing increased prices of patented drugs being responsible for the death of millions in the HIV epidemic was sufficiently hard-hitting. The US and EU countries could no longer ignore the demands of developing and least developed countries for a substantial declaration on the role of TRIPS agreement in

securing public health.[153] It took the death of millions of people including children, for the developed countries to acknowledge the concerns related to the conflict between provisions of TRIPS and public health interests. The right to health of the public had been reduced to a threshold where it was being compared with the right to protection of a private commercial entity's property.

While the declaration may be a strong policy statement with adequate legal enforcement as per the Vienna Convention on Laws of Treaties, however, the practical implications of its provisions, that is, if they resulted in any concrete solutions for public health-related concerns of the developing and least developed countries remain uncertain.[154] Even though the immediate concern for the TRIPS council was to deal with the HIV crisis in Africa, the scope of Doha Declaration wasn't limited to just the HIV epidemic, or epidemics of such kind, but every and any public health concern would fall within the ambit of coverage of this declaration. Similarly, though access to medicines was the main objective for which the meeting at Doha was held, the scope of the declaration, however, covers not just medicines, but any products, methods or technologies related to health, including surgical, therapeutical, or diagnostic devices or any such medical equipment. The declaration also applies to not just patents but all kinds of Intellectual Property Rights that are included within the text of TRIPS agreement.[155]

1.2.TRIPS Flexibilities

The primary goal of developing countries was to seek a formal clarification in the form of a declaration, from the TRIPS council on whether the agreement enabled the protection of intellectual property to override the protection of public health. Through a plain reading of Article 8.1[156] which lays down the underlying principles of TRIPS agreement, it can be ascertained that the provision allows members to adopt any measures required for maintaining public health by enacting local laws, to the extent that such laws are in compliance with other provisions of the agreement. The language of Article 8.1 seems to be contradictory to the

[153] *See* Carlos M. Correa, *"Implications of the Doha Declaration on TRIPS and Public Health"* (WHO, 2002).
[154] James Gathii, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties" (2002) Faculty Publications & Other Works, online: <https://lawecommons.luc.edu/facpubs/414>.
[155] *Supra* note 11. See Scope of The Doha Declaration.
[156] Article 8.1 of TRIPS agreement: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.".

objectives of signing this agreement, which are clearly set out in Article 7.[157] The Doha Declaration affirmed the developing countries' interpretation of flexibilities within TRIPS, and apart from laying down the importance of Articles 7 and 8 for interpretation of its other provisions, the declaration also emphasized the role of TRIPS in protection of public health. The Declaration clarified that none of the provisions of TRIPS agreement stand in the way of any member country's rights of protecting public health, and that the flexibilities available within the TRIPS agreement can be utilized by developing countries to ensure the protection of public health, without fear of violating any other provisions of the agreement.[158] Paragraph 5 of the Declaration specifically lists some of the flexibilities available to developing and least developed countries, within the TRIPS agreement. These flexibilities are:

i. Compulsory Licensing: The Declaration states that, "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". This clarification corresponded to Article 31 of TRIPS agreement, which lists the conditions for granting compulsory licenses. The Doha Declaration re-affirmed that while Article 31 talks about how compulsory licenses must be granted and provides examples for grounds on which they may be granted, it does not limit the grounds on which member countries can grant compulsory licenses, and that may range from non-working of a patent to public health.

ii. Emergency: The Declaration provides members with the discretion to determine what constitutes a state of "national emergency or other circumstances of extreme urgency" within the context of Article 31(b) of TRIPS agreement. This means that member countries can decide the instances of public health crisis to include, such as the HIV epidemic within the meaning of emergency. Pursuant to Article 31(b), this would imply that member countries are not obligated to secure prior permission of patent holders for granting compulsory licenses in such circumstances.

iii. Parallel Imports: The declaration allows member countries to freely incorporate provisions for exhaustion of intellectual property rights within their national legislation without any fear of violation of agreement. Parallel imports were crucial in securing the supply for HIV medicines in South Africa. Parallel imports or grey market imports basically allow the government or any trading firm of member states

[157] Article 7 of TRIPS Agreement: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.".
[158] *Supra* note 153, at 13-17.

to buy products, such as prescription drugs, in some other country and import them without prior authorization from the local rights owner of that product.[159]

1.3.Paragraph 6 of the Doha Declaration

The Declaration calls for action by developed countries to ensure that the developing countries or LMICs with limited or no manufacturing capacity for pharmaceuticals are able to effectively utilize the flexibility of compulsory licensing. Article 31(f) of the TRIPS agreement states that products manufactured through compulsory license shall be predominantly for use in the licensee's domestic market.[160] During the HIV epidemic, the African countries that did not have manufacturing capacity, sought to import generic drugs from other countries that did have this capacity, such as India. However, it was the concern of LMICs that once TRIPS is implemented in full force from 2005, countries would only be able to grant compulsory licenses to products that are going to be used predominantly for the domestic market, and so would not be able to export them to countries without manufacturing capacity in pharmaceutical products. The LMICs strongly advocated for a change in the language or removal of Article 31(f) of TRIPS agreement.[161] However they were met with resistance as the process to amend the TRIPS agreement was cumbersome, as it involved gaining consensus of all WTO members, a subsequent amendment of national laws of all member countries, and further implementation.

The other option considered by the WTO members to deal with the problems mentioned in paragraph 6 was through the interpretation of Article 30 of the agreement. Article 30 allows members to provide for limited exceptions to the grant of exclusive patent rights in a way that such exception is not in conflict with the normal exploitation of the patent and does not harm the legitimate interests of patent owners.[162] One example of such exception is the Bolar exception, which allows generic manufacturers to utilize the patented product before the completion of term of patent solely for research or market authorization purposes. This helps the generic manufacturers to make generic medicines available in markets right after the term of patent protection for the said drug lapses, thus preventing any delays.[163] Using Article 30 of

[159] Keith E. Maskus, *"Parallel imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries"* (WIPO, 2001), at 3-4.
[160] Article 31(f) of TRIPS agreement: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected, (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.".
[161] *Supra* note 153, at 19.
[162] *Ibid.*
[163] *Ibid,* at 13. (See footnote no. 44.)

TRIPS agreement to solve the problem would only require amendment in national laws and not to the TRIPS agreement, making it a more viable solution than amendment of Article 31. However, the language of Article 30 allowed for only a "limited exception" and any exception for the grant of compulsory license would obstruct the normal exploitation of patent and harm the legitimate interests of patent owners. The developed countries were instructed to provide an expeditious solution to problems faced by LDCs by the end of 2002. The developed countries devised a somewhat complicated solution which was nevertheless accepted, and the decision was adopted by General Council, thus settling the problem under paragraph 6 of Doha Declaration.[164]

The decision on paragraph 6 of Doha Declaration was limited in its applicability, that is, it was only applicable and relevant to "patented pharmaceutical products that were in demand due to public health problems"[165], and these products would also include active ingredients needed for their manufacture along with diagnostic kits. The members that did not have adequate manufacturing capacity for such pharmaceutical products were named as "eligible importing member".[166] While all LDCs were eligible to be an importing member within the meaning of this decision, any other members could also become an importer by notifying the Council of TRIPS of their intention to use this system. This system is only applicable in case of national emergencies or situations of extreme emergency, and the member states had the discretion of deciding what would constitute such an emergency.[167] The "exporting member" would be the country that had manufacturing capacity for the pharmaceutical product in need and could use this system to export them to an eligible importing member. The process on how this system was to be used by the LDCs or any other developing country was clearly specified in a way that this system was only meant to meet the demands of medicines in affected countries during public health emergencies.[168] The LDCs or any other eligible importing member had to send a notice to the TRIPS council specifying the names and quantity of the products in need. Any member other than LDCs had to provide an adequate proof showing that they do not have the manufacturing capacity for the product in need.[169] Further, the eligible importing members

[164] WTO, General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (1 September 2003),* WTO Doc: WT/L/540, online: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
[165] *Ibid.*
[166] *Ibid.*
[167] *Ibid.*
[168] *Ibid.*
[169] *Ibid.*

must mention that the exporting country has granted a compulsory license for the export of said product. There were conditions on which a compulsory license could be granted in the exporting member country for this purpose.[170] These were, a) only the amounts of product needed by the importing country could be manufactured under this license, b) the products manufactured under this arrangement had to have unique labelling and packaging which distinguished them clearly from other products, and c) the exporting country had to publish relevant information about the products concerning its quantities, distinguished packaging or labelling etc. on a website. The eligible importing countries had to reasonably ensure that the products imported in their territories under this arrangement are not re-exported further. This decision/solution was adopted as Article 31*bis* of the TRIPS agreement, which has been described as "monstrosity of bad faith, hypocrisy and bureaucratic red tape" by James Love, a well-known advocate of TRIPS waiver for access to essential medicines.[171]

1.4.Technology Transfer

The Doha Declaration also reinforces the need for developed countries to engage in disseminating their technology by transferring it to developing and least developed countries, which was the original and major "quid-pro-quo" condition while signing of TRIPS agreement in 1995. However, in the decision on paragraph 6, developed countries only stated that they recognized their role in transfer of technology to developing and least developed countries. While they affirmed their resolve to pay special attention to technology transfer and capacity building especially in pharmaceutical industry, there was no elaborate plan laid out by them as to how they planned on doing this, in contrast to the elaborate conditions laid down for compulsory licensing. Technology transfer and capacity building were most promising solutions that weren't effectively addressed, despite there being provisions related to technology transfer already existing within the TRIPS agreement. The declaration only led to more promises by the member countries, but no actual concrete action-based solutions for implementation of technology transfer.

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[170] *Ibid.*

[171] *See* James Love, "TRIPS waiver, circa (Feb 7) 2022", (7 February 2022), online: *Medium* <https://jamie-love.medium.com/trips-waiver-circa-2020-450df671a24c>.; (James Love is the director of Knowledge Ecology International, an NGO working on knowledge governance. "The "fix" for the problem in the 20-word Article 31.f was the 468-word Article 31bis, a 1042-word Annex to the TRIPS Agreement, 220 words in nine footnotes in the Annex, plus a 136-word Appendix to the Annex to the TRIPS Agreement.").

In March 2002 session of Council of TRIPS, Kenya on behalf of the developing countries addressed the need for stronger recognition and implementation of technology transfer and capacity building strategies for a more sustainable and long-term response to public health crisis.[172] The statement made by Kenya voiced the need for developed countries to support the acquisition of necessary medical technologies by developing and least developed countries, as this would be the most sustainable way to address public health concerns in these countries. A staff working paper released by WTO discusses the obligation of developed countries under Article 66.2[173] of TRIPS agreement, and states that developed countries have a "positive obligation" upon them to encourage technology transfer in least developed countries. A positive obligation only accounts for voluntary steps from developed countries towards promotion of technology transfer without any legal enforceability.[174] In 2003, the TRIPS council adopted a decision for implementation of Article 66.2, which required developed countries to submit periodical reports on incentives promoted and measures adopted by them for ensuring transfer of technology in LDCs.[175] These reports included steps taken by developed countries towards advancement of foreign investment, trade, technology management and capacity building, in LDCs. Any legislative enactments in developed countries for such promotion of technology transfer was beyond the scope of Article 66.2, or any other provisions in TRIPS agreement.[176] This paper, which was released in 2018, analyses the reports submitted by developed countries till 2016 and identifies the broad areas in which technology transfer initiatives have been widely reported.[177] It concludes by stating that, "LDCs have primary responsibility for their own development" and shifts the responsibility of effective implementation of Article 66.2 on LDCs by criticizing them on their lack of feedback on reports provided by developed countries.[178] The authors of this working paper do not acknowledge the possible need for there being a fact checking body within WTO that ensures implementation of technology transfer in LDCs, but instead put this burden on LDCs.[179]

[172] *Supra* note 153 at 25. (See footnote no. 82)
[173] *Ibid.* "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."
[174] *See* Jayashree Watal and Leticia Caminero, "Least-developed countries, transfer of technology and the TRIPS Agreement" (WTO, 2018).
[175] *Ibid,* at 6.
[176] *Ibid.*
[177] *Ibid.*
[178] *Ibid.*
[179] *Ibid,* at 23.

1.5.Post-Doha Declaration

The Doha Declaration cannot be called a successful endeavor, as the paragraph 6 solution hasn't been effective in diminishing the concerns with respect to access to medicines, especially in Africa. Oxfam, in 2005, reported that the paragraph 6 solution proposed by the rich countries and agreed upon by the WTO members in 2003, was very difficult to use as it involved several complex steps, and the solution hardly seemed feasible for providing access to life saving medicines in the poorest countries.[180] International aid from developed countries was poured into Africa during HIV epidemic as an act of goodwill, which helped in bringing the epidemic under control.[181] However, developed countries, especially the US, were not ready to make any changes in trade related policies that ensured capacity building in LDCs. By 2005, Oxfam points out that the African group had a proposal for WTO members which translated the promises made in Doha Declaration into a formalized amendment.[182] The proposal was not given any attention, as the interest of members had shifted towards implications of TRIPS on agriculture and biodiversity.

The flexibilities available within the TRIPS agreement were highlighted in the Doha Declaration, and developing countries were urged to incorporate them into their national legislation. However, post- Doha there weren't many developing or least developed countries that made any use of these flexibilities, except India and I will talk about the unique position of India later. The flexibility of extended transition periods for LDCs was hardly of any use to them, as most of them had already enacted patent laws in their jurisdictions after signing the TRIPS agreement. Many of these countries were also hesitant in incorporating other provisions such as for compulsory licensing or parallel imports, mainly because their understanding of TRIPS and what it would mean for their trade was very limited.[183]

The US and other developed countries in the EU have been coercing developing countries into signing bilateral Free Trade Agreements (FTAs) that call for enactment of TRIPS plus

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[180] *See Africa and the Doha Round Fighting to keep development alive,* Oxfam Briefing Paper (November, 2005).
[181] UNDP, *Discussion Paper on The Doha Declaration and its Impact on Access to Medicines and Right to Health* (20 December 2011), at 15. "Dedicated financing for ART rose from US$1.6 billion in 2001 to US$15.9 billion in 2009, with substantial increases in funding through the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR) and other bilateral programmes and charitable contributions."
[182] *Supra* note 180.
[183] *Supra* note 181.

provisions in their domestic laws. Brazil, China, Jordan and other Central American nations have had no other option but to avail trade concessions through FTAs by providing TRIPS plus protection to intellectual property rights in their domestic laws.[184] TRIPS plus entails stronger protection of Intellectual Property that limits the use of flexibilities such as compulsory licenses or parallel imports which have helped several countries in securing access to generic medicines. It also calls for a longer term of patent protection extending more than 20 years. However, interestingly, TRIPS plus arrangement does not provide for increased and accelerated provision for technology transfer in these countries, contrary to the objectives of TRIPS agreement. The EU has also been intercepting and detaining the consignments of generic products manufactured in India that are being exported to other countries mainly in Africa, on the grounds that the consignments have products that seem to be in violation of the minimum required IP protection standards provided in TRIPS agreement.[185] In 2011, an understanding was reached between India and the EU over this pending dispute at the European Court of Justice which entailed that the EU will not intercept India's generic drugs consignments unless there is sufficient evidence to establish the likelihood of diversion of these drugs into European markets. However, pursuant to this understanding the EU passed a new set of border regulations that violate the core objectives and principles of TRIPS agreement and Doha Declaration, such as, territoriality, respect of sovereign independence, access to medicines, free movement of foods for international trade, etc.[186]

1.6.India's Use of TRIPS Flexibilities

Before the signing of TRIPS agreement, India like most other developing countries did not grant patent rights to pharmaceutical products under the Patents Act of 1970. This allowed easy manufacture and export of cheap generic copies of patented medicines.[187] Indian pharma industry had established itself as a major producer and supplier of generic medicines. However, with growing industrialization, globalization, rapid economic reforms and opening up of its economy, India being a WTO member had to maintain its trade relations with developed as well as other developing and least developed countries.[188] India's pharma industry was worried about the collapse of generic manufacturing business, and so were other developing and least

[184] *Ibid.*
[185] *Ibid.*
[186] *See* Brook Baker, "Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough" (2012) Joint PIJIP/TLS Research Paper Series, online: <https://digitalcommons.wcl.american.edu/research/24>.
[187] *See Jayashree Watal, supra* note 23 at 296-300.
[188] *Ibid.*

developed countries who were dependent on India for their supply of cheap medicines.[189] The Indian government had no other option but to amend its Patent laws in compliance with the TRIPS agreement, and also to make sure that the flexibilities available within TRIPS were utilized to the maximum extent so as to sustain its generic manufacturing business.[190] Therefore, India's aggressive utilization of TRIPS flexibilities was motivated from the need to make sure that Indian pharma industry maintains its growth and development in the coming years.

India has a well-established Bolar exemption under the Indian Patents Act[191], which has been extensively utilized by the generic manufacturers thereby making sure their medicines are available in the market right after the term of patent of a patented drug expires. The most creative use of flexibilities available within TRIPS agreement was the judicial interpretation of Section 3(d) of Indian Patents Act in the Novartis[192] case. Section 3(d) of the Act aimed at restricting the "evergreening" of patents, as it restricts the grant of patents for products that are only slightly modified versions of already existing products. It basically acts as a limitation on what can be considered as an invention eligible for patent protection.[193] Through this provision, India has identified and utilized a flexibility available under Article 27(1) of the TRIPS agreement which defines what can be included within "patentable subject matter". Therefore, section 3(d) states that, "a mere discovery of a known substance that does not result in enhancement of efficacy of that known substance" will not be considered as a novel invention having an inventive step and will not be granted patent protection. In the Novartis case, the

[189] *Ibid.*
[190] *Ibid.*
[191] Section 107A of the Indian Patent Act is known as India's Bolar Exemption. The fundamental objective of Section 107A is to delineate certain acts which are not to be considered as infringement. The relevant section has been reiterated below- "For the purposes of this Act- (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; (b) Importation of patented products by any person from a person, who is duly authorized under the law to produce and sell or distribute the product, Shall not be considered as an infringement of patent rights"
[192] Novartis AG v. Union of India & Others (Supreme Court of India) Civil Appeal No 2706-2716 of 1 April 2013.
[193] Indian Patents Act (2005 Amended Act) Section 2(1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application; Section 2(1)(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art Section2(1)(ac) capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry; Section 2(1)(l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

patent application for its product Glivec, a drug used for a type of leukemia, was rejected because Novartis wanted to patent a product with the Active Ingredient being a new version of an already existing compound whose patent protection term had expired.[194] The case was appealed in the Supreme Court of India, after the application faced rejection from the Intellectual Property Appellate Board (IPAB), as well as the high court. The patent application for Glivec had seen pre-grant opposition from the Cancer Aid Society of India that was advocating for easier access to life saving cancer medicines, and highlighted the price difference between the patented and generic versions of drugs which could severely limit the access to such drugs.[195] The Supreme Court rejected the appeal, on the grounds that the product was not an invention within the meaning of Section 3(d) of the India Patents Act. This decision was not only important for ensuring supply of cancer drugs in India but also to numerous developing and least developed countries which were dependent on generic drugs exported by India.[196] The flexibility within TRIPS highlighted by Section 3(d) has been used as a model law by several other developing countries. An empirical study conducted on patent cases in India, between the years 2005-2016 to evaluate the decision in cases that faced objections on the grounds of Section 3(d) concluded that the patent applications or patents most likely ended up being abandoned or rejected if they faced pre or post grant opposition on the grounds of Section 3(d).[197] India's creative interpretation of TRIPS provision as a flexibility it can exploit to ensure access to medicines was a positive outcome, despite facing a lot of criticism and objections from the big pharmaceutical companies of developed countries.

While compulsory licensing is stated as most effective in ensuring access to essential medicines in developing and least developed countries, especially during a public health crisis such as HIV epidemic, India's usage of this flexibility has not been extensive. Compulsory licensing is covered under Section 84 of the Indian Patents Act and can be granted after 3 years of any patent being granted if the reasonable requirements for the patented invention in the country has not been met, or if the patented invention is not available at an affordable price, or the patent is not worked in the Indian territory.[198] The first case of compulsory license was between

[194] Niloufer Sohrabji and Kaitlyn Maloney, "Section 3(d) and Pharmaceutical Patents in India" (2020) 25:3–4 JIPR, online: <http://op.niscpr.res.in/index.php/JIPR/article/view/65198>.
[195] *Ibid.*
[196] *Ibid.*
[197] *Ibid,* see Conclusion.
[198] Section 84 of The Patents (Amendment) Act, India, 2005, No. 15, Acts of Parliament, 2005: Compulsory licences: "At any time after the expiration of three years from the date of the 170 [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the

Bayer, a multi-national foreign pharmaceutical company and Natco, a local Indian drug manufacturer.[199] The drug in question was Nexavar, which is used in treatment for kidney cancer. Natco applied for CL to the controller of patents on the grounds that Nexavar is not available to the Indian public at an affordable price and the patent has not been worked in India. Bayer's arguments focused on the need for pharma companies to obtain return of investment for the research and development put into the invention, and also that since the market for the drug in India was limited, it wasn't economically viable for the company to establish manufacturing facilities in India.[200] The controller, IPAB and subsequently the high court granted the compulsory license and noted that not only did the case fulfill all conditions for grant of compulsory license mentioned in section 84 of the Act, the authorities clarified that the objectives of TRIPS agreement is also to ensure protection of public health and access to technology and medicines, and not just the protection of intellectual property rights. Hence, Bayer's arguments did not hold ground and were rejected. Despite a strong judicial interpretation available on compulsory licensing, local pharma companies tend to avoid availing this flexibility and are rather more inclined towards trading through voluntary license agreements. However, the threat of grant of compulsory license has been effective in motivating foreign multi-national companies to enter into voluntary licensing agreements with Indian pharma companies.[201]

Voluntary licensing agreements have been proven to be effective in India for technology transfer. The Indian pharma industry being one of the largest producer and supplier of generic medicines in the world, especially to the developing and least developed countries. It has the capacity and technical knowledge at its disposal to enter into such licensing agreements with multinational pharma companies. These agreements are also usually drafted in a highly complex manner to protect the rights of licensor rather than to ensure faster and efficient access to the technology. The key motivation to utilize technology transfer agreements remains to be

following grounds, namely:- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India."

[199] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).

[200] *See* K D Raju, "The First Compulsory Licencing Case in India under the TRIPS Agreement: An Analysis of Bayer Versus Natco Pharma Ltd" (2016) 1:1 Journal of Development Policy and Practice 71–88.

[201] *Ibid.*

highly commercial with protection of IP being the most important goal of such agreements, rather than efficient access.[202]

As mentioned in the beginning of this part, I summarized the available flexibilities within the TRIPS agreement and how India, South Africa and some other developing and least developed countries have utilized these flexibilities to ensure access to essential medicines. India has been the powerhouse of generic drugs manufacturing, having been the most creative in its utilization of TRIPS flexibilities. However, it is interesting to note how India was also hit by the lack of availability of vaccines in the ongoing COVID-19 pandemic, despite having a well-established pharma industry capable of licensing agreements and technology transfer for securing access to patented drugs. This has also been detrimental for many developing and low-income countries that are dependent on India for the supply of essential drugs, which further signifies the importance of these countries having their own sufficient infrastructural and technological pharmaceutical capacities to develop their own vaccines. It seems that none of the available TRIPS flexibilities have been useful in ensuring fast and effective access to vaccines in COVID-19 pandemic. This calls for an analysis of whether TRIPS flexibilities were ever enough to ensure access to vaccines in an infectious disease pandemic. These concerns have been raised earlier by the LDCs and international NGOs, however they still remain unaddressed. These concerns have pushed India and South Africa to be the first WTO members to call for a waiver of TRIPS agreement to ensure faster access to vaccines in the pandemic. In the next section, I discuss the TRIPS waiver proposal put forward by India and South Africa and their reasons for same. Following that I will discuss the case of vaccines and how TRIPS agreement affects their availability in a pandemic situation. I will then assess whether any of the existing flexibilities can be successfully utilized in securing an efficient access to vaccines, or whether TRIPS waiver is the ultimate solution.

CHAPTER II. COVID-19 PANDEMIC: VACCINES AND IP

2.1. India and South Africa's TRIPS Waiver Proposal

The COVID-19 pandemic has severely burdened healthcare systems throughout the world and has made the need to have sufficient access to medicines and medical equipment such as

[202] UN – ESCAP, Satyabrata Sahu, APCTT-CSIR Workshop on Technology Commercialization and Transfer (1-3 November 2017).

ventilators or diagnostic kits, stronger than ever. This pandemic is a worldwide public health crisis and because of it being a highly transmissible infectious disease, the pandemic will be over for all only when there is proper preventive and medical care available to all. In 2020 which were the early to mid-stages of the pandemic, clinical trials for vaccines and anti-viral medicines had already begun. The rich countries were already entering into preliminary agreements with the pharma companies to ensure supply of vaccines and other essential drugs and medical equipment for their population. The low-middle income countries (LMICs) were left on their own to make the necessary arrangements for their population. India and South Africa recognized the threat of Covid 19 virus claiming millions of lives if access to vaccines, essential drugs and medical equipment weren't secured early and this could only be done if the manufacture and supply of patented drugs and vaccines was enabled freely without the cumbersome process of compulsory licensing and other requirements within the TRIPS agreement. Hence, they tabled the TRIPS waiver proposal at WTO on 2nd October 2020.[203] The TRIPS waiver proposal called for a waiver from implementation of Articles 1, 4, 5, and 7 of Part II of the TRIPS agreement, which means developing countries and LDCs would be exempted from providing protection to copyrights and related rights, industrial designs, patent and undisclosed information (trade secrets) for a particular period of time.[204] India and South Africa have given an explanation for the waiver in their proposal, stating that it is proven through many studies and reports of international organizations that TRIPS flexibilities are not sufficient in ensuring fast and efficient access to essential drugs and medicines in a public health crisis.[205] The proposal received opposition from developed countries especially the EU countries, and they sought clarification on the reasons for proposing the TRIPS waiver at council meetings in October, November and December of 2020. In their responses to these questions from developed countries, developing and least developed countries clarified in detail, their reasons for proposing a temporary TRIPS waiver to fight the Covid 19 pandemic.[206] The key arguments of developed countries against the TRIPS waiver are, a) TRIPS flexibilities such as compulsory licensing are sufficient in ensuring supply of vaccines, b) voluntary

[203] WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19 Communication From India And South Africa (2 October 2020),* WTO Doc: IP/C/W/669.
[204] *Ibid.*
[205] *Ibid.*
[206] WTO, TRIPS Council, Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19 – Responses To Questions Communication From The Plurinational State Of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic Of Venezuela And Zimbabwe (14 January 2021), WTO Doc: IP/C/W/672.

cooperative approaches such as C-TAP and COVAX facilities will solve the Covid 19 crisis, c) voluntary licensing is the solution for covid-19, d) a waiver from TRIPS obligations would severely impede innovation in medical and pharmaceutical technologies in a pandemic, e) suspension of provisions related to protection of trade secrets would lead to trade secrets theft, f) there is not enough evidence that TRIPS compliance has hindered prevention, treatment, containment of COVID-19 so that a waiver is needed, and g) the waiver proposal is not clear as to how it will be implemented in national laws.[207] In the next section I will examine whether these arguments against TRIPS waiver advanced by the developed countries hold or not. While the proposal calls for the application of waiver not just on vaccines, but also on other essential medicines and medical devices, I have restricted my analysis of application of TRIPS flexibilities to vaccines.

2.2. The Case of Patent Protection of Vaccines in a Pandemic

One of the major arguments that developed countries have always made in favor of stricter protection of intellectual property, especially patents for pharmaceuticals and vaccines is that protection of intellectual property is crucial for incentivizing innovation. This is commonly known as the economic theory of patent protection, that is, patents incentivize innovation by providing them monopoly rights on the patented product for a limited period of time. Turner in his article explains how the economic theory of patent protection for vaccines in an infectious disease pandemic does not hold, due to the existence of various other factors that provide enough incentive for innovation to manufacturers, even without patent protection.[208] COVID-19 pandemic is not the first public health crisis that has brought these issues with patent protection and vaccines to the surface. Similar concerns from developing countries in ensuring access to vaccines have been seen in previous infectious disease epidemics, and yet developed countries question the role of TRIPS agreement in limiting access to vaccines. Evidence from previous pandemics show that vaccines are the fastest way of limiting the effects of an infectious disease pandemic, and the countries that can secure sufficient vaccines for their population are in a better position to fight the pandemic.[209] Securing sufficient access to vaccines is typically a challenge for developing and least developed countries, and at the same time it is crucial for them to secure sufficient access as many of them do not have well established health care systems. The overwhelming burden of increasing infectious disease

[207] *Ibid.*
[208] *See Mark Eccleston-Turner, supra* note 1 at 577.
[209] *Ibid.*

cases can cripple the already weakened health care systems in these countries thereby leading to increase in mortality rate of the population.

The argument that patents are essential for incentivizing vaccine production in a pandemic is flawed, and this can be seen in the evidence gathered in previous such public health crisis. The basis of arguments based on the economic theory for patent protection of vaccines is focused on the assumption that such patent protection will prevent generic manufacturers from introducing cheap copies of vaccines in the market, which could significantly harm the incentive for vaccine manufacturers to manufacture vaccines.[210] However, complex licensing requirements makes it incredibly difficult for generic manufacturers to manufacture generic vaccines at a fast and efficient rate in a pandemic.[211] Further, generic manufacturers cannot rely on the safety and efficacy data of the innovator and have to prepare a novel regulatory dossier. Since the test data of original manufacturer of vaccines is also protected through trade secrets and legal instruments for protection of undisclosed information, the generic manufacturers do not have free access to the test data and cannot rely on it to prove the bioequivalence of a generic vaccine to the original vaccine.[212] The preparation of a regulatory dossier entails collection of safety and efficacy data through pre-clinical trials and trials involving human subjects, which is not the case for manufacture of other generic drugs. The heavy costs and complex regulatory process makes the manufacture of generic vaccines a much more cumbersome process than the manufacture other traditional drugs, thereby reducing the incentive for generic manufacturers to enter the market.[213]

Vaccines are also complex package of technologies. Each technological element may be protected through different patents, thereby creating a situation called patent thickets. Patent thickets are commonly understood as overlapping of different patents constituting a single product, which means that any generic manufacturer will have to obtain licenses for all the patented technologies that form the vaccine. This will further impede the research and development activities in vaccine manufacturing.[214] Since, pandemics are random events and the research and development process of vaccines takes years, there is already much less incentive for pharma companies to enter the vaccine market. Demand for vaccines is also

[210] *Ibid.*
[211] *Ibid.*
[212] *Ibid.*
[213] *Ibid*, 584-586.
[214] *Ibid,* 586.

highly fluctuating since the demand may be more during the pandemic and will subside once the pandemic is over. As the primary goal of patent owner is to financially exploit the patents and since the financial returns on vaccine patents is highly uncertain, research and development for vaccine patents is already limited to few well-established pharma companies or research organizations. Developed countries have already made provisions and created funded organizations for research and development of vaccines, however such efforts cannot be afforded by most developing and low-middle income countries.[215] Case studies on Hepatitis B[216] and EBOLA[217] vaccines further show that existence of patents on vaccine technologies and complicated patent licensing processes create major hindrances in access to vaccines during pandemic. The case study of H1N vaccine shows the procurement strategies that delay the access of vaccines in developing countries.

A) Hepatitis B Vaccine[218]

The plasma Hepatitis B vaccine was brought to market by Merck & Co. in the 1970s at an unbelievably high price due to the complicated technologies used for the manufacture of these vaccines, thereby rendering it unaffordable by the developing countries. Deeply motivated to counter the high prices and inaccessible Merck vaccine, Dr Alfred Prince of New York Blood Center combined all his research efforts in inventing a new Hepatitis B vaccine technology expressly for the purpose of transfer of technology in the developing countries. Dr Prince's vaccine technology was "transferred to" or "acquired by" Korean manufacturing companies that began the production immediately. A Hepatitis B vaccine task force was set up in the 1980s to accelerate the production of vaccine to solve the problem of diminished availability in developing countries. Subsequently, there were several manufacturers of Dr Prince's Hepatitis B vaccine by the end of 1980s. There were no relevant patents protecting the vaccine technology and the prices of vaccines reduced astonishingly owing to the high market competition between numerous manufacturers in the market. The price of Merck vaccine in 1970s which started at 30 dollars per dose, but by the end of 1990s the price competition between several manufacturers in the market reduced the price of vaccine to just 0.50 dollars per dose. The first recombinant DNA vaccine for Hepatitis B was invented by a company called

[215] *Ibid, 584. "Since this time, however, the Biomedical Advanced Research and Development Authority ("BARDA") has invested heavily in the industry, to ensure the United States has sufficient domestic vaccine manufacturing capacity in the event of a pandemic."*
[216] *See Chris Garrison*, supra note 13 at 18.
[217] *See* Matthew Herder, Janice E Graham & Richard Gold, "From discovery to delivery: public sector development of the *r* VSV-ZEBOV Ebola vaccine" (2020) 7:1 Journal of Law and the Biosciences lsz019.
[218] *Supra* note 216.

Biogen that was granted a patent for rDNA vaccine technology. The patent was licensed for manufacture to Merck and SmithKlineBeecham at a maximum royalty rate of 15%. It was noted that the significant portion of increase in cost of vaccine was not due to the royalties but due to lack of competition in the market, which means that patent licensing did not lead to similar fall in prices of vaccines as did the market competition which existed when there were no patents. Even though there was a drop in the price of rDNA vaccines, it took double the time for the price to drop in case of patented rDNA vaccine as compared to the plasma vaccine technology. A much more significant drop was seen after Biogen's patent term expired and the patent was also revoked in 1999.[219] The Biogen patent was revoked as it was too broad and the patent owner had monopolized the rDNA vaccine market by manufacturing it through any way but only disclosed one way of manufacturing them in their patents. This case was prior to the signing of TRIPS agreement when the developing countries did not have product patents for pharmaceutical products. With the sort of monopoly created by Biogen, the generic manufacturers in developing countries would not have been able to compete with the bigger pharma companies despite having no patent protection and all the necessary know-how prior to the TRIPS agreement. The signing of TRIPS agreement meant much more stringent patent protection which would give significant market power and monopoly to patent owners of vaccines and would leave no space for innovation in developing countries to manufacture vaccines at the same rate.

B) EBOLA rVSV-ZEBOV Vaccine

A vaccine candidate for EBOLA virus or the rVSV-ZEBOV vaccine was invented by a team of scientists in a laboratory in Winnipeg, Canada in early 2000s, and a provisional US patent application for the vaccine was soon filed by Canadian government as early as 2002.[220] Contrary to the belief that patents are meant to incentivize innovation and development in pharma industry, there was little or no interest in the commercialization of Ebola vaccines as there was no demand for it in the market. This case study further provides evidence as to how the economic theory for patent protection fails when applied to vaccines, as it shows that pharma companies will only invest in commercial development of a vaccine if there is demand for it in the market. Whether the vaccine is protected by a patent or not is irrelevant for the pharma companies. It is critical to note that the big pharma companies showed no interest in

[219] *Ibid.*
[220] *Supra* note 217.

developing a vaccine for Ebola, even though the vaccine candidate had shown great deal of success in clinical trials with animals as early as 2002.[221] The interest and efforts to develop the vaccine only emerged during the peak of Ebola epidemic in West Africa. The public sector in Canada financed and contributed towards the development of cGMP grade rVSV-ZEBOV vaccine and licensed its commercialization to a private company that had no regulatory experience.[222] The private company failed to carry out its obligations under the contract. When the Ebola epidemic outbreak in West Africa began to claim many lives, and was declared a global health emergency by WHO in 2014, Merck purchased the patent rights on rVSV-ZEBOV. However, it was the public sector that paid for the Phase I clinical trials, and the Phase III trials held in West Africa during 2014-15 Ebola epidemic were also led by a WHO-consortium.[223] Merck was lauded for its cooperation, though its role in the development of vaccine was only limited to providing permission to access the clinical grade vaccine that was originally developed by the Canadian public sector.[224] It is critical to note how big pharma companies gain commercially through such epidemics, by only providing access to their patents.

C) 2009-H1N1 Vaccine

The case study on H1N1 vaccine highlights how developed countries enter into various procurement agreements for vaccines during a pandemic, and how these agreements limit the access to vaccines in developing countries and LMICs.[225] Advance Procurement Agreements (APAs) are utilized the most by developed countries for procurement of vaccines in an influenza pandemic, such as the H1N1 pandemic in 2009. In order to ensure the urgent immunization of "at risk" population in a pandemic, countries enter into agreements with vaccine manufacturers in advance. The agreements are in form of sleeping contracts which remain dormant and become legally enforceable only after the occurrence of a pre-determined event. Such arrangements are high-risk that require significant preliminary investment, and are therefore only affordable by the developed countries. During the HINI pandemic, several developed nations had signed APAs to secure the availability of H1N1 vaccines for their population.[226] This meant that the first batches of vaccines were all secured for the developed

[221] *Ibid.*
[222] *Ibid.*
[223] *Ibid.*
[224] *Ibid.*
[225] *See* Mark Turner, "Vaccine procurement during an influenza pandemic and the role of Advance Purchase Agreements: Lessons from 2009-H1N1" (2016) 11:3 Glob Public Health 322–335.
[226] *Ibid.*

nations and LMICs were forced to be the last to vaccinate their people. Many developing countries could not enter into APAs even if they could afford to do so, as the pharma companies already had several orders from developed nations to take care of.[227] While the people in developed nations were all vaccinated against the virus, people in LMICs had to purely depend on donations from developed nations for securing procurement of H1N1 vaccines. WHO developed a Pandemic Influenza Preparedness (PIP) framework which called for donation of 10% of the vaccine production to WHO. This 10% would indirectly be distributed in the LMICs. However, this framework had little impact on access to vaccines as the APAs required the pharma companies to supply the vaccines to developed countries on priority basis.[228]

2.3. Compulsory and Voluntary Licensing of vaccines

Compulsory licenses are not viable tools for governments of developing countries to procure vaccines because the licensee will still need to develop their own safety and efficacy test data for their generic vaccines, and such data is protected by the patent owner through trade secrets or as undisclosed information. Further, most developing and least developed countries lack the necessary infrastructure and technical know-how to manufacture the licensed vaccines, thereby making it impossible for generic manufacturers to quickly and efficiently manufacture vaccine in a pandemic.[229] Article 31*bis* demands a complicated procedure with several requirements on a case-to-case and country-by-country basis for the grant of compulsory licenses (as discussed in previous section on solution for paragraph 6 of Doha declaration). This will only make the already complex procedure of licensing vaccine patents more cumbersome for developing countries.[230] Some academics have also suggested TRIPS compliant measures for involuntary transfer of technology through compulsory licensing of trade secrets, which they claim remains an unexplored flexibility within the TRIPS agreement for developing countries and LMICs to utilize for ensuring access to vaccines.[231] Trade secrets and undisclosed information are not patents, and are protected through various different legal instruments such as extremely strict non – disclosure agreements. A compulsory license would in-turn burden the licensee with the obligation to ensure confidentiality of information transferred through such an arrangement. This arrangement is very similar to the kind of obligations that exist in standard voluntary

[227] *Ibid,* 324-325.
[228] *Ibid,* see Conclusion.
[229] *Supra* note 216*,* 22-25.
[230] *Supra* note 11, see Solution for Paragraph 6 of Doha Declaration.
[231] *See* Olga Gurgula & John Hull, "Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer" (2021) 16:11 Journal of Intellectual Property Law & Practice 1242–1261.

technology transfer licensing agreements, though made involuntary and compulsory by the governments. However, the scope of what information will be disclosed would still be at the discretion of disclosing parties. Such an arrangement seems as complicated and burdensome as the compulsory licensing of patents.

Voluntary licenses can be of many forms and structures that may or may not involve the transfer of technology and know-how as part of the licensing arrangement. The main reason behind voluntary licenses not being sufficient in bringing down the prices of vaccines or in ensuring fast and efficient access to vaccines is because of the complexity of their arrangement and the fact that the patent owner has more negotiating power that the licensee. Patent thickets, which are very common in vaccine patents would also mean the obtaining of several patent licenses in order to manufacture one vaccine.

2.4. Access to Vaccine Technologies in Developing Countries

While there have been some initiatives to ensure access to vaccine technologies in developing countries, most developing countries and LDCs are yet to have manufacturing capabilities for developing their own vaccines. Gavi, a public-private partnership for vaccine alliance was launched in 2000 with the aim to immunize the population, especially, children in low-income countries with gross national income per capita below or equal to US$ 1630. Gavi helps low-income countries to scale up national vaccine manufacturing and immunization programs through co-financing arrangements.[232] While Gavi's efforts have been of some relief to low-income countries, many low-middle income countries cannot take the benefit of Gavi alliance.[233] A WHO study on trends in transfer of vaccine technologies in developing countries concluded that there has been a shift from public sector to private sector in the initiation of technology transfer arrangements through various mechanisms, such as joint ventures, licensing agreements and so on.[234] However, since creation of manufacturing infrastructure in developing countries is often not cost-effective, it suggested that local governments and generic manufacturers shift their efforts in scaling up research and development, to attract transfer of technology arrangements from multinational pharma companies.[235] The conclusion of this

[232] JB Milstien, P Gaulé, M Kaddar, "Access to vaccine technologies in developing countries: Brazil and India" (2007) Vaccine, 1;25(44):7610-9. doi: 10.1016/j.vaccine.2007.09.007. Epub 2007 Sep 20. PMID: 17913312, at 7612.
[233] *Ibid.*
[234] WHO Report, Increasing Access to Vaccines Through Technology Transfer and Local Production, 9-24.
[235] *Ibid,* at 24.

study does not take into account the interests of developing and low-middle income countries that are already burdened with health infrastructure challenges, and have weak health care systems. Therefore, putting the burden on governments of these countries to scale up their vaccine research and development efforts, without any mandated international aid seems to be unreasonable and a morally deprived conclusion.

CHAPTER III. COVID -19 VACCINE LANDSCAPE

In the introduction chapter, I described the most recent data available on vaccine landscape at the time of writing. As of September 2022, over 68% of the world's population had received at least one dose of Covid-19 vaccine, however only 22.7% of people in low- and middle-income countries had received one dose of covid vaccine.[236] Almost all the patent owners or patent application filers for covid-19 vaccines are from the developed countries. As developed countries are now securing 3rd and 4th booster shots for their populations to combat with evolving Covid-19 variants, billions in low-income countries remain unvaccinated without a single dose. With new emerging variants of the virus, and increased transmission ability of the virus, vaccinating the world's population is an urgent need to fight this pandemic. While there are some voluntary licensing initiatives between pharma companies of developed and developing countries to scale up the production of vaccines, these efforts are not even remotely close to meeting the world-wide demand for immunization against covid.[237]

3.1. CTAP AND COVAX

C-TAP is an initiative for pooling of IP, technology and know-how on vaccines created by WHO in collaboration with government of Costa Rica. It is based on the model of Medicines Patent Pool which is affiliated with the UN for providing equitable access to HIV medication. C-TAP invites voluntary sharing of covid-19 vaccine and medicine related IP, technical know-how and data to fight the pandemic. To date, however, pharma companies have not shown any significant interest or made any contributions to the scheme.[238] COVAX is part of the Gavi vaccine alliance, and therefore it is accessible to only limited low-income countries. Since COVAX is dependent on donations and goodwill of developed nations, it is limited in its scope

[236] Ritchie et al, supra note 6.
[237] See Siva Thambisetty et al, "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic" (2021) SSRN Journal, online: <https://www.ssrn.com/abstract=3851737>.
[238] *Ibid*, at 12-13.

and is not a sustainable system for scaling up vaccine production.[239] COVAX is designed for meeting the immediate urgent vaccine requirements of LMICs, and while it has achieved some success in that regard, it has not been able to meet its targets due to governance and other external issues.[240]

3.2. Private Sector Practices as a Major Barrier to Access

The private sector driven vaccine production and its lobbying for retaining IP protection continue to be the major reasons for inequity in worldwide access to vaccines. The Ebola vaccine case study shows how there is lack of incentive for the private sector to invest in vaccine development, due to the uncertain demand in market leading to an uncertain return on investment. Therefore, research and development on vaccine technologies is majorly funded by the public sector, with most of the novel innovations in vaccine research occurring in university laboratories. The rich countries in Europe and North America have vaccinated their populations with mainly Pfizer/BioNTech and Moderna vaccines, which are both manufactured using the mRNA technology.[241] The mRNA technology which was licensed to BioNTech in Germany and Moderna in USA, was both perfected and developed with the help of public sector funding. BioNTech was supported by the German government and Moderna developed its mRNA vaccine with help from National Institutes of Health (NIH).[242] Furthermore, a significant element of the mRNA technology called the "lipid nanoparticle" (LNP) delivery system was originally invented and developed by researchers from University of British Columbia (UBC)'s spin-off biotech companies.[243] Despite the fact that majority of funding for research and development of vaccines has come from the public sector, this pandemic has only helped in making the big pharma richer by billions.[244] The pandemic has provided lucrative financial incentives to the pharma companies. After having earned billions

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[239] *Ibid.*

[240] *Ibid*, at 14. "In March 2021, Dr Tedros Adhanom Ghebreyesus (DG WHO) stated that: COVAX is ready to deliver, but we can't deliver vaccines we don't have. As you know, bilateral deals, export bans, vaccine nationalism and vaccine diplomacy have caused distortions in the market, with gross inequities in supply and demand." The authors also provide an example of India's Serum Institute that had to stop its supply to COVAX and redirect it towards meeting India's own increasing demand during the devastating second wave of COVID-19, in May 2021.

[241] Ritchie et al, *supra* note 6. (Access by clicking "vaccinations by manufacturer data" at (https://github.com/owid/covid-19-data/blob/master/public/data/vaccinations/vaccinations-by-manufacturer.csv).

[242] Julia Kollewe, "From Pfizer to Moderna: who's making billions from Covid-19 vaccines?", *The Guardian* (6 March 2021), online: <https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines>.

[243] *See Herder, et al, supra* note 15.

[244] *Supra* note 242.

from the Advance Purchase Agreements with governments of rich countries, these vaccine manufacturers that are driven solely by profit maximization objective are now aiming to continue their earnings from the pandemic, by selling annual booster shots to developed countries at high prices.[245] As the rich countries provide booster shots to their people, millions in LMICs will not even receive the first dose of vaccine until 2024.[246]

Astra Zeneca (AZ)'s collaboration with Oxford University has been proclaimed as more ethical when compared to Pfizer or Moderna, because of its royalty-free, non-exclusive bi-lateral agreements with India's Serum Institute, or its MoU with Brazil to provide vaccines "at cost", until the end of pandemic.[247] These agreements or arrangements are not free of caveats. In compliance with their arrangement, India's Serum Institute had to supply vaccines to UK and other EU countries as AZ couldn't reach its manufacturing targets for the developed countries. This meant that the Serum Institute had to halt its supply of vaccines to LMICs through COVAX and prioritize its supply for the developed countries.[248] AZ's arrangement with Brazil is until the end of pandemic, however, as per their legal arrangement, it is AZ that gets to decide when the pandemic will end.[249]

Private companies have also shown a negligible number of efforts in making their technology voluntarily available to the LMICs, which is why there has been hardly any contribution from the pharma companies in WHO's vaccine technology pool initiative, C-TAP. A Canada-based pharma company issued a public statement stating that it had the capacity to manufacture COVID-19 vaccine and sought a license from Johnson & Johnson (J&J) to manufacture the generic version of its adenovirus vaccines for developing countries.[250] J&J refused to provide a voluntary license to Biolyse. Biolyse, then decided to attempt to file for a compulsory license on J&J vaccine in Canada, through Canadian Access to Medicines Regime (CAMR).[251] However, the process of obtaining a compulsory license in Canada is far more complex than it is in India or other developing countries, since Canada firms have only used this flexibility

[245] Matt Stoller, "Why Joe Biden Punched Big Pharma in the Nose Over Covid Vaccines", (9 May 2021), online: *BIG by Matt Stoller* <https://mattstoller.substack.com/p/why-joe-biden-punched-big-pharma>.
[246] *Ibid.*
[247] *Supra* note 237.
[248] *Ibid.*
[249] *Ibid.*
[250] "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law", (12 March 2021), online: *Knowledge Ecology International* <https://www.keionline.org/35587>.
[251] *Ibid.*

once before.[252] Going back to the case of lipid-nanoparticle (LNP) technology which came out of spin off companies of UBC, LNP is crucial to the development of the only two mRNA vaccines in the world, that is, Pfizer/BioNTech and Moderna vaccines.[253] It is currently unclear as to who owns this technology because its ownership is subject to the outcome of patent wars in USA between the spin-off companies and Moderna.[254] There have been no efforts from either of the companies to voluntarily make this technology available to vaccine manufacturers in LMICs who have not yet been able to perfect this technology for their own mRNA vaccines.[255] In early stages of the pandemic, Moderna had announced that it would not enforce any patents related to its Covid-19 mRNA vaccines and earlier this year Moderna also stated that it would not enforce Covid-19 vaccine patents in the 92 LMICs that were part of GAVI alliance.[256] And yet Moderna has recently sued Pfizer-BioNTech for infringing its patents by copying its LNP technology used in making the Covid-19 mRNA vaccines.[257] Therefore, whether LNP technology would be available to LMICs or not is still unclear due to the uncertainty of its ownership. While many novel technologies are invented in university laboratories, they are often licensed to private spin-off companies, and the universities cannot keep track of the activities of these companies. A voluntary transfer of technology initiative without the involvement of patents or spin-off companies, as was done by Dr Prince in the case study on Hepatitis B vaccines would have been far more impactful.[258]

With help from WHO, a South African biotech pharma company called Afrigen has been able to make a mRNA vaccine candidate, despite there being no voluntary efforts of technology transfer from Moderna or Pfizer/BioNTech.[259] However, it would still take approximately two years before the vaccine enters the market, due to the time required for conducting clinical trials and getting regulatory approvals. This delay could be avoided if Pfizer and BioNTech share their clinical test data and technical know-how with Afrigen.[260] There has been no sign

[252] *Ibid.*
[253] *Supra* note 243.
[254] *Ibid,* see Box no. 1.
[255] *Ibid.*
[256] Derek Lowe, "The mRNA Vaccine Patent Fight Expands", online: <https://www.science.org/content/blog-post/mrna-vaccine-patent-fight-expands>.
[257] *Ibid.*
[258] See Hepatitis B Vaccine case study at 53.
[259] "South Africa's mRNA hub progress is foundation for self-reliance" (11 February 2022), https://www.who.int/news/item/11-02-2022-south-africa-s-mrna-hub-progress-is-foundation-for-self-reliance.
[260] *See* "Moderna's Vaccine Copied by WHO-Backed S. African Scientists", *Bloomberg.com* (4 February 2022), online: <https://www.bloomberg.com/news/articles/2022-02-04/s-africa-s-afrigen-has-made-covid-vaccine-similar-to-moderna-s>.

of voluntary transfer of LNP technology from the Canadian companies either.[261] Pfizer offered to ship millions of doses of vaccines to Africa, but that is not what LMICs want. LMICs want transfer of vaccine technology, which the developed countries are obligated to share as per the "quid-pro-quo" arrangement under TRIPS agreement.[262] Substantial efforts will have to be made by the governments of developed countries such as US, UK, Canada and rich countries of the EU, to mandate technology transfer from private entities, to ensure ownership of crucial IP in such technologies remains with public sector, and towards ensuring new technologies are developing in an open access environment.[263] These efforts, however, may be fruitful in future, but the current pandemic calls for urgent action. This may only be possible by allowing the waiver of TRIPS agreement to LMICs.

3.3. Involuntary/Mandated Transfer of Technology and Open Access Arrangements

Scholars across the world have weighed in on global vaccine inequities and provided numerous alternative suggestions, such as the compulsory licensing of trade secrets. However, implementation of such a licensing scheme by governments would require amendment of national legislation and will also face resistance from other WTO members and the private sector. Fischman-Afori et al, have suggested the adoption of a global vaccine procurement scheme by the issuance of a mandatory and exclusive global compulsory license, wherein in all WTO members collaborate to essentially create a centralized buyer/licensee for vaccine technologies.[264] This proposed global scheme ensures that the private pharma companies receive substantial royalties from combined payments made by the WTO members participating in such a scheme.[265] While the obvious challenges faced in implementation of such a scheme would be gaining consensus of WTO members to collaborate, resistance towards mandated compulsory license and unequal bargaining power of the members, this scheme also fails to take into account that vaccine R&D is usually funded by the public sector.[266] This scheme does nothing to ensure that big pharma does not have a monopoly in production of vaccines, and does less to ensure that LMICs develop their own technological independence.

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[261] *See* Matthew Herder and E. Richard Gold, "A South African company addresses vaccine supply inequity, despite Canada's lack of support" *The Conversation* (28 February 2022), https://theconversation.com/a-south-african-company-addresses-vaccine-supply-inequity-despite-canadas-lack-of-support-177416.
[262] Kamran Abbasi, "Give Africa what Africa really wants" (10 February 2022), s: BMJ 2022;376:o345, https://www.bmj.com/content/376/bmj.o345.
[263] *Supra* note 259, at 9.
[264] *See* Orit Fischman Afori, Miriam Marcowitz-Bitton & Emily Michiko Morris, "A Global Pandemic Remedy to Vaccine Nationalism" (2021) SSRN Journal, online: <https://www.ssrn.com/abstract=3829419>.
[265] *Ibid.*
[266] *Ibid,* at 40.

In contrast to a mandated or involuntary licensing and procurement mechanism, open access initiatives ensure the achievement of both objectives, that is, equity in global access to vaccines and technological independence of LMICs. It provides for a sustainable alternative to the mandatory and complex compulsory IP licensing schemes which governments often resort to, even though these are of no use in the COVID-19 pandemic. A group of scientists, academics and lawyers collaborated their efforts in creating the Open Covid Pledge (OCP) which calls for organizations to pledge their patents and copyrights, making them available freely for the fight against COVID-19.[267] The licenses which are available under this pledge provide for temporary and specific-use pledges from participating organizations.[268] As expected, there has been very little participation from the big pharma in OCP, and so because of its voluntary nature it hasn't been able to solve the problem of global vaccine inequity.[269] For encouraging pharma companies and universities to enter into open access arrangements instead of choosing voluntary licensing agreements with the private sector, the governments will have to provide them with extensive financial and regulatory incentives.[270]

CHAPTER 4. TRIPS WAIVER – CHALLENGES

The challenges that I have highlighted in previous sections with respect to protection of IP in vaccines make it clear that creating an efficient framework to secure equitable access to vaccines without waiving the intellectual property rights protection on vaccines, will be a complex affair. A TRIPS waiver proposed by India and South Africa is aimed towards reducing these complexities and ensuring easy and fast dissemination of vaccine technologies. A waiver will lead to market entry of many capable pharma companies that can use the technical information and undisclosed data to accelerate the manufacture of generic vaccines, thereby creating sufficient market competition. As seen in earlier case studies, generic market competition tends to lower the prices of vaccines far more than what is possible through patent licenses, especially in a pandemic of a scale as large as Covid-19. This would further help vaccines to be available at affordable prices for several LMICs to purchase and vaccinate their population. Efforts from governments and international organizations towards pooling of IP, or the limited voluntary efforts made by pharma companies, are inadequate in helping

[267] Open Covid Pledge (https://opencovidpledge.org/about/).
[268] *Ibid.*
[269] *Ibid*, see participating companies.
[270] *Supra* note 259.

developing countries manufacture their own vaccines. Aa a result, access to vaccines and vaccine technologies in developing countries and LMICs continues to be largely inadequate. The TRIPS waiver along with a combination for incentives for technology transfer will help in scaling up of manufacture and worldwide availability of vaccines to a great extent.

The waiver has seen a lot of support from developing countries, civil societies, NGOs, and other important international organizations all over the world. In April 2021, the United Nations Committee on Economic, Social and Cultural rights released a statement urging the international community to allow the temporary waiver of TRIPS agreement, in order to ensure equitable access to vaccines in developing countries.[271] The committee acknowledged the failure of flexibilities within the TRIPS agreement in this regard and reiterated that intellectual property rights are social rights, the protection of which must not come in way of protecting the human right of right to health of millions in developing countries and LMICs.[272] While most developed countries, especially in the EU, continue to oppose the waiver, there was a change in the US's position under the direction of Biden's administration, to support the waiver. While this may have been a significant blow to the pharma companies, the US position is temporary and only limited to vaccines. A waiver limited to vaccine technologies and not to other pharma products, medical devices, treatments etc. would only help in scaling up of vaccine production, however, issues of access to medical treatments and devices would surface as and when there are new inventions in treatment for COVID-19. With support from US and feedback of other member countries, the original waiver proposal of 2020 was revised and resubmitted by India and South Africa in May 2021. The 2021 proposal specified that the waiver must apply to "health product and technologies including diagnostic, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture".[273] The revised proposal also specified that the waiver must remain in force for a minimum period of three years to successfully fight the pandemic.

[271] UN. Committee on Economic, Social and Cultural Rights, *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property : statement / by the Committee on Economic, Social and Cultural Rights,* UN Doc E/C.12/2021/1, 2021.
[272] *Ibid.*
[273] TRIPS Council, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID19: Communication from India and South Africa' (IP/C/W/669/Rev.1, 21 May 2021), see Paragraph 1.

As discussed in previous sections of this thesis, the arguments advanced by developed countries against TRIPS waiver do not hold. However, at the same time, the waiver itself may be difficult to implement. The proposal submitted by India and South Africa in 2021 is silent on implementation of the waiver and leaves it open for discussion among the WTO members. If the waiver does get approved unanimously by all members, the next step would be to carefully formulate an implementation mechanism, which would also take a lot of time. Parallels can be drawn to the case of implementation of Paragraph 6 of Doha declaration, as discussed in the previous section.[274] The WTO members hesitated in amending Article 31 of TRIPS, and also denied the removal of Article 31(4) despite their being strong advocacy for such amendment from the LDCs. The reason and justification behind this given by the developed country members was that such amendment would entail a long and cumbersome process requiring gaining consensus of all WTO members, amendment in the national laws of member countries and further implementation of such laws. The solution devised by developed countries was in the form of Article 31*bis*. I have already discussed, in previous sections, the drawbacks of this solution and how it did not turn out to be a favorable outcome for the developing and least developed countries.[275] Considering the track record of WTO in adoption and implementation of Article 31*bis,* the TRIPS waiver may face similar constraints and its effect maybe delayed till the next pandemic.[276] The member countries will have the additional task to devise a mechanism compliant with WTO rules and regulation that allows the waiver to come into immediate effect.

Even if the waiver is adopted quickly and brought into immediate effect, the next challenge faced would be its implementation into national laws. The governments will face policy debates at domestic level which could further slowdown the process of implementation of the waiver.[277] Correa et al in their paper also bring forth the effect a TRIPS waiver might have on the implementation of TRIPS plus obligations in some countries, which do not emanate from TRIPS agreement but from bilateral agreements such as FTAs.[278] A narrow interpretation of

[274] *Supra* note 11. (See discussion on Paragraph 6 of Doha Declaration at 39-41)
[275] *Ibid.*
[276]Peter K. Yu, "A Critical Appraisal of the COVID-19 TRIPS Waiver" (October 19, 2021). Intellectual Property Rights In The Post Pandemic World: An Integrated Framework Of Sustainability, Innovation And Global Justice, Taina E. Pihlajarinne, Jukka Mähönen and Pratyush Upreti, eds., Edward Elgar Publishing, 2022, Forthcoming, Texas A&M University School of Law Legal Studies Research Paper No. 21-32, SSRN: https://ssrn.com/abstract=3945304.
[277] *Ibid.*
[278] *See* Carlos M. Correa, Nirmalya Syam and Daniel Uribe, "Implementing A Trips Waiver For Health

the text of waiver proposal, does not indicate that it will be applicable to TRIPS plus obligations as well. These obligations, that come from compliance with FTAs deal with restricting generic products to enter the market during the term of patent of the original product, and also granting data exclusivity to clinical test data submitted by the original inventor.[279] These challenges to implementation of TRIPS waiver will have to be addressed by the WTO members effectively and urgently.

CONCLUSION

Just as how the Doha Declaration had sprouted legal and political debates across the world on conflicts between protection of intellectual property and public health, this waiver proposal revived the old debate and brought forth many new challenges, such as, TRIPS flexibilities, licensing arrangements, role of private sector in IP maximalism and so on. While a critical analysis and scrutiny of the waiver proposal may raise several concerns with regards to its implementation, it is crucial that members of WTO do not limit their interpretation of the proposal to a legal formalistic one but see it as a legal and political tool that will have wide ranging economic and social implications on public health. It is pertinent that the waiver is not just subjected to legal criticism but also gains support from lawyers, scientists, academics, and policymakers across the world, who can devise a way for its quick and effective implementation. A TRIPS waiver is important for mandating the sharing of knowledge and data, and for encouraging open access arrangements in the private sector. The discussion and debate surrounding TRIPS waiver has already generated positive responses from governments and forced the private sector to shift from their profit maximization motive, towards more ethical goals.

In the next Part, I will conduct a bioethical enquiry into the current IP framework for vaccines with the intention to propose an ethical framework for fostering innovation in vaccines that will be more beneficial for enabling equitable global access to vaccines in future pandemics.

Technologies And Products For Covid-19: Preventing Claims Under Free Trade And Investment Agreements" (2021), SOUTH CENTRE, https://www.southcentre.int/research-paper-135-september-2021/.

[279] *Ibid.*

PART III: A BIOETHICAL ENQUIRY INTO THE IP FRAMEWORK FOR INNOVATION IN VACCINES

CHAPTER 1. CHOOSING THE RIGHT APPROACH WITHIN THE METHODOLOGY OF BIOETHICS

The methodology of bioethics reflects a wide range of moral theoretical approaches in normative ethics, including utilitarianism, deontology, contractarianism, virtue ethics, communitarianism, and feminist ethics.[280] Solving practical problems through applied ethics

[280] *See* James Childress, "Methods in Bioethics" in "Moderna's Vaccine Copied by WHO-Backed S. African Scientists", *Bloomberg.com* (4 February 2022), online: <https://www.bloomberg.com/news/articles/2022-02-04/s-africa-s-afrigen-has-made-covid-vaccine-similar-to-moderna-s>."Moderna's Vaccine Copied by WHO-Backed S. African Scientists", *Bloomberg.com* (4 February 2022), online: <https://www.bloomberg.com/news/articles/2022-02-04/s-africa-s-afrigen-has-made-covid-vaccine-similar-to-moderna-s>.

requires bioethicists to apply these broad moral theories and principles to specific practical issues in biomedical sciences, clinical research, healthcare, etc. However, principle-based methods seem to dominate bioethics. Consequentialist principles require analyzing a problem by judging the intended consequences of different courses of action and balancing those consequences towards the desired overall effect.[281] Act-consequentialist methods are mostly utilitarian, since they analyze the anticipated consequences of different courses of actions and apply the principle of utility with an aim to determine which courses of action would result in the greatest good for the greatest number.[282] Rule-consequentialist methods are also utilitarian; however, they take into other considerations apart from just targeting the greatest good of greatest number and aim to create objectively justifiable rules based on their overall anticipated consequences.[283] In contrast to consequentialist principles, deontological principles state that some actions, despite their consequences can be objectively and morally wrong, and those actions must be avoided.[284] There are several deontological principles which may be of higher priority than consequentialist principles, such as, avoidance of killing, veracity, autonomy, justice, etc. However, in bioethical dilemmas such as a case of euthanasia, a bioethicist may be faced with a clash between the two deontological principles: respecting autonomy and avoidance of killing.[285] Rawls's theory of justice or the social contract theory, provides a theoretical and procedural framework for achieving social justice through fair and equitable distribution of resources, goods, rights, capital, and so on. Bioethicists have heavily utilized this theory for building frameworks that provide equitable allocation of resources and uplifting the disadvantaged through a fair and just system of distribution.[286]

A principle-based approach provides medical practitioners or bioethicists with general principles in the form of "action guides" that inform their moral and ethical reasoning.[287] Beauchamp, and Childress, in their classic text called "Principles of Bioethics" devised "Principlism", an approach for doing bioethics or conducting a bioethical enquiry which is largely based on deontological, utilitarian, and justice principles. Principlism is an ethical

[281] *Ibid.*
[282] *Ibid,* at 18.
[283] *Ibid.*
[284] *Ibid,* at 20.
[285] *Ibid.*
[286] *Ibid.*
[287] *Ibid.*

framework with general and unranked principles that are all prima-facie obligatory.[288] Beauchamp and Childress have identified four unranked and prima facie binding principles for solving bioethical problems. They are equal in importance; however, one may outweigh the other during bioethical enquiry and based on specificities of the problem.[289] These principles are a) respect for autonomy (the obligation to respect the decision-making capacities of autonomous persons), b) non-maleficence (the obligation to avoid causing harm), c) beneficence (obligations to provide benefits and to balance benefits against risks), and d) justice (obligations of fairness in the distribution of benefits and risks). Despite facing some criticism in the early years following its formation, Principlism has become the most popular and influential framework for solving bioethical dilemmas in medical practice. In application of Principlism as a method of bioethical enquiry, bioethicists weigh and balance the principles, and through the process of specification they tailor the norms according to the case at hand. Beauchamp and Childress define specification as "a process of reducing the indeterminateness of general norms to give them increased action guiding capacity, while retaining the moral commitments in the original norm".[290]

Emmanuel Kornyo has utilized some of the abovementioned ethical theories and principles to analyze arguments used by developing countries in favour of patent infringements within the TRIPS framework for increased access to essential medicines, especially in context of HIV/AIDS pandemic in South Africa.[291] Kornyo bases his analysis on utilitarian, deontological, justice and beneficence/non-maleficence principles. On the basis of a utilitarian perspective, breaking patents would lead to the greatest good of greatest number as it would render the essential HIV medication affordable to all low-income countries around the globe and strengthen their healthcare systems by reducing the healthcare expenditure and creating more jobs for local people through local manufacturing of medicines.[292] The counter to this utilitarian argument is the deontological argument of categorical imperative which obligates people to respect other peoples' rights and autonomy.[293] Can breaking patents and infringing

[288] *See* T L Beauchamp, "Methods and principles in biomedical ethics" (2003) 29:5 Journal of Medical Ethics 269–274.
[289] *Ibid.*
[290] *Childress, supra* note 280.
[291] *See* Emmanuel Kornyo, "Patent Protection and the Global Access to Essential Pharmaceuticals during Patent Infringements under TRIPS" (2014) Voices in Bioethics Archives (20142015).
[292] *Ibid,* at 5.
[293] *Ibid,* at 6.

the rights of patent holders who invest a lot of time, money, and effort to attain patents for their inventions, and can using their IP as a means to attain essential medicines for the population of developing countries without providing them incentives be justified in an emergency situation? Perhaps in the case of IP and Covid-19 vaccines these arguments can be countered with some facts that have been discussed in the previous chapters. The TRIPS waiver proposal can be justified using the same arguments as made by Kornyo in favor of patent infringements based on the utilitarian perspective, and the deontological counter argument may not apply in the case of access to vaccines. As shown in the previous chapter, the argument that patents incentivize private vaccine manufacturers to further innovation in vaccine technologies in a pandemic is flawed.[294] Also, as discussed in the last chapter of Part II of the thesis, most innovation in vaccines during pandemics is funded by the public sector.[295] However, it is unclear whether these factors will sufficiently solve the conflict between the deontological and utilitarian arguments and allow the waiver from protecting IP rights of the pharma companies to cater the larger humanitarian need for global vaccination against Covid-19. The principle of justice warrants that essential medication should be made available to the most vulnerable populations expeditiously in emergency situations such as the HIV or the present Covid-19 pandemic, even if that would mean breaking patents or granting of a waiver from TRIPS obligations.[296] However, since justice warrants fairness and equal protection of rights under law, the supporters of pharma companies can claim injustice if their patents are broken, or if a TRIPS waiver is granted. The principles of beneficence or non-maleficence should support the risk of breaking of patents or allowing a TRIPS waiver as doing so would benefit the most vulnerable patients across the globe. Kornyo acknwoledges the indeterminateness of who is the most vulnerable or who benefits the most by taking the risk of breaking patents or a TRIPS waiver which may affect the innovation and production of vaccines in a pandemic.[297] In conclusion, Kornyo's analysis is based on the principles derived from traditional ethical or moral theories within bioethics. However, often in case of using Principlism as a framework for doing bioethics, one principle may come in conflict with another and so it is up to the bioethicist to choose the best applicable principle or ascertain the scope of their application.

[294] [cite Turner and discussion]
[295] See pages 50-61 of the thesis.
[296] *Supra* note 291 at 7.
[297] *Ibid,* at 8-9.

Raanan Gillon, who is possibly one of the most ardent proponents of the Principlism approach, defends the approach against its criticism of being too "reductive" by stating that the purpose of the four principles is not to choose the one that fits best but to provide a "culturally neutral", common moral language that everybody must consider while dealing with a bioethical concern.[298] He claims this approach to be "neutral between competing religious, political, cultural, and philosophical theories, can be shared by everyone regardless of their background".[299] However, when it comes to the scope of application of the principles, it is for bioethicists to reflect on the scope and decide the same. Considering these four principles originated with scholars in US, the argument against Principlism that it is a Western approach and not universally applicable across cultures is obvious. To this Ruth Macklin asks ethicists to focus on the distinction made by Beauchamp and Childress between "universal morality" and "community specific morality".[300] She explains a bioethicist must regard cultural practices, traditions, and values of a community and consider the application of the four principles accordingly.[301] Gillon explains the scope of application of these principles in the following words:

> We may agree about our substantive moral commitments and our prima facie moral obligations of respect for autonomy, beneficence, non- maleficence, and justice, yet we may still disagree about their scope of application - that is, we may disagree radically about to what or to whom we owe these moral obligations. Interesting and important theoretical issues surround the scope of each of the four principles. We clearly do not owe a duty of beneficence to everyone and everything; so whom or what do we have a moral duty to help and how much should we help them? While we clearly have a prima facie obligation to avoid harming everyone, who and what count as everyone? Similarly, even if we agree that the scope of the principle of respect for autonomy is universal, encompassing all autonomous agents, who or what counts as an autonomous agent Who or what falls within the scope of our obligation to distribute scarce resources fairly according to the principle of justice? Is it everyone in the world? Future people? Just people in our own countries? And who or what has rights? Do plants have rights? Does the environment have rights?

[298] *See* R Gillon, "Medical ethics: four principles plus attention to scope" (1994) 309:6948 BMJ 184–184.
[299] *Ibid.*
[300] Ruth Macklin, "Can one do good medical ethics without principles?" (2015) 41:1 J Med Ethics 75–78 at 76.
[301] *Ibid.*

> Does a work of art have rights? Do animals have rights and if so, which animals? Conversely, against whom may holders of rights claim the correlative moral obligation? Similar questions concern the scope of legal justice.[302]

Members of the WTO and signatories of the TRIPS agreement are countries with diverse values and conflicting socio-economic interests. As discussed in Part I, the political history of formation of the TRIPS agreement shows how developed countries especially the US at the behest of their private sector, coerced developing countries into entering the TRIPS agreement despite conflicting socioeconomic interests. Therefore, if the WTO members were tasked with conducting a bioethical analysis of the current IP framework for vaccines, there will be numerous conflicts regarding the scope of application of principles, as the developing and low-income countries will use the principles to justify their support for the TRIPS waiver proposal, whereas the developed countries and their pharma companies will use the principles to oppose the same. For example, in the previous chapters I showcased how developed countries enter into Advance Purchase Agreements to hoard more than sufficient supply of vaccines for their populations without considering the lives of people in developing countries who will suffer from shortage of supply of vaccines, and they may justify this by limiting the scope of application of the principles to just people in their own countries. Or the pharma companies may use the principle of autonomy and justice to justify why their IP rights must be protected even if they cause inequitable vaccine distribution. Thus, using the Principlism approach of bioethics to analyze the thesis problem will only result in creation of conflicting positions with no possible solutions or ethical alternatives for the current IP framework of vaccine innovation.

One may also conclude that the Principlism approach may not be appropriate for global health concerns as too much importance is given to individual interests and not to interest of communities. Daniel Callahan, who characterized himself as a communitarian philosopher, also criticized the four principles and scope approach by pointing out that the individualism bias underlying Principlism results from the "central place given to autonomy".[303] Callahan described how non-maleficence, beneficence, and justice all lead back to ultimately reinforcing the autonomy principle. He stated the following:

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[302] *Supra* note 298.
[303] D Callahan, "Principlism and communitarianism" (2003) 29:5 Journal of Medical Ethics 287–291 at 288.

> Non-maleficence, for instance, comes down to a right not to have our mind or body harmed by another, to be left intact; and that is a historical variant of autonomy. Beneficence has always had an unclear place, in great part because to act kindly or generously toward others requires that we have some sense about what is actually good for them. But of course liberal individualism is nervous about going in any direction labelled "the" good of another, as if that was something that others, not the individual himself, could determine. It is no accident, I suspect, that only religious believers are willing to take beneficence seriously, and usually because they are part of traditions that make that both possible and desirable. As for justice, I take it that the whole point of treating people justly, or allocating resources to them in an equitable manner, is to allow them to function as autonomous persons, not discriminated against or harmed by inequitable treatment.[304]

Callahan, thus, prescribes the communitarian way of doing bioethics, which he explains does not consider humans as isolated individuals but as social animals, "whose lives are lived out within deeply penetrating social, political, and cultural institutions and practices".[305] Therefore, the communitarian way of doing ethics is to analyse how certain decisions will affect not just the individual but the community to which that individual belongs. Gillon's response to Callahan's criticism is that the communitarian approach is also compatible with the four principles and scope approach, as bioethicists may base their analyses in accordance to the values that are important to the concerned community.[306] Gillon explains this argument by suggesting that people living in China, who according to their cultural values may choose to give less weight to the autonomy principle when it conflicts with the concerns of beneficence of the entire community.[307] Clearly, Gillon did not consider the implications of using such an approach for making global health decisions that involves balancing the scope of applicability of principles according to cultural, political, social, and economic interests of several countries. As most global health scholars have noted in their work, solidarity and a sense of shared responsibility among communities across the globe is crucial for advancing global health and international development. I wonder if adding another principle supporting 'solidarity and

[304] *Ibid.*
[305] *Ibid.*
[306] R Gillon, "Ethics needs principles--four can encompass the rest--and respect for autonomy should be 'first among equals'" (2003) 29:5 Journal of Medical Ethics 307–312 at 310.
[307] *Ibid.*

shared responsibility' to the four principles, would make Principlism more suitable for solving global health concerns.

In conclusion, despite Gillon's and Macklin's defending arguments about the scope of applicability of the four principles, the fact remains that Principlism is an approach originating from the US and like all the traditional moral theories, it aims towards providing a common and universal moral theory[308] which supposedly also can be culturally specific through adjustment of the scope of applying any or all of the principles. In the first Part of the thesis, I discuss the trends of imperialism resulting globalization of Western theoretical concepts of knowledge and property underlying the adoption of a West-based IP framework for all countries despite varied interests. It is important to note how imposition of Western moral theories or laws on the rest of the world leads to epistemic injustice as it causes the systematic exclusion and silencing of ideologies from the world other than West.[309] Taking into account the abovementioned issues in applying the Principlism approach, I am more inclined towards using an approach that challenges these traditional theories but supports values of solidarity and shared responsibility in addressing global health concerns such as my thesis problem. Communitarianism offers a theoretical framework that defies the liberal individualism rhetoric within bioethics, or, as described by Kuczewski, "communitarianism is about the fundamental importance or ontological priority of the community in regard to human flourishing".[310] However, for reasons that will be discussed in the next chapters, I have chosen the theoretical framework of feminist ethics and ethics of care to analyse IP laws and to explore ethical alternatives to the present IP framework for vaccines. In the next chapter, I describe the theoretical foundation of feminist ethics and ethics of care as moral theories within bioethics, how feminist scholars have demonstrated the application of the fundamental values of feminist ethics and ethics of care to issues in global health and international development.

CHAPTER 2. A FEMINIST EHICS AND ETHICS OF CARE APPROACH

2.1. Brief Introduction to Theoretical Foundation of Feminist Ethics and Ethics of Care

[308] *See Callahan, supra* note 24; "Universalizability, as Kant and other Western moralists have so rightly argued, is a necessary and indispensable condition of morality".
[309] *See* Godfrey B Tangwa, "Globalisation or Westernisation? Ethical Concerns in the Whole Bio-business" (1999) 13:3–4 Bioethics 218–226 at 224-225.
[310] *See* Mark G Kuczewski, "The common morality in communitarian thought: reflective consensus in public policy" (2009) 30:1 Theor Med Bioeth 45–54 at 45.

Feminist ethics challenges traditional ethics by pointing out gender-bias and ignorance of women's perspectives in the formation of theories of traditional ethics.[311] It also challenges the core concepts that lay the foundation of traditional ethics, such as the concept of moral agency in Aristotle or Kant's philosophical theories.[312] Feminist ethics rejects the traditional ethical pillars framed around the idea of an "independent", "autonomous" and "rational" individual, and considers persons to be relational beings whose relationships define their identities, thus acknowledging the "social nature" of moral agency.[313] Feminist scholars consider Gilligan's work in her book *A Different Voice*[314] as the point of inception for feminist ethics, and some may say, also for ethics of care. Gilligan noted the differences in responses of males and females in moral dilemmas and concluded that while women focused more on the narratives and relationships, men focused on rationalizing, reasoning, general moral principles and applying justice.[315]

Virginia Held, who has done pioneering work in the field of ethics of care, considers Sara Ruddick's *Maternal Thinking* as the original source for care ethics.[316] *Maternal Thinking*[317] was published in 1980, in which Ruddick discusses the values that are derived from the relationship between mother and child.[318] Many psychologists have conducted extensive research on the moral development of humans and have reported that moral development of persons is exclusively based on the male perspective, as women's experiences have largely been excluded from the discourse. Ruddick says in her book, "I am increasingly convinced that there are female traditions and practices out of which a distinctive kind of thinking has developed".[319] Her vision in the book is to introduce maternal thinking to the public realm and diffuse it into everyday thinking, thus changing the structures of society which are primarily based on the traditional male models or morality.[320]

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[311] *See* Anne Donchin & Jackie Scully, "Feminist Bioethics" in Edward N Zalta, ed, *The Stanford Encyclopedia of Philosophy*, winter 2015 ed (Metaphysics Research Lab, Stanford University, 2015).
[312] *Ibid.*
[313] *Ibid.*
[314] Carol Gilligan, *In a different voice: psychological theory and women's development*, 38. print ed (Cambridge, Mass.: Harvard Univ. Press, 2003).
[315] *Ibid.*
[316] Virginia Held, *The ethics of care: personal, political, and global* (Oxford: Oxford University Press, 2006).
[317] Sara Ruddick, "Maternal Thinking" (1980) 6:2 Feminist Studies 342.
[318] *Ibid.*
[319] *Ibid,* at 342.
[320] *Ibid.*

Ethics of care is an approach to bioethical enquiry that greatly emphasizes fulfilling the moral responsibilities we have towards those to whom we are responsible. It acknowledges dependence among human beings, which means that humans are not just concerned about individual interests but also of the interests of those whom they care for. This approach values the role of emotions in determining a moral course of action, and propagates the use of emotions such as empathy, sympathy, sensitivity, etc. in making moral decisions. It rejects the dependence on reason and rationality for conducting a moral enquiry, and methods that are primarily based on dominant universal theories such as, autonomy or justice. Ethics of care and feminist ethics are against the Kantian "rule-worship" approach to morality. It motivates an approach that takes interdependent relationships among people into account. Ethics of care extends its prime concepts of valuing caring relations and dependency among individuals to macro-level institutions as well. Modern and developed forms of this approach provide a method of moral enquiry into socio-political transactions for transforming international relations with an emphasis on the moral significance and value of caring.

The ethics of care theory criticizes the concept of a person being "rational", "autonomous", "self-interested", "self-sufficient" and "independent" individual, which forms the basis of dominant moral theories, and is then imported into liberal, political, and economic theories.[321] Liberal individualism propagates the view of society being a culmination of individual and autonomous persons for whom development means furthering one's interests.[322] Liberal feminists also endorse a similar theory stating that for flourishing of groups there needs to be flourishing of all individuals. In ethics of care, persons are not seen as independent individuals, but are "relational" and "interdependent" within a society.[323] They are not born into this world as individuals, but as dependent beings who are then nurtured by families and make relations with other people as they grow in a society. These relations are critical components of a person's identity. Ethics of care acknowledges these relations of people and motivates them to be responsible for their relatedness, whereas liberal individualism is focused on autonomy of persons and freedom or ability to achieve their self-interests.[324] Liberal individualism is

[321] *See* Virginia Held, "The Ethics of Care as Moral Theory" in *The Ethics of Care*, 1st ed (Oxford University Press New York, 2005) 9.
[322] *Ibid* at 13.
[323] *Ibid,* at 13-14.
[324] *Ibid.*

absorbed into neo-liberal economic models which are prevalent in the developed world. Perhaps the most important feature of the ethics of care approach, in the context of my thesis problem, is how it challenges traditional moral theories based on Kantian categorical imperative or the principle of utility that also dominate within political theories. As Virginia Held states, "political theory *is* focused on hypothetical contractual agreements, on universal rights, and on maximizing individual interests in a version of a marketplace".[325] As discussed in Part 1, these same traditional moral theories have been used to justify protection of intellectual property rights in vaccines.

When it comes to the methodology of ethics of care, or applying ethics of care to a bioethical concern, Rita Manning has provides a strategy with four processes: moral attention which calls for specific attention to details of the situation to understand its complexity, sympathetic understanding requiring one to be sympathetic to those suffering in the situation, relationship awareness for extending the value of relationships for human flourishing, and accommodation and harmony which calls for accommodating the needs of everyone for real harmony instead of accepting the superficial harmony inherent in an oppressive society where harmony comes at the cost of those it oppresses.[326] Manning states that the values which motivate a person to be caring in their relationships can be studied and then extended to situations with distant strangers.[327] While Manning provides a well-defined 4-step methodology, it is crucial for the purpose of my thesis to explore how ethics of care can be used for transformation of society at the macro level and apply my conclusions to the problem of this thesis.

2.2. Ethics of Care Vs Ethics of Justice

Carol Gilligan was the first to recognize 'care' as a value other than justice that was showcased by both men and women in their paths to moral development. Scholars have studied her work and identified further distinctions between justice and care perspectives and extended the application of caring values to political theories. Annette Baier's theorizing of Gilligan's work notes how legal instruments of contracts are utilized to further the enjoyment of individual

[325] Virginia Held, "Care and justice, still" in Daniel Engster & Maurice Hamington, eds, *Care Ethics and Political Theory* (Oxford University Press, 2015) 18 DOI: 10.1093/acprof:oso/9780198716341.003.0002.
[326] *See* Rita C Manning, "A Care Approach" in Helga Kuhse & Peter Singer, eds, *A Companion to Bioethics* (Oxford, UK: Wiley-Blackwell, 2009) 105.
[327] *Ibid.*

rights of people by restricting interference from others, however, the implications of such contracts for the "powerless" or as I understand the ones with least number of resources would mean "ignorance".[328] Baier argues that the theory of justice is just a Rawlsian version of Kant's "individualism" that allows people to pursue their own individual interests freely as long as they do not transgress the enjoyment of interests of other individuals in a society.[329] Baier challenges the priority that is given to "justice" and "rights" in traditional moral theories by pointing out that "rights" have historically been reserved for the privileged, and the laws which seemingly follow the "justice perspective" do no ensure that those rights will not be reserved for just the elite in a society.[330] An ethics of justice focuses on arriving at a fair and just solution when a problem showcases competing interests of individual entities, whereas ethics of care rejects the competing nature of interests and focuses on caring relations between people and their mutual interests.[331] Held notes that Rawls's theory of justice is also a representation of both deontology and utilitarianism theories. The subjects of Rawls's theory of justice are free, rational, and autonomous individuals whose rights must be recognized and respected if they are within certain moral constraints.[332] Utilitarianism emphasizes the principle of utility, and justice is reduced to the goal of achieving maximum utility. Kantian and utilitarian ethics are both rationalistic and individualistic moral theories that are considered as more suitable to be applied to in the public sphere than in private moral issues within families.[333] Since ethics of care recognizes persons as relational beings and focuses more on their caring relations, it contrasts with Kantian and utilitarian theories epistemologically. Held writes the following to further describe the distinction between ethics of care and ethics of justice:

> In the dominant moral theories of the ethics of justice, the values of equality, impartiality, fair distribution, and noninterference have priority; in practices of justice, individual rights are protected, impartial judgments are arrived at, punishments are deserved, and equal treatment is sought. In contrast, in the ethics of care, the values of trust, solidarity, mutual concern, and empathetic

[328] Annette C Baier, "The Need for More than Justice" (1987) 13 Can j philos Suppl vol 41–56 at 49.
[329] *Ibid,* at 50.
[330] *Ibid.*
[331] *See* Virginia Held, "Justice, Utility, and Care" in *The Ethics of Care*, 1st ed (Oxford University Press, New York, 2005) 58.
[332] *Ibid,* at 63-66.
[333] *Ibid.*

> responsiveness have priority; in practices of care, relationships are cultivated, needs are responded to, and sensitivity is demonstrated.[334]

While Gilligan and other feminist scholars including Baier enforced the need to have caring as an alternative approach to justice, Held notes the lack of instruction in Gilligan's work on how and when to choose between justice and care approaches and questions why one must have to choose between the two at all.[335] She rejects the idea that values of justice should be dominant when dealing with issues within the public sphere meaning politics and law, whereas care values should dominate the private sphere meaning families and relations between people.[336] She supports the formation of ethics of care as a developed moral theory as she believes care to be the "most basic moral value".[337] Baier argues that if care values were to be enforced using the theories of justice, some individuals will be allowed to follow a care approach as long as it did not limit other individuals to autonomously choose the moral approach that best suited their interests.[338] Held furthers Baier's analysis and states that values of care are more inclusive and focuses on the fact that human beings are not rational autonomous agents but relational and interdependent beings within a society who are concerned not just about individuals interests but also about interests of those who they care for.[339] Therefore, for Held, justice should be sought within the broad framework of ethics of care instead of vice-versa where care is pushed to the sidelines.[340]

Michael Slote points out how traditional moral theories are so fundamentally different from ethics of care, and that trying to mesh them whether in public or private spheres will lead to unavoidable conflicts.[341] He attempts to find a way to convince people to think of political rights and justice not in terms of traditional values that champion individual rights but in terms of empathy and sensitivity among each other.[342] Slote argues that people feel empathy not just for those who are close to them, but also for the distant populations of people who suffer from

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[334] *Ibid,* at 59.
[335] *Ibid,* at 63.
[336] *Ibid,* at 69.
[337] *Ibid,* at 72.
[338] *See Baier, supra* note 328.
[339] *Supra* note 331.
[340] *Ibid.*
[341] *See* Michael Slote, "Care ethics and liberalism" in Daniel Engster & Maurice Hamington, eds, *Care Ethics and Political Theory* (Oxford University Press, 2015) 37 at 38, DOI: 10.1093/acprof:oso/9780198716341.003.0003.
[342] *Ibid.*

poor conditions of life.[343] He then examines how empathy as a value of care ethics can fair better in creating a welfare society than justice. He states that both liberalism and care ethics want welfare for people who are the worst-off in society, but liberalism assumes that justice will ensure such "welfarist equality" whereas care ethics places importance on the value of empathy for such welfare.[344] While liberalism's way of achieving welfare is to lower the emphasis on civil liberties and refocus that emphasis on welfare of society, however doing that often makes people uncomfortable as they think in terms of their rights and autonomy being compromised.[345] Care ethics will instead focus on the values of empathy and sensitivity that people feel towards those who are worse-off, and that will make people want to choose welfare over autonomy.[346] The difference between liberalism and ethics of care, as Slote notes, is that "Rawls's liberal theory of justice, as applied to developed societies, gives basic civil liberties a lexical priority in relation to considerations of welfare", whereas the priority for ethics of care theory is thinking about political issues of morality with empathy for others.[347]

Kittay argues that an ethics of care may not necessarily be in opposition of theory of justice, but in opposition to other ethical theories (mostly Kantian ethics) on which Rawls's justice theory is based on.[348] Kittay acknowledges that justice is considered as the utmost virtue for political theories that govern social institutions whereas ethics of care are primary values governing interpersonal relationships.[349] However, since political theories underlying social institutions are aimed at promoting ethical functioning of communities that are based on these interpersonal relationships among people, political theories must also promote values of ethics of care within social institutions.[350] She proposes a framework of Rawls's justice theories that instead of promoting the Kantian moral ideal of individual rights and autonomy, promotes the ideal of care.[351] More importantly, she promotes the reconfiguration of the justice theory that instead of assuming humans as autonomous independent individuals, gives importance to the "mutual dependence and interdependence" among humans which forms the very basis of our

[343] *Ibid.*
[344] *Ibid,* at 43.
[345] *Ibid,* at 46.
[346] *Ibid.*
[347] *Ibid.*
[348] *See* Eva Feder Kittay, "A theory of justice as fair terms of social life given our inevitable dependency and our inextricable interdependency" in Daniel Engster & Maurice Hamington, eds, *Care Ethics and Political Theory* (Oxford University Press, 2015) 51 DOI: 10.1093/acprof:oso/9780198716341.003.0004.
[349] *Ibid.*
[350] *Ibid.*
[351] *Ibid.*

societies. She then proposes certain reconfigured principles of justice that are based on ethics of care and that acknowledge the interdependency among humans.[352] These principles of a justice theory based on care ethics emphasize the "relational self" and promote the realization of responsibilities that arise not just from enforcement of rights but also from the relations and connections between human beings, especially for those who are dependent and vulnerable.[353]

2.3. Feminist Global Health Ethics and Ethics of Care for Transformation of Society

The Covid-19 pandemic has seen bioethicists publishing articles on ethical enquiries and analyses of new issues that were surfacing as the pandemic ravished health systems across the globe. One such piece was written by Rosemarie Tong, titled "Towards a feminist global ethics", wherein Tong furthers a model of bioethics that is "non-imperialistic" and based on the theoretical formations of feminist ethics.[354] Interestingly, Tong's non-imperialist feminist global ethics model is a care-based model. She criticized a rights-based approach, which is based on the traditional western theories of deontology and justice.[355] Her criticism highlights the need to accept the cultural and social differences between western feminists and feminists of the non-western world, instead of enforcing a western standard as the uniform standard for the world.[356] A care-based approach does not tell people what to do or offer a standard of justice and equality, but invites people to develop caring relations of empathy, sympathy, and sentimentality among each other, despite their diverse social, economic, and cultural backgrounds.[357]

Benatar, Daar and Singer offer a framework to apply bioethics globally, which may not explicitly discuss care-based strategies but proposes development of human values such as empathy and solidarity in international policies and institutions to improve global health.[358] A feminist framework for public health ethics is also endorsed by W.A. Rogers, who states that feminist public health ethics embraces the complexities and specificities of public health

[352] *Ibid,* at 7-9.
[353] *Ibid.*
[354] *See* Rosemarie Tong, "Towards a feminist global ethics" (2022) 33:1 Global Bioethics 14–31.
[355] *Ibid.*
[356] *Ibid.*
[357] *Ibid.*
[358] *See* Benatar, Daar & Singer, *supra* note 119.

demands and addresses health issues arising from economic inequities, oppression, and discrimination.[359] However, Tong's emphasis on ethics of care in global bioethics is unique:

> As important as an ethics of justice will be during an influenza pandemic, even more important will be an ethics of care…[For] in the end we human beings are a very vulnerable lot. We are radically dependent on each other for survival, and we need to view ourselves as passengers in a lifeboat in the middle of the ocean with no visible sign of rescue. If there aren't enough supplies to go around until help arrives, we can do several things: we can ask for volunteers to jump off the boat; we can start drawing straws for who gets pushed off the boat; we can have a majority vote about which lives are most dispensable; or we can look into each other's eyes and see ourselves - - fearful, hopeful, and in need of compassion - and then we can start paddling together to get to shore, knowing that although we might not all make it, we didn't turn on each other in our panic. What we most need to weather a pandemic is an ethics of trust, reciprocity, care, and solidarity. If we have that, we will have the most precious health care resource of all.[360]

Many scholars have propagated the application of ethics of care in the transformation of the structure of society, however, this would imply a "fundamental reordering" of social, political, and economic priorities which reflect the emphasis given to caring relations among people. For the remaining part of this section, I focus on the work of scholars who apply ethics of care to problems in the global context. Through this analysis, I aim to derive an understanding of how I can apply ethics of care to the global concern of intellectual property laws and access to vaccines. Transformation of society through ethics of care entails the restructuring of relations between domains of society from contractual to caring. We must begin by envisioning the functioning of society and its institutions, legal, political, and economic, through the lens of caring ethics and caring relations with not just those who are close to us but also with distant others. This makes ethics of care the most radical moral theory for doing bioethics.

2.3.1. *Care in International Relations and Policies*

[359] *See* W A Rogers, "Feminism and public health ethics" (2006) 32:6 Journal of Medical Ethics 351–354.
[360] *Tong, supra note* 74.

According to Held, international relations and politics, which have been under formation since the world wars, have focused on realism.[361] Agreements have been put in place between nation states that further their own interest as a means of avoiding situations like wars.[362] However, wars have not been avoided and the current state of the world, as Held describes, is "global near-anarchy of rival states each pursuing its national interest".[363] Morality of international relations and actions of nations states are central concepts of international law, and the traditional moral theories of justice, equality, individual rights, and universality have been a dominant influence.[364] Based on the distinction drawn by Held between ethics of care and other dominant moral theories - that is, justice, deontology, utilitarianism, and virtue ethics – she argues that, while traditional moral theories frame international relations in a manner that furthers individual interests as a means to attain fairness and justice among competing interests, ethics of care focus on social cooperation and creating bonds among nations.[365]

Held highlights the influence of gendered constructs of cultures in societies and international relations. Since wars and international politics have been historically assumed as the domain of men, feminist theories have been ignored in framing of international laws and the ideal behavior of nation states towards each other.[366] Therefore, military power and economic growth have been the primary national interests of nation states. Instead of fostering cooperative relations and solidarity among each other for assuming shared responsibility of global problems, economic disparities between the global north and south continue to widen as international policies, particularly those related to trade that enable growth and prosperity of wealthy nations and ignore the disadvantaged and deprived state of low-income countries, are allowed to exist.[367]

Following behaviors of empathy, sensitivity, and responsiveness as action guides rather than focusing on what one "ought to do" based on those theories that claim to be universal truths, seems more plausible.[368] Incorporating caring relations into the practice of law and politics can

[361] *See* Virginia Held, "Care and Justice in the Global Context" in *The Ethics of Care*, 1st ed (Oxford University Press, New York, 2005) 154 at 154.
[362] *Ibid.*
[363] *Ibid.*
[364] *Ibid,* at 155.
[365] *Ibid,* at 158.
[366] *Ibid.*
[367] *Ibid,* at 157.
[368] *Ibid,* at 166.

transform the current state of the world in a radical manner, especially in preserving culture and the environment, or countering the invasive expansion of markets for economic gains over the interests of vulnerable populations.[369] Ethics of care calls on members of rich nations to realize their social responsibility for alleviating economic and health disparities in the poorer nations.[370]

Talking about the future of care, Held gives examples of the domains of society and international relations in which caring relations can be integrated. Feminist theories began by fighting the oppression of women but have advanced to include members of all vulnerable communities to fight for their causes through feminist action. An ethics of care stems from feminist theories and opposes the international culture of neglect. A "globalization of caring relations" instead of globalization through neo-liberal economic policies focused on attaining economic prosperity would help international relations by improving social cooperation. A sense of responsibility and solidarity could then take the center stage.[371]

2.3.2. Care and Neo-liberal Markets

Joan Tronto has critiqued the free-market system that prevails in most economies, especially in the US, in which markets are considered as the best organizers of healthcare.[372] The "market-foremost democracy" or "market fundamentalism" is based on the contemporary neo-liberal model of economy which furthers the idea that markets provide the best way of allocation of resources, and they need to be free from government intervention for maximum competition.[373] Competition makes people work harder, and so the only way for people to get their needs fulfilled is to "toughen up" and work hard. In this worldview, everything becomes a matter of "personal responsibility", including care or healthcare.[374] However, not all have the same resources to fulfill their personal responsibilities of care towards themselves and others. Market-foremost democracies encourage the idea among people that those who are not able to rise in the competition are not adequate and must work themselves to reach the top of the

[369] *Ibid.*
[370] *Ibid.*
[371] *Ibid.*
[372] *See* Joan C Tronto, *Caring Democracy: Markets, Equality, and Justice* (New York University Press, 2020) at 114.
[373] *Ibid.*
[374] *Ibid.*

hierarchy.[375] Market fundamentalism is based on the belief that people are required to arrange for their own care and for the care of people who are close to them, without considering that not all people have the capability to approach the market and decide for their own care.[376] Tronto also notes that in markets all human interactions are viewed as contracts, and contracts are often entered between unequal parties with different bargaining positions and power imbalances.[377] Thus, a market-foremost democracy for caring only perpetuates greater inequalities.

To address corporate marketization and commodification of health and health related products and services from ethics of care perspective, it is important to note Held's account of markets and her representation of why feminist ethics and ethics of care, rather than liberal individualism, are more suitable to answering concerns about the moral principles that must guide limitations on markets.[378] Here, I focus on Held's ideas for using an ethics of care perspective to apply limits on markets, as opposed to traditional Kantian and utilitarian kinds of liberal individualism. Held explains that following Kantian principles based on liberal individualism leads to a "welfare state liberalism" in which governments interpret their responsibility of providing people with the basic necessities such as food, healthcare, etc., as simply providing them with an equal right to enter the market, which can be done through housing vouchers, health insurance, etc.[379] Kantian liberal individualism does not adequately address the concerns about whether areas within the market that have values other than just economic gains such as healthcare should be the responsibility of profit driven corporate sector or a "cooperative and socially responsible" government.[380] According to Kant's theory, no person can be treated "as a means to an end", meaning that no person should be treated as a market commodity that has a price, and this theory works perfectly for abolishing slave markets. Kant's theory does not similarly oppose the marketization of human labour or other human activities as long as the rights of people providing such labour are respected, or in other words if their autonomy to pursue their interests is being respected.[381] Held notes that utilitarianism is

[375] *Ibid.*
[376] *Ibid.*
[377] *Ibid.*
[378] *See* Virginia Held, "Care and the Extension of Markets" in *The Ethics of Care*, 1st ed (Oxford University Press, New York, 2005) 107.
[379] *Ibid,* at 117-119.
[380] *Ibid.*
[381] *Ibid.*

even less adequate to answer the question about limits to the market, because utilitarianism theory is restricted to maximizing individual preferences and general welfare and not values of "shared enjoyment or social responsibility, or collective caring".[382] For example, the utilitarian justification for a universal healthcare system is frequently criticized, since all people will receive the same level of healthcare services regardless of their individual preferences. The moral reasoning for not commodifying services such as healthcare, education, etc. should therefore be based values of "shared enjoyment or social responsibility, or collective caring" which are central to ethics of care.[383] If political institutions approach issues concerning governance of markets from a care perspective, they will be able to limit the markets from extending into domains that primarily require promotion of values of mutual caring and shared responsibilities, such as, in healthcare.

2.3.3. Care as a Global Policy for Development

Amartya Sen, the leading theorist of development ethics, advanced a capabilities approach for development which now influences several international policies on global development. The capabilities approach advocates for theories of well-being, freedom, or justice to not just consider the fair allocation and distribution of goods and resources as a way to achieve development, but to also consider the abilities of people and what they can do or be in their lives based on their circumstances and diverse needs.[384] Sen denotes capabilities as real freedoms, as it allows people to achieve everything that they actually can achieve based on their capabilities without any "potential impediments".[385] The normative over-emphasis on "freedom" in Sen's capabilities approach reflects a similar understanding to the values of autonomy or liberty.[386] When a vague conception of freedom based on capabilities is the dominant value or an end for societies to achieve, other values that may affect how one achieves that freedom are neglected.[387] Gasper and Truong advocate for a model of development ethics that incorporates an ethics of care approach focusing on peoples' vulnerabilities.[388] Gasper and

[382] *Ibid.*
[383] *Ibid.*
[384] *See* Ingrid Robeyns & Morten Fibieger Byskov, "The Capability Approach" in Edward N Zalta, ed, *The Stanford Encyclopedia of Philosophy*, winter 2021 ed (Metaphysics Research Lab, Stanford University, 2021).
[385] *Ibid.*
[386] *See* Des Gasper & Thanh-Dam Truong, "Deepening Development Ethics: From Economism to Human Development to Human Security" (2005) 17:3 Eur J Dev Res 372–384.
[387] *Ibid.*
[388] *Ibid.*

Truong's ethics of care approach to development ethics suggests a renewed understanding of moral responsibility in which the human emotion of empathy and interconnectedness among people plays a central role.[389] Merich favours the empathy driven approach taken by Gasper and Truong instead of Sen's capabilities approach in guiding international development, however, Merich's conception of empathy for international development differs from that of Michael Slote, who also advocates for empathy as an integral value in care ethics.[390]

I have discussed Michael Slote's approach to ethics of care in previous section on *page 79* of the thesis. Here, I discuss Merich's criticism of Slote's theory. Merich criticizes Slote's deontological approach towards understanding empathy as the foundation for care ethics. Slote does not completely accept the critical distinction that is commonly made between ethics of care and Kantian ethics for moral reasoning but criticizes deontology for its strictly rational considerations and rejection of sentiments, such as empathy.[391] In other words, Slote proposes an approach which is deontological in nature as well. However, instead of a categorical imperative that is strictly based on rational and unemotional rules, Slote suggests that imperative to be the act of empathy in caring relations.[392] An act not done in empathy towards those to whom we have a moral responsibility would be immoral. Merich suggests that Slote's approach is of virtue ethics in which empathy is a virtue, and such an approach is specifically related to those who are in familial relations, excluding those who are distant others.[393] Instead of a deontological notion of empathy, which Merich suggests "misses the more transformative potentials of an ethics of care", Merich advocates for an understanding of empathy not as a virtue or a value, but as a process that is "fed with intersubjectivity giving an epistemology that is experiential and inherently social".[394] He gives the example of the International Child Development Program (ICDP), an international development strategy for providing education to children and their care givers in local communities, entirely based on care ethics with their motto being "empathy in action".[395] The program has assisted many caregivers in developed and developing countries and has transformed them to have an empathetic and caring

[389] *Ibid.*
[390] Diego de Merich, "Empathy in pursuit of a caring ethic in international development" in Tula Brannelly, Lizzie Ward, and Nicki Ward, *eds, Ethics of Care: Critical advances in international perspective* (Oxford University Press, 2015).
[391] *Ibid,* at 98.
[392] *Ibid.*
[393] *Ibid.*
[394] *Ibid,* at 101.
[395] *Ibid,* at 102-104.

understanding towards children who are the perfect representation of vulnerability.[396] In contrast to ICDP, Merich criticizes the UN's Millennium Development Goals (MDGs) that aim to make strategic improvements to the condition of poverty across the globe via setting achievable targets. The MDGs are structured around Sen's Human Capabilities Approach which has the theoretical foundations of justice, freedom, rights, and capabilities and do not reflect the "social inequalities of wealth, power and status".[397] Merich concludes by highlighting the need for international development ethics to focus on vulnerability instead of poverty, since poverty reflects the defenselessness and must be responded with empathy. Merich's final note on role of ethics of care in international development is:

> If the past 20 years of international development could be said to have reflected a focus on human development, then an ethics of care informed by a stronger appreciation for empathy could point us in the direction of a development of human relationships, thus strengthening the web of care within and across national boundaries.[398]

2.4. Summary

The discussion above demonstrates how an ethics of care theory does not just provide criticism of traditional ethics theories but provides a way of transforming society. The purpose of the sections above was to showcase the political character of feminist care ethics that challenges the dominance of Western traditions and provides epistemological alternatives based on moral pluralism. Ethics of care guides international policies concerning social welfare or economic development to foster caring relations, solidarity, empathy, and values of shared responsibility among nations, instead of focusing just on championing individual rights and preferences. Ethics of care promotes limits on markets that undermine relationships and are primarily driven by maximization of profits. Ethics of care theory argues for recognizing responsibilities that arise from relations between people and not just imposition of rights and duties. Based on the abovementioned examples of application of care ethics in the international realm and keeping in mind how an ethics of care approach formulates an argument against dominant traditional

[396] *Ibid.*
[397] *Ibid.*
[398] *Ibid,* at 107.

ethics theories, I will now challenge the theories that are commonly used as justification for protection of IP rights.

CHAPTER III. A FEMINIST CARE ETHICS ANALYSIS OF INTELLECTUAL PROPERTY RIGHTS IN VACCINES

While a few scholars in bioethics and law have attempted a bioethical analysis of the problem of intellectual property laws restricting access to vaccines, most have stuck to the traditional theories of consequentialism, deontology, or justice, and have not attempted to explore how feminist ethics or ethics of care can provide solutions for this global concern. In this Part, I provide a brief analysis of not just the problem, but also of the theories commonly used for justifying intellectual property rights in vaccines. Towards the end, I introduce an alternative to the intellectual property framework in vaccines, which is based on core values of feminist and care ethics theories.

3.1. Locke's Property Theory vs Care Ethics

Locke's theory on property has been greatly utilized by scholars to justify rights in intangible property as well as providing justification for intellectual property rights. Locke's property theory is based on primarily two aspects, the commons and appropriation of resources through mixing of labor.[399] His theory states that nature is commonly available to all people and provides the common resources for people's taking.[400] When a person applies effort and annexes or mixes their labor to the commonly available resources, they have appropriated that resource which gives rise to property rights in the resource. Thus, the person who mixes their labor to a commonly available resource in nature makes it their property and has a legitimate claim of ownership on such property.[401]

In applying Locke's theory to IP, scholars consider the public domain to be the common resources that supply raw material for people to work on and to which they can apply their creative labor. However, intellectual objects are different from tangible items since more than one person can use them simultaneously. They are also known as non-rivalrous objects. The

[399] Robert P Merges, *Justifying intellectual property* (Cambridge, Mass.: Harvard University Press, 2011) at 32.
[400] *Ibid.*
[401] *Ibid.*

public domain of intellectual property law is also different from the commons described by Locke, as it contains material that was created by individual human labor and was previously subject to ownership claims that may have lapsed or expired. Therefore, the integral difference between physical property and intellectual property for the purpose of Lockean theory is that to claim intellectual property rights, a person must apply labor and create novel creations from common resources.[402]

There are some glaringly obvious shortcomings of this theory. Supporting Kantian principles of respecting individual rights and autonomy of persons, Locke's theory also provides people exclusive rights over materials that they have personally labored on, thus giving them rights to also restrict access to such materials regardless of their need to use them. Locke offers provisos to his theory to address some of the shortcomings such as scarcity of resources and wastage. His "sufficiency" proviso states that people may appropriate resources from the commons as long as there is enough left for everyone to use, and his "spoilage" proviso rejects any wastage of resources. However, in applying the provisos to IP, due to non-rivalrous nature of items in intellectual property's public domain, scholars note that there will always be sufficient intangible resources such as "information" in the public domain for people to use without any possibility of "spoilage".[403] But what about the innovations that are needed by those who cannot afford to pay for access to them? To that, Robert P. Merges says that there is another proviso to Locke's theory which is generally ignored, that is, the charity proviso. He claims that for Locke, the poor can access the goods they need to survive, even when those goods are otherwise legitimately owned by others, either through "valid original appropriation" or a "subsequent transfer from an original acquisition".[404] Merges clarifies that the focus of Locke's property theory is not non-interference with tangible goods, but the individual appropriation through labor that helps people to flourish in a society. Providing Locke's theory, a new direction, Merges states,

> Locke's theory does not concern itself with the difference between tangible and intangible assets; that is largely irrelevant. It is centrally concerned with the conditions under which an individual claim to property may be justified in light of the overarching goal of human flourishing. If I use something you have worked on,

[402] *Ibid* at 35-36.
[403] *Ibid.*
[404] *Ibid,* at 38-93.

> and that harms you, interferes with your ability to thrive, I may be in violation of your property.[405]

Peter Drahos focused more on the idea of positive and negative community as Locke's commons.[406] A negative community is a version of commons in which property rights only provide people with exclusive rights to restrict other people from using what they have appropriated from the commons through their labor, and not a "right to be included in the commons".[407] A positive community is a version of commons that belongs to all, and everyone has the right to be included in that community. To use the resources of commons, individuals must obtain consent from all members of commons. Locke's theory overcomes this through labor theory and justifies the appropriation of resources from commons without consent of other commoners if sufficient labor has been applied.[408]

Locke's theory of property when applied to justify intellectual property rights can lead to a neo-liberal model of intellectual property, which assumes that the commons provides equal resources to everyone, and it is up to people to apply sufficient labor to appropriate these resources and thrive individually in a society. Locke's theory may be seen as "superiorly capitalistic", as with introduction of money people can also acquire property through the labor of their workers, the benefits of which are transferred to them in the form of wages.[409] Locke's theory may be used to justify the protection of intellectual property rights of pharma companies in vaccine technologies, and his provisos may not offer adequate solutions to the problem of access to vaccines. People and communities across the globe do not have the same resources or the same level of access to all resources in the commons as contended by Locke. Even when we talk about the public domain of intellectual property with non-rivalrous items, people do not have the same kind of capabilities that allow them an equal opportunity to use the resources available in the commons. Low-income countries do not have the money or infrastructure to appropriate the knowledge from public domain and apply it to innovate and develop their own vaccines. But developed countries do. Considering that only developed countries and their multi-national pharma companies can develop a vaccine for all humankind, the only way in

[405] *Ibid.*
[406] Peter Drahos, *A philosophy of intellectual property* (Australia: ANU Press, 2016).
[407] *Ibid* at 64.
[408] *Ibid.*
[409] *Ibid* at 66.

which developing or low-income countries can obtain those vaccines is through charity. If charity would have worked, everyone in the world would have been vaccinated with the covid-19 vaccines. Vaccinating the entire world's population with only few companies in developed countries having the capacity to manufacture them is an astonishingly unsustainable model. Rich countries have hoarded the vaccine supply and low-income countries are left at the mercy of charity. The big pharma manufacturers of covid-19 vaccines in developed countries do not want to share their intellectual property with other companies in developing countries and continue to have monopoly over the production of vaccines. They justify these rights through the labor used by them to appropriate knowledge from common resources for making these vaccines.

A feminist ethics of care approach to intellectual property rights will focus more on the idea of positive community shared by Drahos, in which everyone has the right to be included in the commons. Individuals may use the commons for their own purposes by applying their labour to obtain property rights in objects they extract from the commons without consulting with other members of commons. A care-based approach will propagate the importance of caring relations and empathy among the members of common. A care-based approach will not provide a framework where everyone must have the same kind of capabilities or the same level of access or resources to innovate. Instead, a care-based approach will focus on the collective and shared responsibility of members of the commons to ensure that innovations are made available to everyone for humankind to flourish, and the resources needed to innovate will be shared with everyone. The simplicity of this solution is the result of an ethical theory that is based on relations between individuals and not just the rights and autonomy of individuals or the furthering of individual interest. The economic theory of patents which is related to a form of Lokean property theory claims that, granting exclusive monopoly rights over inventions to patent-holders for a certain time gives people the incentive to innovate more. This means people will put in more labor to appropriate resources if they can claim property rights on such resources, and this will increase productivity and lead to human flourishing. However, the economic theory fails to acknowledge other incentives that people might have for innovation and focuses only on the economic gains and self-interest. A care-based approach will consider other incentives that people can have to innovate, which may arise from their relations with others in the society.

3.2. Deontological and Utilitarian Justifications vs Care Ethics

A deontological approach to property has the manifestations of individualism and autonomy, which are values integral to Kantian ethics. Merges explains how Kantian ethics demonstrates the need for individuals to "impose their will" on objects, to use the objects for all sorts of projects and they must be given the freedom to control the objects for their purposes. Individuals must be able to have steady claims over objects to utilize them freely for a considerable amount of time.[410] For Kant, as Merges notes, the imposition of will by persons onto objects was enough to claim ownership over those objects.[411] Locke's idea of annexing labor to objects could be considered as an abstraction of Kant's idea of will. This individual will, personal choice, and freedom of desire to carry out individual projects by claiming ownership on objects was integral to Kant's justification for property rights.[412] To address the problem of access to vaccines, a Kantian approach would simply state that property rights must not interfere with any other fundamental freedoms and rights of persons. This is similar to the solution provided within human rights discourse on intellectual property rights. So, if intellectual property rights are restricting the enjoyment of basic right to health of humans, must they not be protected? A Kantian theory would almost always lead to a solution in which one would have to balance two seemingly conflicting claims to freedom. Such a balance is hard to attain and is often followed with a utilitarian analysis.

The utilitarian approach to a moral problem is to choose the course of action that ensures maximum amount of pleasure for the greatest number of people and minimal harm. Under utilitarianism, an action is ethical if it maximizes utility. The utilitarian justification for intellectual property rights is that, if monopolistic economic rights can provide people with an incentive to create more, then there will be many innovations which would be better for society.[413] For those whose preference lies in obtaining IP, will utilize this approach to say that the question whether innovation will happen without intellectual property rights is irrelevant, because they only need an approach that maximizes innovation which is presumed as the good for society. In the previous chapter, I discussed the economic theory of patents and how it fails when applied to the case of vaccines in influenza pandemic. The claim that pharma companies make about patents providing them with a significant incentive to innovate

[410] *Merges, Supra* note 399 at 69.
[411] *Ibid.*
[412] *Ibid.*
[413] *Ibid.*

is not completely true when it comes to vaccines. Due to the complex nature of vaccines, the incentive to innovate in influenza pandemics is strong regardless of patents because of lack of competition in the market and non-existence of any imitators. Though, pharma companies are corporate entities that aim for maximization of profits, and so they only enter the market of vaccines during epidemics or pandemics when the demand is high, as they can acquire patent rights over their innovations and create monopolies in the vaccine market. Therefore, it is the maximization of profits and not innovation that attracts pharma companies to patent rights, implying that it is not the good of the society that pharma companies but their own good that they wish to maximize.

The utilitarian analysis will also look at the preferences of those who cannot access vaccines. So, in a public health crisis such as that of Covid – 19, the utilitarian ethic can be used to support the argument that breaking of patents can make vaccines available to more people. Since the number of people who don't have access to vaccines outweighs the pharma companies, and since pharma companies are not actually maximizing innovation but only their profits, breaking patents should maximize utility. Looking back at the first chapter of the first part of my thesis, the history of TRIPS agreement shows that its formation was driven by a group of private corporate actors including pharma companies that were relentlessly pursuing their self-interest of profit maximization. When the disastrous effects of TRIPS on global health were realized, and the interests of pharma companies were pitted against the global interest of promoting health, the Doha declaration was signed that amended TRIPS and introduced TRIPS flexibilities as a way of balancing between competing interests. As discussed in Part II, these flexibilities failed to increase access to Covid-19 vaccines, and so the temporary waiver was proposed with the same goal of balancing competing interests. Can a utilitarian analysis, however, offer a more sustainable solution such as a permanent TRIPS waiver at least in vaccine technologies as vaccines pose a problem that TRIPS flexibilities cannot address? Some may argue that considering how pharma companies are only interested in maximization of profits and not innovation, without an economic incentive there will be no reason for them to innovate in vaccines. And, since innovation in vaccines is ultimately essential and the preference of all people, pharma companies need to be given an incentive to innovate and manufacture vaccines. The utilitarian theory is primarily concerned with maximizing preference satisfaction, assuming that all individuals are pursuing their self-interests, without any consideration of shared interests among people, such as the shared global interest of vaccinating everyone in a pandemic. Both deontological and utilitarian approaches provide

shaky solutions and justifications that do not appeal to everyone, and only further the conflict between individual interests and public interests. An ethics of care theory provides a better approach to address this conflict because it focuses on the shared responsibility of all nations towards furthering the interests of humankind. Care ethics is concerned with promoting collective caring within communities and promoting the interests of those who are the most marginalized and disadvantaged. A care-based policy to address the challenge to access essential covid-19 vaccines in a pandemic would require the international community to enact policies that protect and promote the needs of low-income nations and provide them with the support to manufacture covid – 19 vaccines for their citizens.

3.3. Rawls's Theory of Justice vs Care Ethics

Rawls's theory of justice has been efficiently used by bioethicists for creating just and equitable frameworks for allocation of resources. Rawls's theory seeks to establish principles for fair distribution of goods, capital, benefits, power, and rights including intellectual property rights. Drahos discussed the distributive effects of intellectual property rights on information, which he considers to be a primary good as, based on Rawls's theory, primary goods are essential for the execution of peoples' life plans.[414] Therefore, in a society in which citizens have equal rights and liberties, the distribution of information that is essential to their functioning in their lives must be fairly and justly distributed among people.[415] Drahos notes that information is not a scarce resource, as I also discussed above. The nature of information is such that it keeps growing through dissemination by humans, especially in today's digital society.[416] Drahos further explains the effects of intellectual property rights on distribution of information and claims that considering the nature of intellectual property rights, they create "artificial conditions of scarcity for information".[417] Keeping this in mind, I will now discuss Rawls's principles of justice applied to the distribution of information and evaluate how intellectual property rights fair against these principles.

[414] *Peter Drahos, supra* note 131; See Chapter 8: Justice of Information.
[415] *Ibid.*
[416] *Ibid* at 205.
[417] *Ibid.*

For application of Rawls's principles of justice, a procedure has been provided which begins with people being in a hypothetical "original position" and behind the "veil of ignorance".[418] This is a position in which individuals are not aware of their status in the world, or their social affiliations, economic conditions, or their intelligence levels, their capabilities and so on. Since they are completely unaware about where they stand in society, they will be impartial, fair, and unbiased towards forming rules that will only cater to their personal preferences. Once individuals are behind this veil of ignorance, Rawls says they will agree on two principles of justice: i) each person must have equal rights to the most extensive scheme of basic liberties, such as, right to access information, and ii) social and economic equalities are to be ordered so that they are both (a) to the greatest benefit of the least advantaged and (b) attached to offices and positions open to all under conditions of fair equality of opportunity'.[419] Considering the lexical order of the two principles, most scholars, including Drahos, argue that the first principle has priority over second, and intellectual property rights fall under the second since they provide temporary economic privileges, and political liberties cannot be sacrificed for economic gains.[420]

Rawls clearly did not see his principles applying to the international realm. However, applying Rawls's principles of justice to the problem that intellectual property rights create when it comes to access to vaccines, we can argue that the basic right to health is affected by protecting intellectual property rights of pharma companies in vaccine technologies. Therefore, intellectual property rights in vaccine technologies and related goods must not be protected. Pharma companies have argued that research and development to innovate treatments and vaccines for novel diseases, such as covid – 19, requires a lot of capital and investment. They claim that if their patent rights are not protected, they will incur high administrative costs and industry related complications, which will reduce the incentives for them to innovate. However, as I pointed out towards the end of the last chapter that majority of investment in developing vaccine technologies for the mRNA Covid-19 vaccines was public funded. The second principle, which is popularly known as the "difference principle", allows certain inequalities if they better the position of the least advantaged members of society. Pharma companies argue that patent rights provide incentives for faster innovation in medicines and vaccines for diseases such as malaria, tuberculosis, Ebola etc. which saves lives of many in the

[418] *Robert P. Merges, supra* note 399 at 103; See Chapter 4: Distributive Justice and IP Rights.
[419] John Rawls, "A theory of justice.", *Ethics*. Routledge, 2004. 229-234.
[420] *Supra* note 414.

low-income countries where such diseases are popular. However, Covid-19 vaccines are equally required by everyone across the world, and if pharma companies were using patent rights to help the least advantaged countries, then they would have supplied Covid-19 vaccines to these countries before the developed countries. This begs the question, if justice and equity were foundations of most social institutions and nation states, then why do we still have intellectual property rights protection for vaccines?

This is reminiscent of Jonathan Wolff's criticism of Rawls's social contract theory. Wolff states that Rawls's theory is supposed to bind an entire society in a social contract, in which despite conflicting interests, individuals agree to a system of justice as a "compromise" and for mutual benefit of everyone to avoid a state of total chaos.[421] Wolff recounts Glaucon from Plato's Republic who asks why would any individual who can get away with injustice, bind themself in a social contract of justice for the benefit of others if they are only concerned with their self-interest?[422] To this, Rawls's principles provide the veil of ignorance, and yet, the question remains. Why would individuals agree to go behind a veil of ignorance if clearly, they have privileges that makes them better off in a society? As Wolff states, "given that different people have opposed interests, social contract morality looks minimal: There is not all that much everyone would agree to".[423] Wolff explains Galucon's idea of the compromise aspect or the "you scratch my back, I scratch yours"[424] aspect of Rawls's theory in the following lines:

> Why should, say, a privileged, rich white man be interested in this argument? If I were behind the veil of ignorance, such a person might say, I might well choose rules that are fair to everyone; but from my position of knowledge, I prefer rules that favor me. This question shows that Rawls's methodology presupposes a type of human goodwill: that human beings do want to find fair terms of cooperation. Therefore, Rawls's contract methodology does not provide an answer to the moral skeptic. Its purpose is to offer a procedure for turning what he calls "a sense of justice" into an explicit moral code that is capable of taking everyone's interests into account.[425]

[421] *See* Jonathan Wolff, *An Introduction to Moral Philosophy*, 2nd edition ed (plaats van uitgave: uitgever, 2021) at 108.
[422] *Ibid,* at 109.
[423] *Ibid,* at 122.
[424] *Ibid,* at 112.
[425] *Ibid.*

Vaccine nationalism by rich countries to protect the interests of their citizens coupled with the profit maximization motive of pharma companies are the reasons why international institutions that promote justice and equity haven't been able to waive intellectual property protection in vaccines and increase the access to vaccines in low-income countries. It is true that the ethics of care theory is epistemologically different from a theory of justice, as it assumes humans to be relational beings and not individuals looking out for their self-interests. Wolff notes that in Rawls's theory of justice, people will agree to be governed by a social contract, because it is in their best interests to follow the procedure of justice and to be bound by it.[426] If they aren't bound, then neither is anyone and a lawless situation would prevail, where one would have more to lose than to gain. But those who can get away in a lawless situation, will avoid the procedure of justice, just as pharmaceutical companies can and so can the rich countries. A care-based approach will encourage the idea that people are not just looking after their interests, but of those who they care about as well. Care ethics does not provide a compromise contract between individuals with competing interests but encourages individuals to strengthen their relations and a sense of shared responsibility, instead of only pursuing self-interests. Global policies and theories built on such presupposition, will call for extending the same caring relations towards distant others. However, the question is how can a policy based on care ethics help in a social structure where individuals are presumed, encouraged, and pushed towards following their self-interests? The next section will propose a caring alternative to IP framework for vaccines based on the radical societally transformative nature of ethics of care.

3.4. A *Caring* Intellectual Property Framework for Vaccines?

There are clear epistemological differences between the ethics of care and traditional moral theories. Intellectual property rights function within social, economic, and political structures that are based on the traditional theories of equality and justice, and an efficient caring approach to intellectual property must ideally be preceded by serious transformation in those structures. There are, however, alternatives to the present intellectual property law framework that operate on the values that align with feminist ethics and ethics of care. These alternatives currently exist within the same traditional structures and continue to flourish despite conflicting with current legal framework of intellectual property. I contend that intellectual property rights, like

[426] *Ibid.*

many other facets of healthcare, could be among the first examples of social and legal transformation based on care ethics, on a global level. Before I jump on to explain this alternative, I will give a brief account of the feminist interpretations of intellectual property rights.

Halbert commented on the evident gendered construction of intellectual property rights, and the different roles women and men have had in the "social construction of knowledge"[427]. She highlights the dichotomy of feminine and masculine ideologies with respect to the culture, creativity, property, and innovation.[428] Feminist scholars in intellectual property laws have identified that just like other areas of law, intellectual property laws are also designed to suit only male ideologies and interests. Burk discusses bifurcation between "discovered" and "invented" underlying patent laws wherein, anything that isn't original but only discovered naturally existing is designated as non-patentable and part of the public domain.[429] Ironically, as Burk notes, designating a natural resource in the public domain "benefits those who already hold the greatest stake in privately held intellectual property", meaning that "material in the public domain may be freely exploited, but not everyone will necessarily benefit equally from the availability of the resource".[430] I provided a similar criticism while discussing Lockean property theory as justification for IP rights in the previous section. This doctrine of originality which separates "inventive" form "creative" only creates further disparities between who gets to own IP and who does not. High–end technology produced by developed countries that have ample resources will satisfy the patentability criteria of originality, but a natural or biological resource that is found in nature only in rare amounts in developing countries cannot be patented and is free to be appropriated by those who have access to the public domain.[431] Feminist scholars, such as Burk have thrown light on such imperialistic characteristics of IP laws that tend to take away the innovation and cultural creations of not just women but also economically and socially disadvantaged people from of countries other than the west.[432] Intellectual property rights are also designed to benefit only the advantaged and do not consider the

[427] Debora Halbert, "Feminist Interpretations of Intellectual Property" (2006) 14:3 Journal of Gender, Social Policy & the Law, 431-460.
[428] *Ibid.*
[429] *See* Dan L Burk, "Feminism and Dualism in Intellectual Property" (2006) SSRN Journal, online: <http://www.ssrn.com/abstract=928421>.
[430] *Ibid.*
[431] *Ibid.*
[432] *Ibid.*

difficulties in access to resources for innovation that is faced by people in low-income countries. Feminist theories do not just question the criteria for eligibility of intellectual property rights, but also question the very existence of such criteria.

While there is a fair amount of scholarly work on feminist theories of intellectual property, Malla Pollack's feminist analysis of intellectual property laws is particularly useful in considering different kinds of feminism and how they can be used to challenge various aspects of intellectual property.[433] Pollack notes that male dominated economic relations and political interests have propagated the approach of economic efficiency through individual ownership, especially when its central feature is the right to exclude others.[434] She also comments on the history of intellectual property laws being that of expansion of "both the subjects protectable and the rights given individuals over their property".[435] She goes on to explain the different kinds of feminism, such as, liberal feminism, essential feminism, communitarian feminism and humanist feminism and how they can be used to critique different aspects of intellectual property rights based on feminist ideologies.

Pollack describes the four features of the public domain that makes it inherently feminist. She endorses Held's feminist view of a non-contractual society and states that "the public domain is feminine because it is not commodified"[436]. Feminist theory rejects the idea of the liberal market wherein all individuals contract with each other to further their self-interests with money making being their prime motivation. Thus, feminist theory rejects the idea that in the public domain people will only innovate if their inventions guarantee monetary returns. Secondly, she states that the public domain is feminine because individuals do not innovate in alienation. They cannot innovate from nothing and use the resources of the community. Hence, their innovations have the imprint of their community or society. Thirdly, she states that the public domain is feminine because it is nurturing, as it provides the members of communities with free gifts. Individuals are constantly using property rights to protect their self-interests with the fear of their property being taken away. A nurturing domain takes care of its vulnerable members by nudging them into growing and being independent, instead of making them suffer

[433] *See* Malla Pollack, "Towards a Feminist Theory of the Public Domain, or Rejecting the Gendered Scope of United States Copyrightable and Patentable Subject Matter", (2006) 12 Wm. & Mary J. Women & L, 603.
[434] *Ibid.*
[435] *Ibid* at 603.
[436] *Ibid.*

by competition. Lastly, the public domain is feminine because it provides the necessary nourishment to its members. People receive the necessary information to innovate from the public domain.[437] Pollack's feminine public domain echoes many aspects of communitarian theories as well. However, Pollack focusses more on the fact that inventions are only attributable to individuals and not communities, following the Western tradition of valorizing values of autonomy in IP laws. Sticking to the striking features of a feminine public domain described by Pollack, that align with the values of ethics of care, I introduce the alternative to intellectual property framework for vaccines.

Empirical studies shows that research productivity is declining. Gold talks about the role of intellectual property in declining research productivity.[438] Three of the factors that cause this decline as highlighted by Gold are: a) an increasing requirement to absorb knowledge due to increased complexity of science, b) the misalignment of incentives, and 3) knowledge silos created by intellectual property rights.[439] Knowledge silos occur when information does not easily flow across actors due to stringent intellectual property protection, and affects research productivity from repetition of experiments, failure to share solutions to similar problems, etc. Gold gives the example of vaccine innovation in Covid-19 and how intellectual property laws halted Covid-19 vaccine innovation.[440] Early in the covid-19 pandemic, researchers and companies found ways to overcome the abovementioned factors by rapidly sharing information among each other. However, pharma companies started introducing intellectual property agreements to protect their innovations, knowledge silos were created and created delays and disparities in access to vaccines. Therefore, Gold examines the potential of collaborations – called Open Science Partnerships (OSPs) – to increasing the efficiency of research[441]. OSPs are collaborations between different actors from different sectors coming together with a common motive to solve a problem, agreeing upfront to waive their intellectual property rights completely which removes the most restrictive factor affecting innovations. The only kind of restriction is the confidentiality agreements between researchers and patients. OSPs do not just have money as incentives but there are multiple other incentives that promote innovation.

[437] *Ibid.*
[438] E Richard Gold, "The fall of the innovation empire and its possible rise through open science" (2021) 50:5 Research Policy 104226.
[439] *Ibid.*
[440] *Ibid.*
[441] *Ibid.*

Some feminist scholars have advanced how key features of feminist theory and methodology can support the growth of open science. The authors of *Bridging Feminist Psychology and Open Science* provide a distinctive approach to develop open science by giving importance to integral themes of feminist theory, such as who is included and excluded from research, reflecting on the personalities of researchers and how they are situated in society, improving collaboration, and expanding access to research.[442] However, going back to Pollack's feminine public domain that is aligned with the values of care ethics, open science provides a similar feminine and caring alternative to the intellectual property framework for vaccine innovation. In open science collaborations, members participate to share their knowledge resources instead of contracting with each other to prevent the other from using one's resources. A sense of shared responsibility is created among the members who work towards a common goal of success in innovation of vaccines. Money is not the only incentive, as there is scope for other incentives which may arise from shared relations of members with each other or with those outside the collaboration. By ensuring that no member will enforce their intellectual property rights, an open science collaboration can foster nurturing relations among members that will lead to better and faster innovation.

Open science is a feminine and caring alternative to intellectual property framework for vaccines, and open science collaborations can provide a perfect practical example of the transformation of society that is sought by ethics of care theory. Developing open science models would require infrastructural support and the support of concrete global health policies that advance open science for research in vaccines. A collaborative and care-based model for innovation that values shared responsibility, collective caring, and solidarity, and offers social and economic benefits to people while promoting global health is the perfect caring alternative to intellectual property framework for vaccines.

[442] Jes L Matsick et al, "Bridging Feminist Psychology and Open Science: Feminist Tools and Shared Values Inform Best Practices for Science Reform" (2021) 45:4 Psychology of Women Quarterly 412–429.

CONCLUSION

Feminist ethics of care is an approach that sees humans as relational beings, and therefore focuses on caring relations, shared responsibilities, solidarity, and empathy among humans as a means to establish principles that can lead to moral decisions. The epistemological differences between care ethics and traditional moral theories make it difficult to bring changes in global policies that are primarily built to support structures based on traditional theories of rights, autonomy, equality, and justice. Intellectual property rights and laws are also based on these traditional concepts and economic theories that are meant to work perfectly in neo-liberal economies that promote liberal individualism. In the first Part, I gave an account of international politics surrounding the negotiation of the TRIPS agreement among nation states. I elaborated on how developed nations coerced developing and low-income countries in signing the TRIPS agreement, despite there being a conflict of interests among nations. While the general discourse among scholars is focused on the conflict between intellectual property rights and access to essential drugs, I limited my thesis to address the problem of access to vaccines in pandemics. As the title suggests, I started writing my thesis with the goal of providing a framework of intellectual property protection in vaccines that is ethical and upholds the integral interests of the field of bioethics with respect to protecting and promoting global health. After a bioethical analysis, I conclude that we need a framework of intellectual property rights for vaccines that is caring and aligns with the core values of ethics of care theory.

In the final part of my thesis, I conducted a bioethical enquiry into the intellectual property framework of vaccines. By examining the drawbacks of human rights discourse, I identified the significance of an alternate bioethical discourse for an ethical solution to the problem. Bioethics is best suited for global health problems because of its interdisciplinary nature. I chose a feminist ethics and ethics of care theories-based approach for the subject matter because of their distinctiveness from traditional principle-based theories that form the basis of several international legal instruments, including intellectual property laws. Through a comprehensive review of scholarly literature on feminist ethics and ethics of care principles

and their application to global concerns, I analyzed intellectual property theories and built my arguments for an alternative caring and feminine framework for vaccine innovation. I conclude that open science can be a perfect example of a caring and feminine model for innovation as an alternative to intellectual property framework for vaccine.

The thesis builds arguments for drawing from feminist ethics and ethics of care theories to rebuild the current IP framework and explains how such a radical interpretation of traditional theories that underlie IP laws will be better at providing ethical solutions for the global health problem of inequitable Covid-19 vaccine distribution. For scholars and researchers who are trying to address these issues within IP laws, this thesis provides reasons to look beyond IP and advocate for solutions based on feminist ethics and ethics of care theories. While open science is an example of such a solution, work needs to be done to create a strong theoretical framework that support implementation of such solutions. Therefore, the next step would be to create a theoretical framework for laws that incentivizes innovation in science and technology and reflects the principles of shared responsibility, solidarity, caring relations, and collaboration among people towards attaining international development and securing global health. Most importantly global health scholars, ethicists, lawyers, and policy makers must work together towards developing institutional pathways for leveraging our governments and international organizations to adopt such a feminist caring framework for innovation.

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