Rethinking the Pharmaceutical Knowledge-Economy: Patents, the TRIPS Agreement, and Skewed Utilitarianism in the Evolving Ideological Paradigms

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Abstract

The TRIPS Agreement introduced a unique globalized pharmaceutical patent economy. This article examines the social costs of this patent regime in low-income countries and makes three contributions. Firstly, it highlights how, in the early development of the patent system, nations perceived patents as privileges and displayed considerable reluctance in protecting pharmaceutical products and processes. This allowed net importers of technologies to replicate foreign innovations without the constraints of IP rights, and in some cases, invalidate unnecessary patents. However, this took a different turn towards the tail end of the 20th century when the patent norms and rules were harmonized and globalized. Secondly, the article argues that the new regime is rooted in what can be termed 'skewed utilitarianism,' as patent rights appear extensive while collective rights are undervalued, seemingly favouring specific stakeholders and neglecting distributional consequences for others. The new regime shields the patent system from principles of social justice and leads to adverse outcomes for vulnerable and impoverished populations. Lastly, the paper introduces a three-tier integrated framework as part of the reevaluation of the global patent dynamics. The framework involves an appreciation of the IP norm-making process, democratizing the norm-making process to allow broader representation, and centering 'flexibility' in the policymaking process.

1. Introduction

The high prices of life-saving medicines and vaccines have long been one of the key areas for contesting the scope and normative foundations of intellectual property (IP) rules, especially pharmaceutical patents and trade secrets. Scholars and stakeholders debate the tensions associated with the manufacturing and protection of these medicines and vaccines, on the one hand, and distribution and access to the medications, on the other hand.[1] For instance, patent rules were blamed for the high cost of antiretroviral (ART) drugs during the peak of the HIV/AIDS crisis in the late 1990s and early 2000s. Critics argue that these rules limited generic companies from producing

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1 *See* Brook K. Baker & Rachel D. Thrasher, *From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics,* 41(1) Boston Univ. Int'l L. J. 1–46 (2023).

generic versions of ART at a lower price for low-income countries.[2] ART was sold for $10,000 to $15,000 when it could have been sold for as little as $100.[3] The recent COVID-19 pandemic and the devastating vaccine shortages/inequities experienced by low-income countries during this period reignited discussions about the impact of IP rules on access to medicines. In fact, in March 2020, several countries, led by South Africa and India, proposed a temporary waiver of the IP rights under the World Trade Organization (WTO)'s 1994 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, given the urgent need for 'unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment, and ventilators.'[4] Although the vast majority of medicines on the World Health Organization (WHO)'s model list of essential medicines are off-patent, potential generic producers might still be dissuaded by trade secrets and secondary patents covering non-active and supplementary components of these medicines.[5]

Patents and trade secrets hold particular significance in the pharmaceutical sector due to the high costs associated with drug development, the necessity of conducting expensive and complex clinical trials to secure regulatory approval, and the high rate of research failures while developing breakthrough drugs.[6] Meanwhile, there is the general ease of replicating such new drugs and the associated processes, although, in the case of biologics, it may be difficult (not impossible) to replicate them without access to the know how due its inherent variability.[7]

The prevailing ideology is that without these IP protective measures to deter competition and allow investors to internalize the positive externalities of their medical innovations, it might discourage investments in research and development (R&D) within the industry.[8] So, to allow inventors to recover their R&D investments, they are granted these state-backed, time-limited monopoly rights. The expectation is that the promise of supra-competitive pricing during the monopoly period will encourage companies to make significant investments in R&D for inventions that hold societal value. Some scholars view these monopolies as the most effective approach for addressing market failures related to knowledge goods, often classified as 'public goods.'[9]

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2 *See* William W. Fisher III & Cyril P. Rigamonti, *The South Africa AIDs Controversy: A Case Study in Patent Law and Policy,* Harvard Law School (Feb. 5, 2005), https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf; Fernando Pascual, *Intellectual property rights, market competition and access to affordable antiretrovirals,* 19(3) Antiviral Therapy 57–67 (2014 Supp.).

3 *See* Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions 2 (18th ed., July 2016), https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition.

4 World Trade Organization (WTO) Council for Trade-Related Aspects of Intellectual Property Rights (2020); Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa. IP/C/W/669.

5 Julia Belluz, *The absurdity high cost of insulin, explained,* Vox (Nov. 7, 2019), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.

6 C. Scott Hemphill & Bhaven N. Sampat, *When do generics challenge drug patents?,* 8(4) J. Empirical Legal Stud. 613–49 (2011).

7 Arnold G. Vulto & Orlando A. Jaquez, *The process defines the product: what really matters in biosimilar design and production?,* 56(Suppl. 4) Rheumatology J. (Oxford University Press, 2017).

8 Harold Demsetz, Towards a Theory of Property Rights, 57 American Econ. Rev. 347, 347–48 (1967).

9 William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law 22–23 (Cambridge, MA and London: Belknap Press/Harvard University Press, 2003).

However, the growing prices of medicines and the limited ability of generic manufacturers to access the relevant technologies to produce cheaper equivalents of the originators' medicines, alongside their detrimental toll on human health, have raised critical concerns about the applicability and scope of the patent system within the pharmaceutical sector.[10] Notably, Olga Gurgula pointed out that 'Pharmaceutical companies have been increasingly engaging in strategic patenting to delay or even block generic competition…the patent system is used strategically to artificially block generic competition and prevent a timely arrival of cheaper generic versions.'[11] Therefore, key questions have emerged as subjects of this debate: Are the existing minimum universal patent principles suitable? Is the IP system undermining the industrialization of low-income countries? Should a nation's development status be a fundamental criterion for determining the scope of its patent system? Is it appropriate to link the patent system with other fields like trade and investment regimes? Do the social benefits of the patent system outweigh the social costs? Where should the norms and principles of the patent system be established? These are primarily conceptual considerations that warrant careful examination.

This article attempts to answer some of these questions within the conceptual framework of the historical evolution of the patent system, the social welfare costs of the globalized pharmaceutical patent regime, the influence of privilege and power in perpetuating this system, and the potential for reimagining the model to serve the needs of low-income countries more effectively. Here, low-income countries represent both 'low-income economies' and 'lower-middle-income economies' as defined by the World Bank based on their respective Gross National Incomes (GNI).[12] The term 'low-income countries' is used in this article either independently or within the broader context of developing countries where necessary.

Consequently, this article makes three contributions. Firstly, it highlights how, in the early development of the patent system, nations perceived patents as privileges and displayed considerable reluctance in protecting pharmaceutical products and processes. This allowed net importers of technologies to replicate foreign innovations without the constraints of IP rights, and in some cases, invalidate unnecessary patents. This regime offers insights into contemporary debates about the effectiveness and reform of the current globalized knowledge economy. Secondly, it argues that the evolution and globalization of the patent system are rooted in what can be termed 'skewed utilitarianism.' This perspective highlights that patent rights appear extensive while collective rights are undervalued, seemingly favouring specific stakeholders and neglecting distributional consequences for others, shielding the patent system from principles of social justice, and leading to adverse outcomes for vulnerable and impoverished populations. Lastly, the paper introduces a three-

10 European Commission, *Executive summary of the Pharmaceutical Sector Inquiry Report,* European Union (Aug. 7, 2009), https://op.europa.eu/en/publication-detail/-/publication/a0b3a03c-2806-4894-8755-ee8e7c5e1e7e/language-en.

11 Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?,* 51(9) IIC Int. Rev. Ind. Prop. Copyright L. 1062–85 (2015)

12 World Bank, *World Bank Country and Lending Groups* (last visited Apr. 21, 2024), https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups#:~:text=For%20the%20current%202024%20fiscal,those%20with%20a%20GNI%20per.

tier integrated framework as part of the reevaluation of the global patent dynamics. This framework involves an appreciation of the IP norm-making process, democratizing the norm-making process to allow broader representation, and centring 'flexibility' in the policy-making process.

This article is divided into three parts, with this introduction being the first. The second part examines the historical ideological paradigms of the patent system, highlighting the strategic instrumentalism and public interest understanding associated with the early conceptualization of the proprietary regime. The second part discusses how the patent rules were linked with the international trade regime and globalized without regard to the domestic realities of poor nations. The result is a system that favours nations with the technological capacity to produce and distribute inventions and puts developing nations, struggling with industrialization, at a position of dependency. Furthermore, it analyzes how the normative undertaking of the patent system can be reconceptualized to democratize the IP norm-making process and center the interests of developing countries. It advocates for extending the same liberties that industrialized nations enjoyed when they were at their development stages to developing countries. The conclusion summarizes the findings and conclusion.

II. The Historical Ideological Paradigms of the Patent System

Patents are government grants that provide inventors with exclusive rights to their inventions within specific territories for a limited duration. To secure a patent, applicants need to generally demonstrate the novelty, inventiveness, and utility of their creation, and once granted, a patent remains in force for at least twenty years from the date of application based on the TRIPS Agreement. During the period in which a patent is valid within a particular country, the owner of the patent holds exclusive rights to manufacture and sell products that incorporate the protected knowledge in that country.

The modern patent system began in the pre-industrial era.[13] However, other aspects of the history of the patent system are contentious regarding when, where, and how it started, with discussions typically divided between Western and non-Western cultures. An in-depth analysis of these debates is beyond the scope of this work. It suffices for this work to state that the Western historical account generally traces the origins of the patent system to England and Venice, while non-Western perspectives are associated with ancient civilizations of the Andaman, Kai, and Koryak cultures found in Southeast Asia and North America.[14] Each perspective offers a unique view of ownership, protection, and management of pre-industrial knowledge. My focus, however, is on how patent ownership was theorized historically in Western culture.

The Western historical account traces the origin of patent rights to the Venetian Republic, an Italian peninsula, which was considered one of the most technologically advanced and commercially

13 Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization,* 5 J. Hist. Int'l L. 413 (2003); Joel Mokyr, *Intellectual Property Rights, the Industrial Revolution, and the Beginnings of Modern Economic Growth,* 99(2) American Econ. Rev. Papers & Proc. 349–55 (2009)..

14 The western account has been dominant over the years. Anthropologist Lowie has suggested that the dominance is due to a rationalistic bias that earlier historians held toward non-western civilizations. *See* Robert H. Lowie, Primitive Society 235–36 (New York, Bonie and Liveright, 1920).

sophisticated city-states in Europe in the 15th century.[15] Venice leaders were interested in attracting and retaining the best artisans and inventors 'from diverse parts.'[16] So, in 1443, the Venice government began to issue ad hoc patents to inventors, which were later formalized under the Venetian Statute on March 19, 1474. The statute granted inventors a ten-year monopoly on their 'works and devices' in return for disclosing the invention publicly,[17] and imposed penalties for unauthorized use or infringement of patent grants.[18] Christopher May described the Venetian Statute as 'the first formal quasi-patent system … [f]or the first time a legal and institutional form of intellectual property rights (although the term itself is of somewhat later vintage) established the 'ownership' of knowledge, and was explicitly utilized to promote innovation.[19]

The well-structured nature of the Venetian patent system distinguishes it from other historical accounts.[20] Venice was the first city to consistently apply specific regulations in granting patents instead of issuing random, isolated monopolies.[21] Venetian authorities were clearly concerned with the management of the city's economy and recognized the importance of technological innovation to its success.[22] Eventually, the success of the Venetian Patent system in promoting domestic innovation and economic growth helped to spread the idea of patent protection to other countries in Europe and beyond.[23]

In terms of balancing individual and collective rights, the Venetian patent system considered patents as privileges, not legal entitlements.[24] The patent statute recognized a state-sanctioned public domain and provided a limited patent term. Inventors had a limited term to produce and sell their inventions, after which the knowledge and technologies became available to the public. There was also a fundamental working requirement, patent grants were forfeited by failure to use them within a certain term.[25] The State also had the power to grant compulsory licenses to pursue social objectives, such as addressing public health challenges.[26]

Furthermore, the practical administration of the patent system was also influenced by public interest considerations; the majority of patents recorded in the Venetian State, whether significant or not,

15 Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization,* 5 J. Hist. Int'l L. 413 (2003).

16 *See* E. Kaufer, The Economics of the Patent System 5–6 (Chur: Harwood Academic Publishers, 1980); J. Phillips, *The English Patent as a Reward for Invention: The Importation of an Idea,* 3(1) J. of Legal Hist. 71–79 (1982).

17 *Id.*

18 Moureen Coulter, Property in Ideas: The Patent Question in Mid-Victorian Britain 7 (Missouri: The Thomas Jefferson University Press, 1991).

19 Christopher May, *The Hypocrisy of Forgetfulness: The Contemporary Significance of Early Innovations in Intellectual Property,* 14(1) Rev. Int'l Pol. Econ. 1, 3 (Feb. 2007).

20 Christopher May, *The Venetian Movement: new technologies, legal innovation, and the institutional origins of intellectual property, in* David Vaver, Intellectual Property Rights: Critical Concepts in Law (Vol. 3, London & New York: Routledge, 2006).

21 Giulio Mandich, *Venetian patents (1450–1550),* 30(3) J. Pat. Off. Soc'y 166–224 (2002).

22 May, *supra* note 19, at 4.

23 *Id.*

24 Harold Wegner, Patent Harmonization 4 (Sweet & Maxwell eds., 1993).

25 Mandich, *supra* note 21, at 166–224.

26 *Id.* at 166–224.

were related to the city's specific needs, with social concerns being the guiding principle.[27] From 1490 to 1550, more than 120 privileges were granted, primarily for socially beneficial mechanical devices such as pumps, water mills, and dredging machines.[28]

The instrumental policy of the Venetian patent system was also set out in the preamble of the Venetian Patent statute, providing that the purpose of the patent system was to recognize devices with great utility and benefit to the Commonwealth.[29] With patents, the people of Venice hoped that 'more men would then apply their genius, would discover, and would build devices of great utility to the commonwealth.'[30] Thus, patents were conceptualized as strategic instruments to further domestic technological and economic development.

The English historical account, which is the second Western account, dates to the mid-14th century when the British Crown began issuing letters of patent to foreign inventors to encourage them to bring their trades to England. [31] It started with King Edward II granting patents to John Kempe, the Flemish weaver, in 1331 to incentivize his immigration to England.[32] At this time, England was behind technologically compared to other European regions, like France and the Netherlands.[33] So, the patent system was a medium adopted by the Crown to industrialize England by encouraging technology transfer from foreign countries and promoting local knowledge and skills dissemination.[34] Robert Merges, Peter Mennell and Mark Lemley describe this early patent system as rooted in a utilitarian theory called 'strategic international trade policy,' which seeks to lure skilled and entrepreneurial Europeans to establish their businesses in England and transfer their trade and skills to domestic apprentices.[35] This implies that the exclusive rights granted through these patents were conceptualized through a public interest lens.

When deciding whom to grant letters of patent to, the Crown took into consideration the social value of the invention as well as the amount of effort the inventor had invested in developing the product.[36] The patent system was later extended to cover domestic inventions with the issuance of letters of patent to John of Utynam for stained glass manufacturing in 1449.[37]

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27 Fernand Braudel, Civilisation and Capitalism, 15th – 18th Century 433–34 (Vol. I, London: Collins, 1981).

28 *Id.*

29 Mandich, *supra* note 21, at 166–224, 176.

30 F.D. Prager, *Patent Law of Venice,* in Giulio Mandich, *Venetian patents (1450-1550),* 30 J. Pat. Off. Soc'y 166, 176–77 (2002).

31 J. Gordon, Patent Law Reform, 55 J. Soc'y Arts 26 (1906).

32 *See* E. Wyndham Hulme, *The History of the Patent System under the Prerogative and at Common Law,* 46 L. Q. Rev. 141–54 (1896); P. David, *Intellectual property institutions and the panda's thumb: patents, copyrights, and trade secrets in economic theory and history, in* Global dimensions of Intellectual Property Protection in Science and Technology 45 (Mitchel B. Wallerstein, Mary E. Mogee, & Robin A. Schoen, eds., 1993).

33 *See* W.R. Cornish, Intellectual Property: Patents, Copyright, Trademarks and Allied Rights 111 (4th ed., London: Sweet & Maxwell, 1999).

34 Peter Drahos, A philosophy of Intellectual Property 30 (Routledge, 2016).

35 Robert Merges et al., Intellectual Property in the New Technological Age 125 (2nd ed., New York: Aspen Law & Business, 2000).

36 Simon Lester & Huan Zhu, *Rethinking the Length of Patent Terms,* 34 American Univ. Int'l L. Rev. 788 (2019).

37 *See* Wertheimer, Albert, & Thomas Santella, *The History and Economics of Pharmaceutical Patents, in* Irina Farquhar, Kent Summers, & Alan Sorkin, The Value of Innovation: Impact on Health, Life Quality, Safety, and Regulatory Research 102 (Bingley, UK: Emerald Group Publishing Limited, 2008); Lynn White Jr., *Jacopo Acontio as an Engineer,* 72 American Hist. Rev. 432 (1967).

When successive English Sovereigns persisted in arbitrarily granting patents and creating unjustifiable monopolies, the parliament had to step in and pass the *Statute of Monopolies* in 1623 to reinforce the public interest objectives of the patent system. This event, as Thomas Nachbar rightly pointed out, was a '…revolution in the role of political accountability in the administration of economic regulation.'[38] The intervention was necessary as the Sovereigns turned the patent system into a convenient source of revenue, resulting in unwarranted monopolies that undermined free trade and the mercantile economic order.[39] The Statute of Monopolies declared all monopolies in England to be contrary to the law of the realm and so void.[40] It however exempted patents from the ban, recognizing the positive impact that patents could have on society, such as the promotion of technology transfer and domestic innovation. To this end, the Statute empowered the Crown to grant patents to the 'true and first inventor' of a 'method of manufacture' up to fourteen years of exclusive rights, as long as the rights were in line with the law, did not cause a disruption in trade, were not harmful to the state by raising the prices of commodities at home, hurt trade, or generally inconvenient.[41] The Statute made it clear that the patents were granted to inventors as a privilege, not as a natural right that would allow for strong IP protections.

These historical accounts share a common ideological agenda of public interest-based utilitarianism. Patent rights were mainly conceptualized as privileges with specific public benefit goals rather than strong legal entitlements or property rights as we have them today. These goals included attracting skilled artisans into national territories, promoting technology transfer, enhancing local expertise, and fostering innovations.[42] These norms of the patent system extended to the 18th and 19th countries. As you will see in the next section, some countries abandoned their patent systems for not living up to these ideals. Monopolies were generally viewed unfavourably during this time and considered a 'bad odour,' except for the special case of the patent, which was seen as a means of incentivizing technological advancement.[43] In that sense, the 'embarrassment of an exclusive patent' and the 'monopolies of invention' could only be justified as a special legal privilege that served the 'benefit of society.'[44] This was the popular normative sentiment during the first half of the 19th century, particularly in the context of the pharmaceutical knowledge economy.

a. Pharmaceutical Patent Rights, Public Interests and Patent Abolition in the 19th Century

After the early beginnings of the patent system, the idea of patenting intangible assets spread throughout Europe and North America in the 19th century.[45] It was a period of somewhat chaotic

38 Thomas B. Nachbar, *Monopoly, Mercantilism, and the Politics of Regulation,* 91(6) Va. L. Rev. 1313, 1374 (2005).

39 Peter Drahos, A philosophy of Intellectual Property 29 (Routledge, 2016).

40 Statute of Monopolies 1623, §§ 1, 6.

41 *Id.*

42 Paul David, *The Evolution of Intellectual Property Institutions, in* Economics in a Changiing World 134 (A. Aganbegyan, O. Bogomolov & M. Kaiser, eds., 1994).

43 Lawrence M. Friedman, A History of American Law 255– 57, 435–38 (2nd ed., New York: Simon & Schuster, 1985).

44 Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* The Writings of Thomas Jefferson 326, 334–35 (Andrew A. Lipscomb ed., 1903); *see also* Graham v. John Deere Co., 383 U.S. 1, 7–11 (1966).

45 F. Machlup & E. Penrose, *The Patent Controversy in the Nineteenth Century,* 10(1) J. Econ. Hist. 1, 3 (1950).

growth with much cross-pollination of laws between states.[46] Nonetheless, countries still had the liberty to structure their patent policy to support their domestic socio-economic interests. For example, the US enacted its first federal patent law in 1790.[47]

Recognizing that foreign patents had the potential to limit domestic technological development, the US prohibited foreigners from filing patents in the country for forty-six years. When the restriction on foreigners was eventually lifted in 1836, the patent fees for foreigners were approximately tenfold higher than those for American citizens, with an additional charge of 65% for British nationals. The discrimination was eventually abolished in 1861 and replaced with inter-country reciprocity.[48]

At this time, the US was a net importer of technology, so it apparently wanted to have the liberty to copy foreign technologies to support its industrialization strategy.[49] Even in the publishing industry, the US publishing industry thrived in the nineteenth century by copying and publishing the 'unauthorized' work of European authors. It only started recognizing non-US authors in 1891.[50] Indeed, a 1986 study for the US Congress admitted that 'when the United States was a relatively young and developing country it refused to respect international intellectual property rights because it was freely entitled to foreign works to further its social and economic development.'[51] The US sought to make foreign technologies freely available to its inventors and entrepreneurs to boost its technological capacity. Granting patents on foreign technologies would frustrate that goal. The irony however is that the US is now the primary advocate for stronger patent regimes for foreign technologies worldwide regardless of the development statuses of different countries,[52] privileging the commodification of knowledge and market-oriented ideological paradigms over access to knowledge and technologies.

The legislative liberty of domestic policymakers before and during the early parts of the 19th century resulted in significant divergences and variations between national laws.[53] Some countries, like the US, awarded a seventeen-year patent term, while others, like Germany and France, granted patents

46 *See* Graham Dutfield et al., Dutfield and Suthersanen on Global Intellectual Property Law 147 (2nd ed. Cheltenham, UK: Edward Elgar Publishing Limited, 2020).

47 *See generally* Z.B. Khan, Intellectual Property and Economic Development: Lessons from American and European History (London: Commission on Intellectual Property Rights, 2002); E.C. Walterscheid, The Nature of the Intellectual Property Clause: A Study in Historical Perspective 310 (Hein ed., 2002).

48 Markedly, the U.S. became the first country not to recognize patents for the importation of trades or inventions, requiring that the inventor had to be the first inventor. Evans v. Eaton, 16 U.S. (3 Wheat) 454 (1836) (noting that the discovery must not only be useful, but new; it must not have been known or used before in any part of the world).

49 *Id.*

50 May, *supra* note 19, at 4.

51 U.S. Congress Office of Technology Assessment, Intellectual Property Rights in an Age of Electronics and Information 230 (1987).

52 Peter Gakunu, *Intellectual Property: Perspective of the Developing World,* 19(2) Ge. J. Int'l Competition L. 358–65 (Special Trade Conference Issue, 1989).

53 Graham Dutfield & Uma Suthersanen, Global Intellectual Property Law 23 (Cheltenham, UK: Edward Elgar Publishing Limited, 2020).

for fifteen years, and Great Britain issued patents for fourteen years.[54] Others, like the Netherlands, provided initial terms of five, ten, or fifteen years depending on the nature of the invention.[55] There were also differences in the patent filing processes, the types of inventions eligible for protection, and the exceptions created. For example, in the US and Great Britain, there were no explicit exceptions, while in others, like France and Germany, there were exceptions for certain classes of inventions, such as medicines and foods.[56] There were also disparities in the management of patented products or processes. In some places, like the US, patent holders were under no obligation to commercialize their inventions or even to use them, while in other countries, rival manufacturers could apply for a compulsory license if the patent holder refused to work on the invention or license it willingly.[57]

In the second half of the 19th century, there was serious discontent with the entire patent system for impeding free trade and competition. The discontent was mainly structured around the fact that 'a genius' does not need patent monetary incentives to create new products.[58] This widespread dissatisfaction became increasingly strong, leading to calls for a revision of the patent law or its abolition altogether.[59] In particular, the German parliament criticized the patent system as being 'injurious to the common welfare.'[60] Also, leading economists in Switzerland characterized the patent system as 'pernicious and indefensible.'[61] Similar opinions emanated from the Netherlands and Japan.[62] In particular, the Dutch Society for the Promotion of Industry, having the mandate to promote trade, industry, and social welfare, criticized the patent system for restricting industries and obstructing competition, describing patent rights as 'remnants of historical errors' and called for a repeal of the Netherlands' *Patent Act* of 1817.[63] The anti-patent movement found additional support in the example of Switzerland, a country without a patent system, nonetheless had a thriving innovation industry.[64]

54 *Id.*

55 Act Concerning the Grant of Exclusive Rights to Inventions and Improvements of Objects of Art and Industry, Stb.1817, 6 (Neth.) [the Patent Act of 1817], arts. 3–4.

56 Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting,* 5(5) J. World Intell. Prop. 765 at 766, 767 (2002).

57 *Id.* at 765.

58 Brad Sherman & Lionel Bently, The Making of Modern Intellectual Property Law – The British Experience, 1760-1911 131–32 (Cambridge: Cambridge University Press, 1999); Fritz Machlup & Edith Penrose, The Patent Controversy in the Nineteenth Century, 10 J. Econ. Hist. 1, 5 (1950).

59 *See generally* Robert Andrew Macfie, Recent Discussions on the Abolition of Patents for Inventions in the United Kingdom, France, Germany, and the Netherlands (London, Longmans et al. 1869) (examining the anti-patent movement in Europe in those days); Mark Janis, Patent Abolitionism, 17 Berkeley Tech. L. J. 899, 925 (2002) (providing a historical overview of the 19th-century patent abolitionist movement in England); Stef Van Gompel, *Patent Abolition: A Real-Life Historical Case Study,* 34(4) Am. U. Int'l Law Rev. 878–919 (2019) (discussing the abolition of the patent law in the Netherlands).

60 Eric Schiff, Industrialization Without National Patents – The Netherlands, 1869-1912, Switzerland, 1850-1907 21 (New Jersey: Princeton University Press, 1971).

61 *See* Fritz Machlup & Edith Penrose, *The Patent Controversy in the 19th Century,* 10 J. Econ. Hist. 1–29 (1950).

62 Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization,* 5 J. Hist. Int'l L. 407, 420 (2003).

63 *See* J.C. Faber van Riemsdyk et al., *Report on the Examination of Objections Facing Industry in the Law on Patents,* 17 J. Promotion Indus. 282 (1854), *in* Stef Van Gompel, *Patent Abolition: A Real-Life Historical Case Study,* 34(4) Am. U. Int'l L. Rev. 878–919, 891 (2019).

64 *See, e.g.,* Eric Schiff, Industrialization Without National Patents – The Netherlands, 1869-1912, Switzerland, 1850-1907 14 (New Jersey: Princeton University Press, 1971).

Domestic policymakers began to give attention to this anti-patent movement. The question of whether patent law should be reformed or abolished was consistently raised during legislative hearings and deliberations. For instance, the Netherlands and Japanese governments abolished their patents in 1869 and 1873, respectively.[65] In particular, the Dutch Patent Abolition Bill stated that patents should be abolished as they 'supported neither the true interests of industries nor the public interest.'[66] These abolitions resulted in the governments stopping the grant of new patents while phasing out existing patents. This anti-patent movement, backed by the normative framework of free-trade ideology and economic utilitarianism, was so strong in Europe, and it was anticipated that other countries would follow the Netherlands' abolition policy.[67] The US House of Representatives passed a bill to repeal the patent system, the bill was narrowly voted down in the Senate by a handful of votes.[68]

However, the trend was halted in 1873 due to intense lobbying by IP-driven industries as well as the first 'Great Economic Depression' in Europe and North America that lasted from 1873 to 1878/9.[69] The ideology of the anti-patent advocates was weakened by the financial crisis, and eventually, Japan and the Netherlands re-enacted their patent laws in 1885 and 1912, respectively.[70] On the other hand, Switzerland enacted their first patent statute in 1887, although provided strong compulsory licensing and government use provisions.[71] It also expressly excluded pharmaceutical products, chemicals and textile dyes from patent protection.[72] Similarly, the German *Patent Act* of 1877 prohibited patenting medicines, food articles, and chemical products. Instead, they only allowed the patenting of methods or processes that led to drugs.[73]

As seen above, the notable normative development during this period was the considerable freedom that domestic policymakers enjoyed in shaping their patent policies. Switzerland, the

65 F. Dessemontet, Intellectual Property Law in Switzerland 23 (The Hague, London and Bern: Kluwer Law International, 2000); Ikechi Mgbeoji, *The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization,* 5 J. Hist. Int'l L. 407, 420 (2003).

66 Patent Abolition Bill, 708 (preamble).

67 Stef Van Gompel, *Patent Abolition: A Real-Life Historical Case Study,* 34(4) Am. U. Int'l L. Rev. 878–919, 918 (2019).

68 Buce William Bugbee, *The Early American Law of Intellectual Property: The Historical Foundations of the United States Patent and Copyright Systems* 109 (Unpublished Doctoral Thesis) (Ann Arbor, Michigan: University of Michigan Press., 1961).

69 Ikechi Mgbeoji, The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization, 5 J. Hist. Int'l L. 407, 420 (2003); Elmus Wicker, Banking panics of the Gilded Age (Cambridge, UK: Cambridge University Press, 2000).

70 F. Dessemontet, Intellectual Property Law in Switzerland 23 (The Hague, London and Bern: Kluwer Law International, 2000).

71 *Id.*

72 Report of UK Commission on Intellectual Property Rights (CIPR), Integrating Intellectual Property rights and Development Policy (Sept. 2002), http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf; Eric Schiff, Industrialization Without National Patents – The Netherlands, 1869-1912, Switzerland, 1850-1907 34 (New Jersey: Princeton University Press, 1971); J. H. Reichman & C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (Geneva, Switzerland, International Centre for Trade and Sustainable Development (ICTSD, 2003).

73 *See also* Carsten Burhop, *Pharmaceutical Research in Wilhelmine Germany: The Case of E. Merck,* 83(3) Bus. Hist. Rev. 475–503 (2009).

Netherlands, and Japan refused to grant patents for a considerable amount of time, and the US did not recognize foreign technologies for over six decades. Italy engaged in 'knock-off' productions until 1978.[74] None of these actions attracted immediate foreign sanctions. The only constraint was the existence of bilateral treaties between countries, which were based on the principle of reciprocity.[75] The treaties provided that a country would safeguard the works of foreign inventors if the other nation agreed to protect its own.[76] This broad parliamentary liberty also extended to the recognition of pharmaceutical products and processes.

Early pharmaceutical firms were not dependent on IP rights to fund their R&D due to moral and cultural concerns. Medical patents and trade secrecy within the pharmaceutical industry were viewed as highly unethical by most physicians, pharmacists, and drug manufacturers at the time.[77] For instance, top US universities such as Harvard, Johns Hopkins, and Columbia had formal policies against medical patents.[78] The few who patented their medicines were condemned by the medical community as quacks and violators of the spirit and ethics of scientific medicines.[79] This ideology divided the pharmaceutical industry into two main sections: those within the ethical section who avoided patent protection and secrecy over their medical products and processes, and the so-called unethical section, who kept their manufacturing processes confidential and patented their goods.[80]

Pharmaceutical patents were rarely granted anywhere before the 1970s.[81] Even after England and the US patent laws endorsed protecting new medicines in the late 1700s, medical patenting did not become popular.[82] In 1960, only the UK and the USA permitted patents on pharmaceutical products. In the early 1970s, West Germany permitted drug patents. Japan didn't start awarding pharmaceutical patents until 1976. Belgium, the Netherlands, Italy, Sweden, and Switzerland embraced it in the late 1970s, followed by Canada, Denmark, and Austria in the 1980s. In the early 1990s, countries like Australia, Greece, Ireland, New Zealand, Norway, Portugal, Spain, and post-Communist countries in East Europe and Central Asia also joined the trend.[83] Finland was the last Western European country to allow pharmaceutical patents in 1995.[84] At this time, the pharmaceutical industry and technical capacity of these countries had relatively matured.

74 Mgbeoji, Ikechi, TRIPS and TRIPS Plus Impacts in Africa 264 (2007).

75 S. Ladas, Patents, Trademarks, and Related Rights: National and International Protection 43, 54–55 (Vol. 1, Cambridge: Harvard University Press, 1975).

76 *Id.*

77 Joseph Gabriel, Medical Monopoly 2 (Chicago: The University of Chicago Press, 2020).

78 Peter Lee, *Patents and the University,* 63(1) Duke L. J. 1–87 (2013).

79 Joseph Gabriel, Medical Monopoly 2 (Chicago: The University of Chicago Press, 2020).

80 *Id.*

81 Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, trade and medicines: past, present and future,* 27(1) Rev. Int'l Pol. Econ. 75, 78–79 (2020).

82 *See* Holger P. Hestermeyer, Human Rights in the WTO: The Case of TRIPS and Access to Medicines 28, 37 (Oxford: Oxford University Press, 2007); Carlos Correa, Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 271 (Oxford: Oxford University Press, 2007).

83 M. Liu & S. La Croix, *A cross-country index of intellectual property rights in pharmaceutical inventions,* 44(1) Rsch. Pol'y 206–216 (2015); S. La Croix & M. Liu, *The effect of GDP growth on pharmaceutical patent protection,* 1945–2005, 52(3) Brussels Econ. Rev. 355–75 (2009).

84 *Id.*

The initial exclusion of pharmaceutical products from the patent system was a deliberate utilitarian policy adopted by most nations. The high value and importance of medicines made it socially and morally unacceptable to subject them to the indiscriminate or expansive control of private corporations.[85] Even the *Paris Convention for the Protection of Industrial Property* ('the Paris Convention') of 1883, which harmonized the procedures relating to the registration and treatment of foreign patents, did not obligate signatory nations to protect either product or process patents for new drugs.[86]

However, by the outbreak of World War I, the 'ethical' segment of the pharmaceutical industry in Western countries began to cautiously embrace patenting as a vital tool to defend their scientific innovations and a convenient means of furthering their corporate growth. Given this transformation, the Western pharmaceutical industry emerged that is highly dependent on IP rights.[87] Medical patenting was no longer considered a form of quackery but a legitimate part of scientific drug development and corporate capitalism.[88]

b. The Global South and Pharmaceutical Patenting

Countries in the global south, despite the international trend, were still hesitant to embrace full medical patenting. Kenneth Shadlen et al note that '[h]istorically most developing countries did not allow patents on pharmaceutical products. Patent offices existed, and patents were available for machinery and electronics and many other areas, but not drugs. This prohibition reflected a calculation that the costs of having private rights of exclusion over these sorts of inventions would outweigh the benefits.'[89] The primary objective of this policy was to make cheaper generic medicines more readily available and limit private monopoly over essential drugs.[90] For instance, after India's independence, it repealed the Indian Patent Law of 1856 and replaced it with the Patent Act of 1970, which excluded pharmaceutical products from patent protection.[91] Patent protection for pharmaceutical processes under this new Indian law was only granted for seven years, compared to fourteen years for other forms of inventions.[92] Similarly, in the 1960s-70s, South Korea, Brazil, Argentina, Mexico, and Andrean Pact countries all enacted laws that weakened patent protection for medicines.[93]

85 Report of UK Commission on Intellectual Property Rights (CIPR), Integrating Intellectual Property rights and Development Policy (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

86 *See* Holger P. Hestermeyer, Human Rights in the WTO: The Case of TRIPS and Access to *Medicines* 28, 37 (Oxford: Oxford University Press, 2007); Carlos Correa, Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 271 (Oxford: Oxford University Press, 2007).

87 Joseph Gabriel, Medical Monopoly 3 (Chicago: The University of Chicago Press, 2020).

88 *Id.* at 195–237.

89 Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, trade and medicines: past, present and future,* 27(1) Rev. Int'l Pol. Econ. 75 (2020).

90 Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health, in* Transnational Legal Orders 320 (Terence C. Halliday & Gregory Shaffer eds., Cambridge University Press, 2014).

91 The Patents Act, 1970 (Act No. 39).

92 J.O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* (3 Nat'l Bureau Econ. Rsch., Working Paper No. 6366, 1998).

93 *See generally* G. Gereffi, The Pharmaceutical Industry and Dependency in the Third World (Princeton University Press, 1983).

Indeed, during this period, generic drug companies in these countries were able to copy patented medicines and compete with Western pharmaceutical companies and alliances in the global pharmaceutical market.[94] The liberty to imitate and reverse engineer allowed indigenous firms to absorb innovation and knowledge generated abroad and industrialize.[95] By the 1990s, Indian generic manufacturers were offering some of the lowest prices globally.[96]

Not surprisingly, this approach was met with strong opposition from multinational drug manufacturing companies domiciled in Western nations. They framed their objection in both moral and economic terms.[97] The companies complained that the unrestricted copying of patented medicines was a deplorable form of modern-day 'piracy' and a disadvantage for Western economies.[98] The U.S. government, in particular, initiated a national strategy called the 'Special 301' procedure, which empowered the U.S. Trade Representative to investigate countries with insufficient IP protection and impose trade sanctions against them if they fail to remedy the problem.[99]

Between the 1970s and early 1990s, the U.S. employed Special 301 against over a dozen countries, successfully pressuring governments to implement IP reforms that benefited foreign IP industries, including American-based pharmaceutical companies.[100] Notably, the US listed India under the 'Priority Watch List' on its 2014 edition of the Special 301 Report because the India Patent Act excluded new forms of known drugs from patent protection (section 3(d)) and introduced local working requirements (section 84(1)(c)).[101]

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94 *Id;* Report of UK Commission on Intellectual Property Rights (CIPR), Integrating Intellectual Property rights and Development Policy 20 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf; Nagesh Kumar, *Intellectual Property Rights, Technology and Economic Development,* 38(3) Econ. & Pol. Wk. 209–225, 216 (Jan. 18, 2003); Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector,* 97(6) Cal. L. Rev. 1571, 1578 (2009).

95 Nagesh Kumar, *Intellectual Property Rights, Technology and Economic Development,* 38:3 Econ. & Pol. Wk. 209– 225, 216 (Jan. 18, 2003).

96 S. Chaudhuri, The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries 54 (OUP, 2005).

97 Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health, in* Transnational Legal Orders 314 (Terence C. Halliday & Gregory Shaffer eds., Cambridge University Press, 2014).

98 Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford: Oxford University Press, 2009).

99 *See* Trade Act of 1974, § 301; M. Blakeney, Trade Related Aspects of Intellectual Property Rights (London: Sweet & Maxwell, 1996); Myles Getlan, TRIPS and Future of Section 301: A Comparative Study in Trade Dispute Resolution, 34 Columbia J. Transnat'l L. 173, 179 (1995).

100 Paul Katzenberger & Annette Kur, *TRIPs and Intellectual Property, in* From GATT to TRIPs: The Agreement on Trade-Related Aspects of Intellectual Property Rights (Friedrich Karl Beier and Gerhard Schricker eds., New York: Weinheim, 1996); A. Lynne Puckett & William L. Reynolds, *Rules, Sanctions and Enforcement under Section 301: At Odds with the WTO?,* 90 American J. Int'l L. 675–689 (1996).

101 USTR, *USTR Releases Annual Special 301 Report on Intellectual Property Rights,* Office of the USTR (Apr. 2014), https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.

The U.S., along with other major economies (such as European countries, Japan, and Canada), started pushing for IP protection to become part of the 1986 Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations.[102] The GATT negotiations aimed to enact a better multilateral trading system concerning trading in tangible goods. At that time, the US was the 'single most influential player' in the GATT's forum,[103] the U.S. and its allies included IP rights as a subject of the trade negotiations.[104] The negotiations concluded on April 15, 1994, with the signing of the TRIPS Agreement by over a hundred countries. The Agreement became one of the constitutive documents of the new WTO, binding on all its members.[105] Among several notable provisions, the TRIPS Agreement made it compulsory for all WTO members to grant patent protection on both products and processes, marking the beginning of pharmaceutical patents for most developing countries, including low-income countries not within the category of 'Least Developed Countries', which were granted transitionary grace.[106]

However, this new paradigm, as elaborated upon in greater detail below, is arguably based on a 'skewed utilitarian' that highlights relatively strong and enforceable private property rights while not adequately addressing important collective rights concerns. The result of this imbalance is a disproportionate impact on low-income groups, as access to the pharmaceutical knowledge economy largely hinges on the ability and willingness to pay and market transactions, featuring dominant corporate players, who are seizing every opportunity to expand their private rights.

III. Epistemological Reconstitution of the IP Norm-Making Process

As noted in the preceding section, patent rights were historically viewed as special privileges and strategic domestic instruments. This normative approach created a legal regime that allowed state actors to tailor their patent policies to suit their level of development, which resulted in nationalistic strategies such as refusal to recognize foreign technologies, weakening domestic IP regimes, dismissing international cooperation on uniform patent rules, issuing compulsory licenses for nonworking patents, and disregarding pharmaceutical patents.[107] Some countries, such as the Netherlands, Japan, and Switzerland, even rejected patent legal systems at different times based on domestic values and public interest.

102 For the history of this, *see* Peter Drahos, *Global property rights in information: the story of TRIPS at the GATT,* 13 Prometheus 6–19 (1995); Peter Drahos, *The Universality of Intellectual Property Rights: Origins and Development,* 1999 Intell. Prop. & Hum. Rts. Q. 13–41, 20 (1999).

103 Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting,* 5(5) J. World Intell. Prop. 765, 768 (2002).

104 Peter Drahos, *The universality of intellectual property rights: origins and development,* 1999 Intell. Prop. & Hum. Rts. Q. 13, 21 (1999).

105 The only way a state can become or remain a member of the WTO multilateral trading regime is to agree to be bound by the TRIPS Agreement. *See* World Trade Organization (WTO), *Members and Observers,* WTO (Jan. 6, 2022), https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm; Peter Drahos, *The Universality of Intellectual Property Rights: Origins And Development,* 1999 Intell. Prop. & Hum.Rts. Q. 14, 21 (1999).

106 Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, trade and medicines: past, present and future,* 27(1) Rev. Int'l Pol. Econ. 75 (2020).

107 Keith Maskus & Jerome Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods,* 7(2) J. Int'l Econ. L. 290 (2004).

However, the 20th and 21st centuries, which is the focus of this section, witnessed a 'tectonic shift' in the scope and nature of patent rights, with the emergence of the TRIPs Agreement. IP rights began to be conceptualized as private property rights and market-based tools, not privileges. The TRIPS Agreement represents a 'dramatic shift away from the traditional view that intellectual property law primarily serves the interest of national cultures, values, and politics.'[108] The transformation led to an expansion of patent rights, with the U.S., the European Union, and IP-driven businesses exerting significant influence over international IP norm-setting. This new era also introduced quasi-patent protections for pharmaceuticals such as data exclusivity provision, linkage regulations, and investor-state arbitration.[109]

In this section, I analyze the evolution and operationalization of this new system, how it created a new paradigm in the pharmaceutical knowledge economy that is utilitarianly lop-sided, and three key factors (understanding the IP norm-making process, democratizing the process, and recognizing 'flexibility' as a vital IP issue) that can serve as a basis to reconstitute the IP norm-making process. Although the prevalent policy framework is based on utilitarianism (i.e., the maximization of social welfare), the operationalization of the framework appears as 'skewed utilitarianism.' The new regime emphasizes the benefits of incentivizing innovation without catering to the distributional consequences on the poor and low-income groups. Thus, raising concerns about the need to renegotiate and reevaluate the patent policy to achieve the promised optimal utility of the patent system.

a. The TRIPS Agreement and the New Pharmaceutical Knowledge-Economy

The TRIPS Agreement broadened the scope of patentable subject matter to include matters, such as pharmaceutical products, that had been previously excluded from national IP laws on account of moral, societal, or public health concerns.[110] The traditional justification for this new knowledge economy is utilitarianism. Jeremy Bentham, the main proponent of this concept, believed that laws should be enacted in a way that maximizes the greatest happiness for the greatest number of people.[111] Regarding the patent legal regime, it aims to incentivize the development of new inventions for the benefit of the greatest number of people (i.e., maximization of social welfare).[112]

Law and Economics scholars have provided a conceptual framework for this normative perspective. They argue that to achieve this surplus, there is a need to address a market failure problem,[113] which

108 Vincent Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things,* 21 Mich. J. Int'l L. 333 (2000).

109 James Gathii & Cynthia Ho, *Regime shifting of IP lawmaking and enforcement from the WTO to the international investment regime,* 18 Minn. J. L. Sci. & Tech 427 (2017).

110 The TRIPS Agreement, art. 27.1.

111 John Stuart Mill, Utilitarianism 8 (7th ed., London: Longmans, Green & Co, 1879); Jeremy Bentham, An Introduction to the Principles of Morals and Legislation 1–5 (Oxford, UK: Clarendon Press, 1823).

112 Please note that some commentators have tried to differentiate the economic norm of 'wealth maximization' from the concept of utilitarianism. *See* Richard A. Posner, *Utilitarianism, Economics and Legal Theory,* 8 J. Legal Stud. 103, 111 (1979).

113 Harold Demsetz, *Towards a Theory of Property Rights,* 57 American Econ. Rev. 347–48 (1967); William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law 22–23 (Belknap Press & Harvard University Press, 2003).

is the inability of the competitive market to support the maximum production and distribution of public goods, such as IP products and processes, because they are nonrivalrous and nonexcludable.[114] The term 'nonrivalrous' means that the goods can be consumed by more than one person at a time, while 'nonexcludable' suggests that users cannot be easily prevented from free-riding on the good.[115] Thus, the main essence of the patent regime is to ensure the maximum of inventions based on market preferences.

Pharmaceutical products and processes are characterized as 'public goods' which would be underproduced without state intervention in the form of property rights.[116] In other words, companies and investors may be uninterested in investing the necessary resources to generate breakthrough drugs and vaccines if imitators can easily copy their goods and sell them at a marginal cost. Although social costs could arise from granting monopoly power to an inventor, such as deadweight losses and limited access to technologies, advocates of this theory argue that if the beneficial effects outweigh the costs, then it is an efficient outcome.[117] They argue that patents improve dynamic efficiency by stimulating innovation and technological progress, although this comes at the cost of static efficiency due to monopoly pricing.[118]

The underlying assumption of this theory is that market transactions will maximize wealth – a 'rising tide lifts all boats.'[119] Wealth maximization, in this context, refers to the greatest total consumer and producer surplus that can be generated by goods and services in an economy.[120] Adherents of this economic analysis of the law idealize the market order as the best option to promote social welfare.[121] They believe that efficient policies are neutral and that the market is the most efficient mechanism for allocating resources and promoting individual freedom.[122] This analysis assumes that the distributive implications of legal policies do not matter as taxes should offset those consequences. Hence, given that the pharmaceutical industry caters to a global market, worldwide state intervention in the form of property rights is the most efficient means of addressing this market failure problem and securing beneficial progress.[123] This would allow brand-name companies or originators to internalize positive externalities, including those from foreign countries, and prevent generic firms from reverse

114 Paul A. Samuelson, *The Pure Theory of Public Expenditure,* 36 Rev. Econ. & Stat. 387 (1956).

115 *Id.*

116 *Id.*

117 N. Mercuro & S. Medema, Economics and the Law: From Posner to Post-Modernism Chapter One (2nd ed., Princeton University Press, 2006).

118 UK Commission on Intellectual Property Rights, Final Report of the Commission on Intellectual Property: Integrating Intellectual Property Rights and Development Policy Commission on Intellectual Property Rights (2002).

119 *See* Gene Sperling, *How to Refloat These Boats,* Washington Post (Dec. 18, 2005), http://perma.cc/EQ6A-J8X9 (discussing the history of the phrase).

120 Richard A. Posner, The Economics of Justice 60 (Cambridge: Harvard University Press, 1981).

121 *See* Melinda Cooper, Family Values (New York: Zone Books, 2016); Nancy Fraser, *Contradictions of Capitalism and Care,* 100 New Left Rev. 99 (2016).

122 William M. Landes & Richard A. Posner, The Political Economy of Intellectual Property Law 22 (AEI-Brookings Joint Center for Regulatory Studies, 2004).

123 *Id.* at 22–23.

engineering an original drug, replicating it, and selling it at marginal costs, all without incurring the associated R&D expenses.[124]

This normative analysis has its benefits. It appreciates the significant risks and time associated with the development and commercialization of new technologies, particularly in the context of the pharmaceutical industry. It recognizes the importance of new technologies as critical drivers of socio-economic growth and seeks to incentivize their production through monopoly rights and temporarily ward off competitors. However, it tends to overlook the historical evolution of the patent system and the distributional consequences that arise from granting monopoly rights over essential technologies.

The TRIPS Agreement compelled all WTO member countries including low-income countries that do not fall within the bracket of 'Least Developed Countries (LDCs)' to grant patent protection for pharmaceutical products and processes.[125] For industrialized countries, this may not be a problem from the perspective of developing new drugs due to their robust R&D programs and technological capabilities. They can easily build upon existing technologies and create new inventions, benefiting from decades of investment and the global exchange of ideas. In contrast, less developed nations need to rely on foreign technologies to support their generic companies and industrialization efforts.

The new pharmaceutical knowledge economy impedes the capacity of domestic pharmaceutical companies in these non-industrialized nations to utilize patented products and processes. It also limits the flexibility of policymakers in these nations to exclude medicines or chemicals from their patent systems for reasons related to public health or other developmental considerations, a practice that was permissible in the early stages of the patent system's evolution, I examine the issue of TRIPS flexibilities in the next section.

Furthermore, the TRIPS Agreement mandates member states to provide patent protection for a minimum of twenty years from the date of filing without taking into consideration how long it would require for the company to recover their R&D costs and incentivize future innovation, despite the social costs associated with exercising monopolistic patent rights.[126] The perception among the public health community is that a two-decade monopoly period in some cases is excessive even within the pharmaceutical industry and could sustain the high price of drugs artificially for an unnecessarily long period and stifle innovation in new drugs.[127]

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124 *See generally* Mark A. Lemley, *Property, Intellectual Property, and Free Riding,* 83 Tex. L. Rev. 1031 (2005).

125 Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 218–19 (2nd ed., London: Sweet & Maxwell, 2003).

126 *See* TRIPS Agreement, art. 33.

127 Gary Becker, *On Reforming the Patent System,* Becker-Posner Blog (July 21, 2013), http://www.becker-posner-blog.com/2013/07/on-reforming-the-patentsystem-becker.html ("The current patent length of 20 years (longer for drug companies) from the date of filing for a patent can be cut in half without greatly discouraging innovation . . . . Even pharmaceutical and biotech companies, the main examples where patents are clearly necessary to encourage innovation, usually do not need more than about a decade of monopoly power to encourage their very large investments in new drugs."); Brian Love, *An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?,* 161 U. Pa. L. Rev. 1309, 1409 (2013) ("In a world in which at least some products

In fact, this 20-year provision was a subject of contention during the negotiation phase of the TRIPS Agreement, with most developing countries advocating for flexible patent terms, determined on a case-by-case basis and guided by national interests.[128] Developed countries, on the other hand, suggested a fixed term of twenty years or higher, with Australia and New Zealand proposing shorter patent terms of fifteen and sixteen years, respectively.[129] After several revisions to the draft, the fixed term of twenty years emerged as the prevailing option.

The length of patent protection is a critical factor in the patent bargain as excessive protection can be equally detrimental as insufficient protection in terms of social costs.[130] Excessive protection extends the period during which access to protected products and processes is restricted. This could potentially lead to preventable deaths. For example, it has been reported that globally at 'least 14 million people lost their lives in two years (2020-2021)' during the COVID-19 pandemic.[131] While some of the deaths were inevitable, there have been reports that many of these deaths could have been prevented if COVID-19 vaccines had been readily available and accessible, particularly in low-income countries, and patent rights delayed the scaling up of manufacturing and distribution of the vaccines.[132]

Furthermore, the TRIPS Agreement provides a strong enforcement regime by linking patent enforcement to the WTO's dispute resolution system. The Agreement established two new institutions to guide adherence to the treaty: the Council for TRIPs, an interstate body responsible for conducting transparent reviews of national implementation measures and providing a forum for members to discuss compliance issues, and a Dispute Settlement Body (DSB) responsible for adjudicating disputes and imposing sanctions on non-compliant

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are out of date by the time they hit store shelves, the last few years of a two-decade-long patent term seem unlikely to incentivize greater innovation."); *Time to Fix Patents,* Economist (Aug. 8, 2015), https://www.economist.com/leaders/2015/08/08/time-to-fix-patents (explaining that pharmaceutical firms could live with shorter patents if the regulatory regime allowed them to bring treatments to market sooner and for less upfront cost).

128 *See* Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights, Communication from Colombia, art. 41, GATT Doc. MTN.GNG/TRIPS/W/2 (Oct. 16, 1991); *see also* Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, art. 4(3), GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Communication from Mexico, ¶ 3, GATT Doc. MTN.GNG/NG11/W/60 (Jan. 22, 1990); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Communication from Brazil, ¶ 21, GATT Doc. MTN.GNG/NG11/W/57 (Dec. 11, 1989); Guidelines for Negotiations that Strike a Balance Between Intellectual Property Rights and Development Objectives, Communication from Peru, ¶ 1.4, GATT Doc. MTN.GNG/NG11/W/45 (Oct. 27, 1989).

129 Standards and Norms for Negotiations on Trade-Related Aspects of Intellectual Property Rights, Communication from Australia, ¶ 1, GATT Doc. MTN.GNG/NG11/W/35 (July 10, 1989); Communication from Switzerland - Draft Amendment art. 231(1); Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Communication from the European Communities, art. 10(1), GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990).

130 *See generally* Mark A. Lemley, *Property, Intellectual Property, and Free Riding,* 83 Tex. L. Rev. 1031 (2005).

131 *Analysis finds SA was bullied into one-sided, imperial and immoral Covid-19 vaccine contracts,* Daily Maverick (Sept. 11, 2023), https://www.dailymaverick.co.za/article/2023-09-11-analysis-finds-sa-was-bullied-into-one-sided-imperial-and-immoral-covid-19-vaccine-contracts/.

132 *Id.*

members.[133] This adjudication process involves four main stages: (i) consultation between the parties to find a mutually agreed solution, (ii) adjudication by panels and, if necessary, by the Appellate Body, (iii) adoption of the panel and Appellate Body reports by the DSB, and (iv) implementation of the ruling, which may involve countermeasures if the losing party fails to comply with the ruling.[134]

This adjudication mechanism theoretically restricts the capacity of member States to interpret TRIPS provisions in alignment with their respective local contexts. The adjudicators are likely to be from foreign jurisdictions and may not possess a deep understanding of the local socio-economic and technological factors influencing domestic policy decisions. It essentially deprives local courts, which often incorporate human rights (for example, the right to health and enjoyment of scientific progress) perspective into their adjudication process, of the authority to address disputes arising from the TRIPS Agreement within the context of their local circumstances.

b. TRIPS Flexibilities and 'Inflexibilities' in the Pharmaceutical Industry

The TRIPS Agreement contains certain exceptions to the implementation of the IP regime, commonly referred to as 'flexibilities,' that seek to balance the sharp edges of IP rights and the public interest. In the context of public health, the flexibilities were designed to temper the social welfare costs of patent rights by offering ways to respond to concerns that patents and related pharmaceutical monopoly pricing can limit access to essential medicines.[135] These flexibilities include but are not limited to transition periods for least-developed countries to ease compliance, compulsory licenses and crown use of patented products and processes to promote generic production of health goods, Bolar provisions to ease research and regulatory approvals, limits to the scope of patentability to allow for domestic discretion, international exhaustion of patent rights to enable parallel importation, and the lack of a requirement to apply the principles of TRIPS in areas not covered by the Agreement.[136]

However, Joseph Stiglitz has described the TRIPS flexibilities as 'inflexibilities' due to the challenges that accompany their implementation.[137] The most used, or at least, talked about flexibility is the compulsory licensing tool, which enables state governments to license a patented product or process

133 *See* Communication from Australia—Review of the Implementation of the Agreement Under Article 7I. I, at 2, WTO Doc. IP/C/W/210 (Oct. 3, 2000) ("[M]any WTO Members have undertaken extensive legislative and administrative action to give effect to their obligations under the Agreement. Implementation has been a complex and diverse process in many jurisdictions.").

134 WTO, *The process – Stages in a typical WTO dispute settlement case, in* Dispute Settlement System Training Module (last visited Mar. 23, 2023), https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s1p1_e.htm.

135 World Health Organization, Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade (Geneva: World Health Organization; 2020); Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health, in* Transnational Legal Orders 323 (Terence C. Halliday & Gregory Shaffer eds., 2014); Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 349, 365–66 (2nd ed., London: Sweet & Maxwell, 2003).

136 TRIPS Agreement, arts. 1.1, 8.1, 31 & 66.1; World Trade Organization (WTO), *Members and Observers,* WTO (Jan. 6, 2022), https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

137 Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights,* 57(6) Duke L. J. 1693, 1717 (2008).

to a third party without the authorization of the rightsholder so long as they pay the rightsholder adequate compensation.[138] Indeed, the compulsory licensing system can be a valuable tool for domestic policymakers to address national interest issues such as public health emergencies. It can either directly lead to lower prices of drugs or be used to threaten patent holders to lower their prices during negotiations.[139] The TRIPS Agreement generally allows countries to determine the grounds for making such compulsory licenses and the procedures for taking such steps.

The perception in developing countries is that this compulsory license system has been largely ineffective in addressing public health concerns based on the following reasons. Firstly, developed countries usually put pressure on developing countries not to utilize the compulsory license regime. Pharmaceutical companies, with the backing of their host countries, have traditionally opposed indications by developing nations to exploit domestic compulsory licensing provisions.[140] As noted by Graham Dutfield, the US in particular has openly expressed disapproval when developing nations attempt to limit the full enjoyment of patent rights for American businesses, whether through compulsory licensing, parallel importation, or even just indicating the intention to do so.[141] For instance, from 2006 to 2008, Thailand issued compulsory licenses for several patented pharmaceutical products to improve access to drugs for HIV/AIDS, heart disease, and cancer.[142] In response, the US placed Thailand on its Special 301 'Priority Watch List,' which prevented Thai exports from entering the US market duty-free.[143] The European Commission also expressed concerns about the lawfulness of Thailand's compulsory licensing practices, while Western multinational pharmaceutical companies threatened legal action and eventually withdrew a range of essential medicines from the Thai market, without regard for the impact that would have on human lives.[144] Some commentators pointed out that '[a]lthough this vindictive measure was later reversed, Thai patients suffered unnecessary harm at the hands of private foreign actors. They were deprived of access to essential treatments, some of which had no alternative, for the duration of the entire

138 *See* TRIPS Agreement, art. 31. For pharmaceutical products, The World Health Organization (WHO) has developed specific guidelines for calculating adequate remuneration with respect to patented pharmaceuticals. *See also* James Love, *Remuneration guidelines for non-voluntary use of a patent on medical technologies,* World Health Organization (2005), https://apps.who.int/iris/handle/10665/69199.

139 R. Beall & R. Kuhn, *Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: A database analysis,* 9(1) PLoS Medicine 1 (2012); K.B. Son & T.J, Lee, *Compulsory licensing of pharmaceuticals reconsidered: Current situation and implications for access to medicines,* 13(10) Glob. Pub. Health 1430–40 (2018).

140 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/L/540 (2003) (Decision of the General Council of 30 August 2003) ("WTO General Council Decision of Aug. 30, 2003."). For commentary, *see* Frederick Abbott & Rudolf Van Puymbroeck, Compulsory Licensing for Public Health A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (Washington DC: World Bank, 2012).

141 Graham Dutfield et al., Dutfield and Suthersanen on Global Intellectual Property Law 401 (2nd ed., Edward Elgar Publishing Limited, 2020).

142 Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options Under the WTO Agreements,* 19 J. Int'l Econ. L. 51 (2016); Michael Palmedo, *United States: Unilateral Norm Setting Using Special 301, in* Intellectual Property Law and The Right to Health: A History of Trips and Access to Medicines (Srividhya Ragavan & Amaka Vanni eds., UK: Routledge, 2021).

143 *Id.*

144 Letter from Peter Mandelson, E.U. Trade Commissioner to Krirk-krai Jirapaet, Thai Minister of Commerce (July 10, 2007), https://www.keionline.org/wpcontent/uploads/mandelson07102007.pdf.

dispute.'[145] Several countries, including South Africa, Brazil, Malaysia, and Indonesia, have faced similar backlash from industrialized nations and pharmaceutical in response to their compulsory licensing measures.[146] These retaliatory mechanisms tie the hands of domestic policymakers in utilizing the compulsory licensing system to cater to public health crises even in situations that warrant the same.[147]

Secondly, the issuance of compulsory licenses is usually accompanied by protracted and complicated negotiations. The third-party user of a compulsory license (i.e. the generic company) is required to make efforts to negotiate and obtain authorization from the rightsholder before applying for a compulsory license, except in cases of national emergencies, extreme urgency, public non-commercial use, or judicially or administratively determined anti-competitive remedies.[148] Ordinarily, there is nothing wrong with contacting and discussing with patent holders the impact their invention may have on social welfare but the challenge is that these negotiations can be lengthy and complex, particularly when multiple patented technologies are contained in a product and different companies own these technologies.[149] Even in cases of national emergencies and related circumstances, compulsory licenses have to be granted separately for each technology that makes up the drug. As Ellen't Hoen et al. argued, 'it is not possible to grant blanket compulsory licenses for an entire field of technology or for an overarching purpose such as 'combating a pandemic.'[150] This explains why during the peak of the COVID-19 crisis, developing countries, led by South Africa and India, wanted waiver of certain provisions of the TRIPS Agreement instead of utilizing the existing compulsory license regime.

Additionally, the compulsory licensing regime (pre-2005) was limited to the domestic market and sought to prevent parallel importation. In other words, a compulsory license could only authorize uses that are primarily targeted at supplying a country's population.[151] This means that cheaper generic medicines produced in another state under a compulsory license cannot be exported to another state, making it difficult for WTO members with insufficient domestic manufacturing capacities to use the system effectively. So, if there is no local producer within a country with the

145 Ezinne Miriam Igbokwe & Andrea Tosato, *Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis,* Fac. Scholarship at Penn L. 2802, 2842 (2022).

146 *See generally* Brook K. Baker, *Access to Medicines Activism: Collaboration, Conflicts, and Complementarities, in* Intellectual Property Law and The Right to Health: A History of Trips and Access to Medicines 295 (Srividhya Ragavan & Amaka Vanni eds., UK: Routledge, 2021); South Africa in 1997, Brazil in 2001, Malaysia in 2003, Indonesia in 2004.

147 *Id.*

148 *See* TRIPS Agreement, art. 31; Graham Dutfield et al., Dutfield and Suthersanen on Global Intellectual Property Law 406 (2nd ed., Cheltenham, UK: Edward Elgar Publishing Limited, 2020).

149 Article 31(b) of the TRIPS Agreement; *see* Olga Gurgula, *Compulsory Licensing vs. the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic?,* Policy Brief (Oct. 17, 2021), https://ssrn.com/abstract=3944192.

150 *Id.*

151 *See* TRIPS Agreement, art. 31(f).

necessary infrastructure and know-how to produce a patented product, issuing a compulsory license would be futile.[152] There have been some recent amendments to address this concern, which I will address later.

Another significant drawback of the compulsory license system is that it only applies to existing patents, not patent applications. [153] Article 31 of the TRIPS Agreement, which deals with 'use without authorization of the right holder' is limited to the 'subject matter of a patent.' This limitation creates a gap that can be particularly damaging during public health emergencies. Patent applications can take up to three years in some jurisdictions to be finalized.[154] Waiting for a patent to be granted before applying for a compulsory license can significantly prolong the process of acquiring the license.

Relatedly, trade secrets are not subject to compulsory licensing, and crucial manufacturing processes, or know-how are usually protected under trade secrets. Patent specifications, which are publicly available after 18 months, do not usually contain these trade secret details. This means a compulsory license may not be beneficial to a generic company if they are unable to access the relevant trade secrets or know-how required to reproduce the patented drugs.

Some of these challenges were debated after the explosion of the AIDS crisis in the 2000s, which resulted in significant adjustments to the TRIPS Agreement in 2001, 2003, and 2005. In 2001, the Doha Declaration on the TRIPS Agreement and Public Health recognized the freedom of all WTO members to interpret the provisions of the TRIPS Agreement broadly when public health is at risk. The Declaration expressly mentions that crises 'relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency' under Article 31 of the Agreement. The Declaration allowed least-developed countries to postpone the implementation of patent protection for pharmaceutical products until January 1, 2016.[155] Later, in November 2015, the Council for TRIPS agreed to extend this implementation deadline to January 1, 2033.[156]

152 Ezinne Miriam Igbokwe & Andrea Tosato, *Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis,* Fac. Scholarship at Penn. L. 2802, 2805 (2022).

153 François Pochart et al., *Compulsory licenses granted by public authorities: an application in the COVID-19 crisis in France?,* Kluwer Patent Blog (Apr. 23, 2020), http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licensesgranted-by-public-authorities-an-application-in-the-COVID-19-crisis-in-france-part-1.

154 Christopher Heer et al., *How Long Does It Take to Get a Patent?,* Heer Law (Dec. 11, 2020), https://www.heerlaw.com/how-long-does-it-take-to-get-a-patent (In Canada, the patent application process takes approximately two and half years.); Noah Adam, *How Long Does it Take to Get a Patent,* Patent Rebel (June 20, 2019), https://patentrebel.com/how-long-does-it-take-to-get-a-patent/ (describing that the patent process typically last for two years in the United States); IP Gateway, *Australia: Patent FAQs* (Jan. 7, 2022), https://ipgateway.com.au/wp-content/uploads/2018/03/IPG-Patent-FAQ-sheet-EMAIL-1.pdf (explaining that it takes approximately four years in Australia); Prasad Karhad, The time required for grant of patent in India, Patent in India (last visited Jan. 7, 2022), https://patentinindia.com/time-to-get-a-patent-in-india/.

155 *Id.*

156 *Id.*

However, the 2001 Declaration failed to address the issue of how countries with inadequate manufacturing capacity could use compulsory licenses (i.e., the domestic use limitation). So, in 2003, the Council for TRIPS made a decision confirming the ability of states to import and export pharmaceutical products in exceptional circumstances, provided that a compulsory license was issued by the exporting member state. Subsequently, a WTO 2005 Ministerial Declaration introduced TRIPS Article 31bis, which permanently incorporated the effects of the 2003 decision. Article 31bis required both the exporting and importing countries to notify WTO about the measure, including the name and expected quantities of the products involved, before the exports occur and prohibited re-exportation of the products.

Since Article 31bis' adoption over 19 years ago, the mechanism has only been successfully used once, in 2007, when Rwanda wanted to import 260,000 packs of a generic version of TriAvir, an AIDS therapy drug, from Canada.[157] Despite the efforts by Médecins Sans Frontières (MSF) and Apotex, a generic pharmaceutical company, it took five years before the export of TriAvir was initiated due to regulatory bottlenecks.[158] Apotex later released a public statement indicating that it would not use the parallel importation flexibility under the TRIPs Agreement again unless the compulsory license processes were reformed.[159]

The grievance expressed by Apotex highlights two other broader problems with the compulsory license system: the lack of political courage/will from domestic policymakers and excessive bureaucracy. Leaving the use of compulsory licenses to the discretion of state governments has exposed the system to both international and domestic politics, even during public health emergencies. If Article 31bis genuinely aims to guarantee sustained access to cost-effective generic medicines for developing nations, the TRIPS Agreement should have either made it compulsory for governments to grant licenses during public health crises or expressly prohibit political pressures that hinder such measures. It should not be left to the will of state actors. Article 31bis should be worded as an enforceable legal right, not a matter of political discretion.

Moreover, the notification provisions of Article 31bis as well as government regulatory approval processes have created excessive procedural complexities for the compulsory licensing system.[160] The importing state must notify the TRIPS Council about its intention to utilize the Article 31bis system, supply evidence of its insufficient manufacturing capacities, and specify the exact quantity of the drugs in question ex-ante. Other requirements include that the exporting state must negotiate

157 World Trade Organization (WTO), *Canada is first to notify compulsory licence to export generic drug,* WTO (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

158 Priti Radhakrishnan & Tahir Amin, *Strengthening Patent Standards: An Alternative Route to Compulsory Licensing For Low And Middle-Income Countries, in* Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing (Carlos M. Correa, ed., 2013); Médecins Sans Frontières, *Neither Expeditious, nor a Solution: the WTO August 30th Decision is Unworkable,* MSF Access Campaign (Aug. 29, 2006), https://msfaccess.org/neitherexpeditious-nor-solution-wto-august-30th-decision-unworkable.

159 Médecins Sans Frontières, *WTO COVID-19 TRIPS Waiver Doctors Without Borders. Canada Briefing Note* (2021), https://www.doctorswithoutborders.ca/wp-content/uploads/2023/02/msf_canada_briefer_on_trips_waiver.pdf.

160 Annex to the TRIPS Agreement, 2(a).

with the rightsholder before issuing an export compulsory license,[161] the license must be highly specific in terms of the affected patented technologies, and the rightsholder must be adequately compensated for the license.[162] Also, the exporting state must inform the TRIPS Council about the proposed license and mark the products manufactured under the license with a special colouring and shaping to differentiate them from the original.[163]

These would require some high degree of coordination among the several parties, including the importing country, exporting country, and pharmaceutical corporations. Some commentators have rightly described these disclosure and coordination obligations as acutely problematic, complex, and unrealistic, particularly for developing WTO members.[164] Satisfying all these obligations and alterations may not only be problematic but also expensive and time-consuming.[165] Understandably, the purpose of these procedural rules is to restrict diversion measures, i.e., to prevent the distribution of products made under a compulsory license to markets with sufficient manufacturing and purchasing power.[166] However, in doing so, these regulations have created difficulties for developing countries that want to import essential medicines and undermined the effectiveness of the Article 31bis regime. The drafters should have just simply prohibited the re-exportation of the specific products to markets where there is adequate domestic manufacturing capacity.

Furthermore, the exporting countries' approval processes can also be problematic. Canada was the first country to domesticate Article 31bis, but it imposed restrictions not demanded by Article 31bis.[167] For instance, it requires that all medicines produced under an export compulsory license must meet Canadian marketing approval standards rather than those of the Importing State, circumscribes the type of pharmaceuticals that can be subjected to such license, and limits the

161 *Id.* at 2(b)ii.

162 *Id.*

163 Annex to the TRIPS Agreement, 2(b)ii.

164 *See generally* Carlos Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?,* South Centre Policy Brief No. 57, 59 (2019); Dina Halajian, Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Program, 38 Brook. J. Int'l L. 1191, 1197–98, 1202–4 (2012); Nicholas G. Vincent, TRIP-Ing up: The Failure of TRIPS Article 31Bis, 24 Gonz. J. Int'l L. 1 (2020).

165 *See generally* Jillian C. Cohen-Kohler et al., *Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?,* 3 Glob. Health 12 (2007) (stating that the negotiation procedural requirement was especially problematic in the Canada-Rwanda compulsory license). *See* Muhammad Z. Abbas & Shamreeza Riaz, WTO Paragraph 6 System for Affordable Access to Medicines: Relief or Regulatory Ritualism, 21 J. World Intell. Prop. 32, 39 (2018).

166 Ezinne Miriam Igbokwe & Andrea Tosato, *Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis,* Fac. Scholarship at Penn. L. 2802, 2850 (2022) ("We share the view that the procedural dimension of the Article 31bis System materially hinders export compulsory licensing. The issue lies with the normative aims that shape this body of rules. This entire procedure is designed primarily to ensure that medicines produced under an ECL are not surreptitiously diverted into more pecunious markets and, to a lesser extent, verify that the Importing State is eligible to use the Article 31bis System. Regrettably, the rules under consideration do not prioritize efficiency, simplicity and expediency for the relevant stakeholders. This is both disappointing and surprising given that the explicit mandate of the Doha Declaration was to create a 'solution' to the difficulties faced by Members with insufficient manufacturing capabilities in the pharmaceutical sector in making effective use of the Article 31 regime for compulsory licensing.").

167 Canadian Patent Act of 1985, R.S.C., §§ 21.01–21.19.

duration of the license to two years.[168] These added restrictions, do not have developing countries in mind, and weaken the utility of the Article 31bis system.

The TRIPS flexibilities have been complicated by the emergence of supplementary protections, commonly referred to as 'TRIPS-plus provisions', which are measures adopted by industrialized nations and pharmaceutical companies outside the WTO TRIPS Agreement to further harmonize patent application procedures, expand the exclusive rights of patent owners, compensate for regulatory delays by delaying the approval, delay the entrance of cheaper generic drugs into the market, require that patents be granted to new uses of existing medicines, and restrict the use of compulsory licenses and discretions of national governments.

These additional exclusive rights are beyond what the WTO requires, undercut the Doha Declaration on Public Health, and further skew the patent balance in favour of corporate interest.[169] Examples of supplementary protections include elements such as data exclusivities, market regulatory protection, patent linkage regulations, trade secrets, secondary patenting, and investment rights.[170] The United States, European Union, and Japan have negotiated a large number of regional and bilateral trade agreements with developing countries, often incorporating IP-related chapters with various TRIPS-plus provisions.[171] These agreements 'remove many of the flexibilities available under TRIPS, subjecting signatory countries' patent systems to stricter provisions.'[172] Consequently, this creates an economic model that empowers certain segments of the global community over others.

c. Low-Income Countries and the Economic Model of the TRIPS Agreement

The TRIPS Agreement and TRIPS-plus provisions are arguably rooted in the normative principle that strong IP rights drive technological growth and innovation as they offset the significant costs, time, and risks associated with introducing new technologies, such as breakthrough drugs, to the market.[173] When the technology is invented, this model also fundamentally assumes that market transactions are the most efficient means of accessing these innovations. Proponents of this approach acknowledge potential social costs, such as higher prices and reduced access, but

168 Paige E. Goodwin, *Right Idea, Wrong Result - Canada's Access to Medicines Regime Notes and Comments,* 34 Am. J. L. & Med. 567 (2008); Mark D. Penner & Prakash Narayanan, *Amendments to the Canadian Patent Act to Address Drug Access: Is Help on the Way?,* 60 Food & Drug L. J. 459 (2005).

169 For details regarding the supplementary protections, *see* Ellen T. Hoen, The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access to Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health 70–71, 74–75 (AMB Publishers, 2009).

170 *Id.*

171 Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, trade and medicines: past, present and future,* 27(1) Rev. Int'l Pol. Econ. 75, 81 (2020).

172 *Id.*

173 *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study,* 32 Mgmt. Sci. 173, 174 (1986); Scherer et al., Patents and the Corporation: A Report on Industrial Technology Under Changing Public Policy 130–35 (2nd ed.,1959); C.T. Taylor & Z.A. Silberston, The Economic Impact of The Patent System: A Study of The British Experience 201–07 (1973); Wesley M. Cohen et al., *Protecting their Intellectual Assets: Appropriability Conditions And Why U.S. Manufacturing Firms Patent (Or Not),* 17 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) at 9.

argue that if the benefits, including incentives for innovation and R&D investments, outweigh the costs, it represents an efficient outcome.[174] Essentially, a cost-and-benefit analytical justification. The hypothesis is that market transactions maximize wealth and efficiency.[175] Proponents of this economic analysis idealize the market order as the most effective means to promote social welfare and individual freedom because it is neutral.[176] In this paradigm, the patent system transforms knowledge goods into private property, with owners dictating not only the prices and availability of technologies but also who can access them.

The empirical validity of this normative underpinning remains inconclusive – it is not clear whether IP rights necessarily lead to innovation and socio-economic progress in every society, or whether such progress outweighs the social costs associated with the knowledge monopoly.[177] During the negotiations of the TRIPS Agreement, the advocates of the new regime persuaded developing countries to embrace the globalized IP regime as it would increase inflows of foreign direct investment (FDI) and technology transfers from advanced countries to poor nations. However, since the TRIPS Agreement came into force, there is no empirical evidence indicating a clear link between robust IPRs and the attraction of FDIs in poor countries.[178] It is questionable if foreign investors take into account the IPR regime of these countries when deciding whether to invest.[179]

As some commentators pointed out '[c]ountries with few innovative firms or small markets typically viewed the benefits of patents as limited, since small markets can do little to drive global R&D priorities, and local patents may do more to hurt the development of industry than stimulate invention in the absence of an industrial sector with inventive and innovative capabilities.'[180] For example, '[d]espite the existence of TRIPS-compliant laws on patents, trademarks, and industrial designs, it is virtually impossible to highlight benefits that have accrued to Guinea, Guinea-Bissau, Ghana, Mali, Mauritania, or Niger solely on the basis of their accession to TRIPS.'[181] Similarly, 'it is difficult to point out the benefits that [Central African Countries] have derived from changing their IPR laws and creating the institutions for the enforcement of IPRs.[182] Studies have indicated that drug prices have risen in Egypt since the implementation of TRIPS, whether this is merely

174 N. Mercuro & S. Medema, Economics and the Law: From Posner to Post-Modernism Chapter One (2nd ed., Princeton University Press, 2006).

175 Richard A. Posner, The Economics of Justice 60 (Cambridge: Harvard University Press, 1981).

176 *See* Melinda Cooper, Family Values (Zone Books, 2016); Nancy Fraser, Contradictions of Capitalism and Care, 100 New Left Rev. 99 (2016).

177 *See, e.g.,* Fritz Machiup, An Economic Review of the Patent System (1958) (study No 15 of the Sub-committee on Parents, Trademarks, and Copyrights of the Committee of the Judiciary, United States Senate, 85th Congress, Second Session).

178 For a contrary view, *see* R. Sherwood, *Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries,* 37(2) IDEA I (1997).

179 Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?,* 36 Duke L. J. 831 (1987).

180 Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, trade and medicines: past, present and future,* 27(1) Rev Int'l Pol. Econ. 75, 77 (2020).

181 Mgbeoji Ikechi, TRIPS and TRIPS Plus Impacts in Africa 192, 279 (2007).

182 *Id.* at 287.

coincidental, or a result of a direct cause-and-effect relationship remains unclear.[183]

The globalized IP regime has not also increased funding for research that impacts developing countries. For example, despite the rush to implement IPR laws across the African continent, there is minimal or no financial support for research into diseases that affect Africans. As highlighted by MSF (Medecins Sans Frontieres), diseases that disproportionately threaten the lives of tens of millions of people, primarily in Africa, represented less than 0.001% of the $60-70 billion spent annually on global medical research.[184] Mario Azevedo reported that '[e]ven though Africa accounts for 11–13% of the world population, its disease burden is 24% and Sub-Saharan Africa 'commands less than 1% of global health expenditure.'[185] Most of the treatments available in Africa today were developed during the colonial era and were intended for use by the white population or were created by the US Army to protect its soldiers. Many medicines used in Africa to treat tropical diseases have no connection to the establishment of modern patent laws.[186]

The reason for this situation is not far-fetched; the economic model of the patent system is based on the 'willingness to pay' principle.[187] Since rich nations and individuals are the ones more willing to pay for expensive technologies, they benefit more from the patent system and the associated market exclusive rights. For example, studies have shown that millions of people from low-income groups suffer and die from diseases for which medicines exist that could vastly improve and prolong their lives.[188] They 'suffer and die' because they are not able to afford the relevant drugs, and sometimes, it is because there are no cheaper generic versions in the market.

The system privileges a select group of individuals based on wealth and power, regardless of the adverse distributional consequences on low-income groups.[189] Needless to say, the worst hit are the vulnerable and poor people living in low-income countries. As Christopher May rightly pointed out, the pharmaceutical knowledge economy system 'privileges the rights of owners (predominantly domiciled in already developed countries) and downplays or marginalizes the social costs (and curtailed public benefits) widely experienced in the developing countries.'[190]

183 A.S. Saleh, *Impact of Globalization on Drug Industry: Possible Risks and Means to Overcome Them,* at 7th International Conference on The Impact of Globalization on Development and Healthcare Service in Islamic Countries (Mar. 23–27, 2002). *See also* Jonathan D. Quick, *Ensuring Access to Essential Medicines in the Developing Countries and Least Developed Countries-Framework for Action,* 73(4) Clinical Pharm. & Therapeutics 279–83 (Apr. 2003).

184 The Guardian Weekly, June 5, 2003. (Unsure what this source is)

185 Mario J. Azevedo, *The State of Health System(s) in Africa: Challenges and Opportunities,* in Historical Perspectives on the State of Health and Health Systems in Africa 1–73 (Volume II: The Modern Era, 2017).

186 The Guardian, *supra* note 184.

187 *See* Zachary Liscow, *Is Efficiency Biased?,* 85 U. Chi. L. Rev. 1649, 1658–59 (2018).

188 Graham Dutfield et al, Dutfield and Suthersanen on Global Intellectual Property Law 399 (2nd ed., Edward Elgar Publishing , 2020).

189 Missing footnote citation here.

190 May, *supra* note 19, at 17.

Since the system relies on market transactions for the production of and access to medicines, government interventions to support vulnerable citizens are devalued. It shields market transactions from state democratic regulation and operates under the assumption that the market is impartial. For instance, Milton Friedman, one of the prominent advocates of this market ideology, whose ideas were significant in shaping the economic policy of the US, the UK, and other countries around the world in the 1970s and 1980s, argues that government intervention in the economy often had unintentional consequences of limiting private property rights, competition, and free markets, essential for economic prosperity.[191] Thus, he emphasizes the fundamental right of businesses to own and control their assets, including IP, with limited government intervention, and the need to incentivize individuals and businesses to invest in creating new ideas and innovations.[192]

This ideology encases IP market transactions from democratic principles and prevents human rights advocates and social justice activists from scrutinizing the impacts of the IP system on impoverished groups and the Third World. It decenters the role of power dynamics in the IP norm-making process and facilitates the proliferation of bilateral treaties and international investment agreements that progressively elevate patent standards and other supplementary protections. It permits broad interpretations and constructions of patent policies that favour the interests of the dominant party and IP rights holders. For instance, the TRIPS Agreement grants private monopoly rights that are broad and specific, while the obligations of developed countries to aid technology transfer and public health are outlined in general and ambiguous terms, making it challenging to enforce.[193]

Jedediah Britton-Purdy et al pointed out that although the economy (for example, the pharmaceutical knowledge system) is fundamentally shaped by power dynamics that require legal and policy interventions to promote equity and fairness, the normative system diminishes such interventions by prioritizing efficiency over issues of distribution and equity.[194] It places a higher emphasis on fostering future innovations than on ensuring access to new and essential technologies. It theoretically divorces market power from politics, thereby obscuring fundamental realities.[195] As stated by Laura Murray, privileging proprietary rights and control is a political choice rather than a wealth-maximizing mechanism and such rights and control distort the real-life experiences of socially situated actors and perpetuate the status quo.[196]

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191 *Id.*

192 *See* J. Hearing of the Subcomm. on 'Intellectual Property and Judicial Administration of the H. Comm. on the Judiciary and the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary,' 103d Cong. 297-98 (1994) (statement of Gerald J. Mossinghoff, President, Pharmaceutical Research and Manufacturers of America).

193 Robert Hunter Wade, *What Strategies Are Viable for Developing Countries Today? The World Trade Organization and the Shrinking of Development Space,* 10(4) Rev. Int'l Pol. Econ. 624 (2003).

194 Jedediah Britton-Purdy et al., *Building a law-and-political-economy framework: Beyond the twentieth-century synthesis,* 129 Yale L. J. 1784, 1819 (2019).

195 *Id.*

196 Laura Murray et al., Putting Intellectual Property in its Place: Rights Discourses, Creative Labour and the Everyday (Oxford IP, 2014); Julie E. Cohen, *The Place of the User in Copyright Law,* 74 Fordham L. R. 347 (2005); Jessica Silbey, The Eureka Myth: Creators, Innovators and Every Day Intellectual Property (Stanford UP, 2014).

Furthermore, the pharmaceutical political economy undermines domestic policymaking by globalizing an economic model of commercialization of knowledge goods that is antithetical to domestic social justice reordering. The regime sets 'strong limits on a state's capacity to define territorial property rights in ways that enhance national welfare.'[197] Ruth Okediji argues that the TRIPs Agreement turns 'the traditional national/international paradigm upside down; it appears to contemplate a substitution of domestic processes that have produced a competitive balance in domestic setting with an international process that presumes that the domestic balance should be renegotiated in the light of obligations in TRIPs.'[198] Specifically, it conceptualizes governments' interventionist policies seeking to promote social welfare as having the potential to slow economic growth and cause high inflation.[199]

The TRIPS Agreement is based on norms that prioritize individual rights over collective benefits by treating knowledge as a rigid private property, and public interest initiatives as political matters.[200] Thus, Rochelle Dreyfuss characterized the TRIPS Agreement as a 'one-way ratchet' and suggested the integration of a bill of rights for users to address this issue.[201]

Additionally, the system discourages stakeholders from questioning the political and economic forces that leave TRIPS flexibilities ineffective and unchecked, the unequal influence of various stakeholders and institutions on patent lawmaking, and how national rules and policies have a negative extraterritorial impact and disproportionately allocate resources, and the greatest losers in these contestations are low-income countries.[202] The stark vaccine inequities witnessed during the COVID-19 pandemic are the most recent global reminder.

This situation arises because the market has been insulated from democratic restructuring, guided by the prevailing lopsided utilitarianism that prioritizes the interests of powerful IP owners and nations over issues related to resource distribution and access to knowledge.[203] The primary beneficiaries of this system are the powerful Western states and their multinational corporations (MNCs).[204] It safeguards foreign markets, even in low-income countries, for producers of knowledge goods, who

197 Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 75 (London: Earthscan Publications, 2002).

198 Ruth Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPs Agreement,* 17(2) Emory Int'l L. Rev. 915 (2003).

199 Milton Friedman, Milton Friedman on Economics: Selected Papers 135 (Chicago: University of Chicago Press, 2010); *See* William W. Fisher III, The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States 22 (unpublished manuscript), https://cyber.harvard.edu /people/tfisher/iphistory.pdf [https://perma.cc/YZL2-F8QR].

200 Christopher May & Susan K. Sell, Intellectual Property Rights: A Critical History 164 (Lynne Rienner Publishers, Inc., 2006).

201 Rochelle Dreyfuss Cooper, *TRIPS-Round II: Should Users Strike Back? Special Issue, Colloquium on Intellectual Property,* 71(1) Univ. Chi. L. Rev. 21–35 (2004).

202 *See* James Gibson, *Risk Aversion and Rights Accretion in Intellectual Property Law,* 116 Yale L. J. 882, 884 (2007).

203 *See* Britton-Purdy et al., *Building a law-and-political-economy framework: Beyond the twentieth-century synthesis,* 129 Yale L. J. 1784, 1820 (2019).

204 P. McCalman, *Reaping What You Sow: An Empirical Analysis of International Patent Harmonization,* 5 5 J. Int'l Econ. 161–86 (2001).

are typically industrialized nations and their MNCs. These goods are often offered at high prices, particularly concerning breakthrough pharmaceutical products and processes, like the ART, Insulin, and the COVID-19 vaccines.

Therefore, there is an imminent need for an 'epistemological reconstitution' of the patent norm-making process to establish a more balanced utilitarianism.[205] The existing uniform and market-oriented approach fails to distinguish between those who can afford patented products and those who cannot, and developed countries from developing countries.[206] It privileges a small group of affluent economic and political actors while neglecting the right to health and the pervasive global income disparities, especially in non-European countries. Ironically, the very IP protection that developed economies ignored during their early stages of development is what they argue in multilateral negotiations and treaties would spur economic development in developing countries.

d. The Three-Prong Approach to the Pharmaceuticals Norm-Making Process

The normative underpinnings of the pre-20th-century knowledge system and how it reconciled competing private and public interests provide a solid foundation for re-examining and de-idealizing the prevailing market-oriented regime of the pharmaceutical industry, which has failed to adequately consider public welfare in the dissemination of protected technologies. As discussed in earlier sections, patent rights in that historical era were conceptualized as special privileges and strategic instruments, not necessarily market commodities, allowing for substantial domestic policy discretion and limited recognition of pharmaceutical patent products.

The historical analysis showed that weak patent protection and the relatively free cross-pollination of ideas between then-developing (now industrialized) countries may have contributed to their positive socioeconomic and technological growth.[207] The significance of this analysis lies in presenting an operational system that pursues equitable and public interest-oriented objectives and highlighting the fact that the current conceptual framework has not always been the case.

IP is certainly not a magical solution that can instantly transform a dysfunctional economy plagued by political instability, inadequate infrastructure, and insufficient investments in R&D into an industrialized powerhouse. Nonetheless, IP, especially patent rights and trade secrets within the context of the pharmaceutical industry, does represent a pivotal component in the broader socio-economic puzzle of industrial development and facilitating access to cheaper equivalents of original drugs for developing countries, which, if effectively harnessed and complemented by other factors,

205 Anibal Quijano, *Coloniality and Modernity/Rationality,* 21 Cultural Stud. 168, 169, 176 (2007).

206 Knowledge is an example of a global public good. The concept was articulated in Joseph E. Stiglitz, *The Theory of International Public Goods and the Architecture of International Organizations,* Background Paper No. 7, Third Meeting, High Level Group on Development Strategy and Management of the Market Economy, UNUIWIDER (Helsinki, Finland July 8–10, 1995). *See* Joseph E. Stiglitz, Economics of The Public Sector 469–70 (3rd ed. New York: W. Norton, 2000).

207 E. Schiff, Industrialization Without National Patents-The Netherlands, 1869-1912, Switzerland, 1850-1907 (Princeton University Press, 1971); D. Brennerbeck, *Do as I say, Not as I Did,* 11 UCLA PAB Asian 84 (1999).

has the potential to foster sustainable development in developing countries in general and low-income countries, in particular.

Temporary adjustments and amendments to IP rules, which have dominated discussions about making the IP system work for all, may not provide the solution, or at least not the appropriate starting point. Debates and calls for reform should be focused on the conceptualization of the knowledge economy and the norm-making process, which could potentially touch on several factors. However, for this work, I have limited my analysis to three key factors: understanding the IP norm-making process, democratizing the process, and recognizing 'flexibility' as a vital IP issue.

The first step in this reconstitution process is appreciating how the IP norm-making process works and the power dynamics involved. There is a need to pay attention to the politics embedded in the enactment of existing IP rules and how the rules create endowments that shape economic relationships and influence public decisions, whether through political pressure, investment agreements or representation exercise.[208] Additionally, it entails understanding how the proprietary knowledge economy serves as a crucial bridge between political decision-making and economic structures, with both realms influencing each other.[209]

This understanding highlights how the historical structure and process of the international IP norms and regulations marginalized developing countries. For instance, when the Paris Convention for the Protection of Industrial Property (Paris Convention) and Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) were negotiated in the nineteenth century, at the beginning of the internationalization of IP rights, most developing countries were under colonial rule, and where not part of the negotiations. Therefore, as expected, these conventions paid little regard to non-Western ethos and traditions, such as the protection of indigenous knowledge and folklore.[210]

The TRIPs Agreement was also the product of a dysfunctional negotiation process. The TRIPS Agreement was the outcome of extensive and forceful bargaining tactics and negotiations to establish a robust global IP regime without substantial consideration of the socio-economic interests of low-income countries.[211] The goal was to ensure that the patent protection for drugs that were available in developed countries was also available in developing countries US corporations played a significant role in the negotiations. Susan Sell pointed out that the TRIPs Agreement is a case of twelve US

208 *See also* Jeremy K. Kessler & David E. Pozen, *The Search for an Egalitarian First Amendment,* 118 Colum. L. Rev. 1953 (2018) (asking if the First Amendment has egalitarian elements that could be recovered).

209 *See* Simon Deakin et al., *Legal Institutionalism: Capitalism and the Constitutive Role of Law,* 45 J. Comp. Econ. 188 (2017).

210 P. Kuruk, *Protecting Folklore Under Modern Intellectual Property Regimes: A Reappraisal of the Tensions Berween Individual and Communal Rights in Africa and the United States,* 46 Am. U. L. R. 769 (1999); D. Downes, How Intellectual Property Could be a Tool to Protect Traditional Knowledge, 25 Columbia J. Env't L. 253 (2000); P. Kuruk, *Protecting Folklore Under Intellectual Property Regimes: A Reappraisal of the Tensions Between Individual and Communal Rights in Africa and the United States,* 46 Am. ULR 769 (1999).

211 *Id.* at 113; Peter K. Yu, *TRIPs and Its Discontents,* 10 Marq. Intell. Prop. L. Rev. 369, 379–83 (2006).

corporations making public law for the world.[212] 'Drug companies and their representatives were among the leading advocates of TRIPS, and more generally, of the integration of IP into the trade regime.'[213]

The negotiating history of the TRIPS Agreement shows that member states were divided over whether certain industries, like the pharmaceutical industry, should be exempted from patent protection to allow for flexible domestic regulation.[214] For instance, developing countries, such as India, Nigeria, Mexico, Uruguay, Tanzania, and Argentina, proposed that pharmaceutical products should be excluded or left to the discretion of States.[215] Most developing countries, before the Uruguay Round of negotiations, did not permit patent protection for pharmaceuticals.[216] The few that allowed only protected the processes, not the actual chemical products.[217] On the other hand, the US, European communities and their allies proposed to include 'all fields of technology' in the TRIPS Agreement.[218] The latter position prevailed in the end, and the Agreement was extended to apply to every sector in line with the wishes of wealthy nations.

Furthermore, the IP norm-making process has been established and sustained by imbalanced power dynamics. At the time of making the respective positivist IP laws, the benefits of IP rights are perceived and expressed by well-defined interest groups, such as industrialized nations and brand-name companies. On the other hand, the social costs, including economic, social, political, and moral costs, are diffused.[219] For instance, brand-name pharmaceutical companies are more willing and ready to invest in obtaining favourable laws - a behaviour that has been described as a 'rent-seeking mechanism.'[220] In contrast, users of IP-protected works, generic companies, and low-income countries, are often more dispersed and may not immediately realize how changes in patent law will

212 Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights 1, 96 (Cambridge University Press, 2003).

213 Peter Drahos, *Global property rights in information: The story of TRIPS at the GATT,* 13(1) Prometheus 6–19 (1995).

214 *See* Terence Stewart, The GATT Uruguay Round a Negotiating History (1986–1994) 474 (Kluwer Law International, 1993).

215 *See* Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights, Communication from India, ¶¶ 19–20, GATT Doc. MTN.GNG/NG11/W/37 (July 10, 1989) [hereinafter Communication from India 1989]; see also Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, arts. 3–4, GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990).

216 WCO Indonesia, The TRIPS Agreement and its Impact on Pharmaceuticals 11 (May 2–4, 2000), https://iris.who.int/handle/10665/206475.

217 *Id.* at 7.

218 *See* Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, art. 2(1)(a), GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) [hereinafter Communication from the United States]; see also Suggestion by the United States for Achieving the Negotiating Objective, Revision, ¶ 3, GATT Doc. MTN.GNG/NG11/W/14/Rev.1 (Oct. 17, 1988); *see* Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Communication from the European Communities, art. 10(1), GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990).

219 Yochai Benkler, Through the Looking Glass: Alice and the Constitutional Foundations of the Public Domain, 66 L. & Contemp. Probs. 173, 196 (2003).

220 *See* Jessica D. Litman, *Copyright, Compromise, and Legislative History,* 72 Cornell L. Rev. 857 (1987); Jessica Litman, Copyright Legislation and Technological Change, 68 Or. L. Rev. 275, 337–38 (1989); see also 17 U.S.C. §§ 505-506 (2000).

impact them. For instance, when the TRIPS Agreement was signed, many developing countries did not appreciate the impact the Agreement may have on public health until the HIV/AIDs crisis.

These power dynamics have had far-reaching consequences for both economic structures and political processes governing patent rules creation and enforcement. The lobbying prowess and strategies of IP-driven industries, like multinational pharmaceutical firms, as a well-organized and distinct group have resulted in a century of advantageous IP legislation for them that has come at the expense of the public domain.[221] The prospects of marginal returns are unlikely to be sufficient to incentivize generics to match the brand-name companies' influence in law-making.

Since the mid-2000s, the US and like-minded developed countries have also deployed bilateral and regional negotiations on trade and investment to continue to expand IP protection under the guise of ensuring 'competitive liberalization' and 'free trade.'[222] Examples of these agreements include the Dominican Republic-Central America Free Trade Agreement, the Korea–United States Free Trade Agreement, and the Trans-Pacific Partnership Agreement – which became the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) following the United States' withdrawal from the regional pact. These negotiations persuade (or implicitly compel) developing countries to adopt higher standards of IP protection that exceed those outlined in the TRIPS Agreement.

These TRIPS-plus treaties require developing countries to ratify new WIPO treaties containing TRIPS-plus measures; extend protection terms; reduce the transition period allowed by TRIPS; and eliminate or narrow permitted exceptions.[223] Both the United States and European countries employ these regional and bilateral strategies, but the United States has been notably more assertive.[224] For instance, although the bilateral use of sanctions to enforce WTO-based law is illegal, the US Trade Representative (USTR) has continued to use bilateral pressure to enforce IPRs.[225] At the root of these treaties is the lack of sufficient attention to the interests of low-income countries in the norm-making process.

Today, investment agreements between multinational companies and developing countries are being used to expand IP rights and establish new international IP norms. IIAs are usually the product of trade-offs between states and foreign private investors. The tradeoffs make countries provide IP outcomes (i.e., expansion of IP protection and enforcement) that would have been impossible under

221 Timothy Wu, *Copyright's Communications Policy,* 103 Mich. L. Rev. 278, 291–92 (2004).

222 Letter from Robert Zoellick to David Walker, Comptroller of the United States Patent Office (Dec. 2003), http://www.ustr.gov/releases/2003/12/2003□12□03□letter□gao.pdf.

223 *See generally* Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area (2000).

224 Graham Dutfield & Uma Suthersanen, Global Intellectual Property Law 42 (Edward Elgar Publishing Limited, 2020).

225 Gautam Sen, *The United States and the GATT/WTO System, in* U.S. Hegemony and International Organizations 128 (R. Foot, S.N. MacFarlane, and M. Mastanduno, eds., Oxford University Press, 2003); Daya Shanker, *Legitimacy and the TRIPs Agreement,* 6(1) J. World Intell. Prop. 155–189, 186 (2003).

an 'IP-only' international regime. For instance, in exchange for greater market access to goods and services, the state party would be required to provide strong IP protection.[226] The net implication of this arrangement is that the IIAs constrain the dynamic development of domestic IP rules.

IIAs allow IP owners to sue foreign governments without the backing of their home governments. Ruth Okediji notes, that the intersection of IP and investment is 'not only a new frontier in investment arbitration but more importantly, uncharted territory in the increasingly complex and contested landscape of international intellectual property obligations'.[227] To attract foreign investments, states are left with little choice but to enter into IIAs to protect the investments of foreign investors against state interference.[228] Most IIAs include IP assets as one of the protected investments.[229] This differs from the protection offered by the traditional international IP system. Instead of expanding specific aspects of IP law, 'investment protection offers broad standards that restrict discriminatory, expropriation, or otherwise unfair or arbitrary legislative, administrative, or judicial acts of the host state vis-à-vis a protected investment asset.'[230] The net implication of IIAs is that they provide additional layers of protection for IP rights.

Furthermore, these IIAs seek to avoid possible arbitrariness of judicial institutions in the host state, the so-called 'judicial activism' of domestic courts. They allow private corporations to challenge regional and domestic laws that limit the enjoyment of their IP assets before arbitral tribunals. IIAs usually provide for the resolution of disputes within an international arbitration forum – commonly referred to as the investor-state dispute settlement (ISDS), which is distinct from the state-to-state dispute settlement under the WTO and FTAs. As US Senator Elizabeth Warren observed, ISDS gives corporations 'the right to challenge laws they don't like – not in court, but in front of industry-friendly arbitration panels that sit outside any court system'.[231]

226 *See generally* Henning Grosse Ruse-Khan et al., *Statement of Principles for Intellectual Property Provisions in Bilateral and Regional Agreements,* 36(4) European Intell. Prop. Rev. 207 (2014) [hereafter Grosse Ruse-Khan and others, 'Statement of Principles'].

227 Ruth L Okediji, *Is Intellectual Property 'Investment?' Eli Lilly v. Canada and the International Intellectual Property System,* 35 Univ. Penn. J. Int'l L. 1121, 1122 (2014).

228 *See* Carlos M. Correa & Jorge Viñuales, *Intellectual Property Rights as Protected Investments: How Open are the Gates?,* 19(1) J. Int'l Econ. L. 91 (2016); Henning Grosse Ruse-Khan, *Effects of Combined Hedging: Overlapping and Accumulating Protection for Intellectual Property Assets on a Global Scale, in* Global Intellectual Property Protection and New Constitutionalism 39 (Jonathan Griffiths and Tuomas Mylly eds., Oxford University Press, 2021).

229 *See* Tuomas Mylly, *Human Rights and Intellectual Property in Investor to State Dispute Settlement, in* Research Handbook on Intellectual Property and Investment Law 406 (Christophe Geiger ed., Edward Elgar Publishing, 2020).

230 Henning Grosse Ruse-Khan, *Effects of Combined Hedging: Overlapping and Accumulating Protection for Intellectual Property Assets on a Global Scale, in* Global Intellectual Property Protection and New Constitutionalism 39 (Jonathan Griffiths & Tuomas Mylly eds., Oxford University Press, 2021).

231 Deirdre Fulton, *As Countries Line up to Sign Toxic Deal, Warren Leads Call to Reject TPP,* Common Dreams (Feb. 3, 2016), http://www.commondreams.org/news/2016/02/03/countries-line-sign-toxic-deal-warren-leads-call-reject-tpp.

Peter Ku rightly lamented, 'ISDS could take away the many limitations, flexibilities, and safeguards that have been carefully built into the TRIPS Agreement and the larger international intellectual property system.'[232] Others have noted that ISDS cases could also undermine a country's sovereign ability to protect its citizens and regulate harmful activities to avoid costly arbitrations and ISDS processes.[233] Since international investment tribunals and their arbitrators usually have limited experience with IP systems, they are unable to understand the 'human rights issues that operate in the background in IP limitations and exceptions and exclusions from protection.'[234] This produces interpretations that favour exclusive rights and property interests of private corporations.

Furthermore, there is the concept of 'full protection and security' (FPS) that requires host states to adopt steps and measures to protect the investor's assets (including IP assets) against harm from private parties.[235] Of course, justiciable actions under the IIAs are limited to activities of host states, not private rights in private law relations unless they are 're-packaged' to implicate state obligations under the IIAs.[236]

An examination of the norm-making process of IP rights cannot be comprehensively exhausted without appreciating the colonial imposition of IP laws and institutions on developing countries.[237] For instance, the IP laws and institutions in Africa are in many instances a verbatim reproduction of the IP laws of their former European colonial masters without regard to the continent's cultural, economic and practical experiences.[238] Until 1962, patent law in French Africa was governed by French laws. Administratively, the French National Patent Rights Institute (INPI) was the National Authority for members of the African French Union.[239] Also, the Philippines adopted the Spanish patent law while it was a Spanish Colony, but when the US took over the running of the Philippines in December 1898, the US patent law applied in the Philippines.[240]

232 *See* Peter K. Yu, *The Second Transformation of the International Intellectual Property Regime, in* Global Intellectual Property Protection and New Constitutionalism: Hedging Exclusive Rights 9 (Jonathan Griffiths & Tuomas Mylly, eds., Oxford University Press, 2021).

233 Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS,* 49 Loy. U. Chi. L. J. 479, 505 (2017).

234 Tuomas Mylly & Jonathan Griffiths, *The Transformation of Global Intellectual Property Protection, in* Global Intellectual Property Protection and New Constitutionalism 1 (Jonathan Griffiths & Tuomas Mylly eds., Oxford University Press, 2021); *see also* Tuomas Mylly, *Human Rights and Intellectual Property in Investor to State Dispute Settlement, in* Research Handbook on Intellectual Property and Investment Law 406 (Christophe Geiger ed., Edward Elgar Publishing 2020).

235 *See generally* Christoph Schreuer, *Full Protection and Security,* 1(2) J. Int'l Disp. Settlement 353 (2010).

236 Monique Sasson, Substantive Law in Investment Treaty Arbitration: The Unsettled Relationship between International and Municipal Law 66 (2nd ed., Wolters Kluwer, 2010).

237 Ruse-Khan, *supra* note 230, at 41.

238 A. Endeshaw, *The Paradox of Intellectual Property Law-Making in the new Millennium: Universal Templates as Terms of Surrender for non-industrial Nations; Piracy as an Offshoot,* 10 Cardozo. Int'l Compar. L. 47–77 (2002).

239 Ikechi Mgbeoji, TRIPS and TRIPS Plus Impacts in Africa 266 (2007).

240 Otherwise known as the Union Coloniale Framaise, the group is composed of sixteen French-speaking African colonies outside French North Africa. These are Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Coted'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo. *See* Ikechi Mgbeoji, TRIPS and TRIPS Plus Impacts in Africa 266 (2007).

These colonial legacies manifest themselves even in the 21st century through political and economic pressure by Western nations on developing countries. Despite the uncertainties around the benefits of strong IP regimes in the economies of developing countries, powerful Western states still exert pressure on the governments of these countries to embrace such IP regimes.[241] This approach aims to prevent developing countries from free-riding on technological breakthroughs made by Western states.

Unlike in earlier centuries, the industrial know-how and manufacturing abilities of industrialized nations are now within the reach of developing countries.[242] The emergence of the so-called 'information economy' has made it ideologically imperative for industrialized nations and their big pharmaceutical companies to establish a system where their manufacturing advantage is preserved through global protection of the knowledge embedded in innovative products regardless of how it impacts public health and needs.[243]

ii. Democratizing the Process

This second step involves democratizing the IP norm-making process, addressing power asymmetries and hierarchies within the patent norm-making process, and the necessity to grant substantive decision-making responsibilities to low-income countries. It goes beyond mere representation of developing nations at the table; rather, it ensures that their positions and interests are duly considered in the final draft. For example, there are valid concerns regarding the ongoing negotiations and versions of the proposed Pandemic Treaty, which aim to rectify the failures in the distribution of COVID-19 vaccines. Despite being represented, it is observed that the wishes of low-income countries are not fully reflected in these negotiations. Four international human rights groups: Amnesty International, the International Commission of Jurists, the Global Initiative for Economic, Social and Cultural Rights, and Human Rights Watch note as follows: 'The drafting process has repeatedly failed to ensure effective and meaningful participation by all stakeholders, especially those from marginalized and criminalized communities. In early 2022, the Civil Society Alliance for Human Rights in the Pandemic Treaty drew attention to the need to ensure full participation in the drafting process. The negotiating body disregarded these calls. Instead, the draft reflects a process disproportionately guided by corporate demands and the policy positions of high-income governments seeking to protect the power of private actors in health including the pharmaceutical industry.'[244]

241 *Id.*

242 Ruth Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System,* 7 Sing. Int'l & Compar. L. 315 (2003).

243 Christopher May, *Cosmopolitan Legalism Meets 'Thin Community': Problems in the Global Governance of Intellectual Property,* 39(3) Gov. & Opposition 393–422 (2004).

244 K. Maskus, Intellectual Property Rights in the Global Economy (Institute for Int'l Economics, 2000); G. Evans, A Preliminary Excursion into TRIPS and Non-Violation Complaints, 3 World Intell. Prop. 1 (2000); S. Cho, *GATT Non-Violation Issues in the WTO Framework: Are they the Achilles Heel of the Dispute Settlement Process?,* 39 Harv. Int'l L. J. 311 (1998).

Substantive representation also requires identifying suitable forums for patent rulemaking and empowering social and public interest coalitions that advocate for the interests of vulnerable populations. The perception in many low-income countries is that the patent system serves as a facade for imposing import controls and perpetuating neocolonialism due to the political pressure and forceful negotiations involved in the IP norm-making processes and where the dominant players have their way at the end of the day.[245] Laurence Helfer explains how dominant IP stakeholders shift international IP negotiations and rulemaking to venues that support their interests, describing the successive ways in which strong IP norms and counter-norms are produced as a strategic process of 'regime shifting.'[246] Civil societies and IP users are more attracted to venues like the United Nations (UN) such as the WIPO and World Health Organization (WHO) that engage with human rights issues and are interested in developing exceptions and limitations of IP protection.[247] On the other hand, IP owners and multinationals are more interested in international rulemaking venues and processes like the WTO and investment tribunals that allow for the creation of overlapping IP protection and TRIPS-Plus treaties. For instance, the recent TRIPS waiver negotiations were conducted under the WTO regime, which is why, arguably though, the eventual Ministerial Decision did not reflect the wishes of the waiver supporters.

On June 17, 2022, the Ministers waived the obligation set out in Article 31(f) of the TRIPS Agreement, allowing developing countries to export COVID-19 vaccines and related ingredients that were produced under compulsory licenses or government use authorizations to other developing countries.[248] Also, the waiver amended Article 31bis to allow eligible members to re-export COVID-19 vaccines to other eligible members for humanitarian and not-for-profit purposes, but only in 'exceptional circumstances.' Additionally, the notification requirements under Article 31bis were slightly revised, enabling the notifications to be submitted as soon as possible after the information becomes available instead of immediately.

However, the waiver did not include COVID-19 diagnostics and therapeutics and was limited 'to the extent necessary to address the COVID-19 pandemic.'[249] These provisions were inserted to assuage the concerns of pharmaceutical companies and vaccine developers that mRNA technology may later be used for other diseases or non-COVID-19 products, highlighting the fact that it is the interest of for-profit companies that are paramount in these negotiations.[250]

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245 Human Rights Watch, *Draft 'Pandemic Treaty' Fails to Protect Rights,* HRW (Nov. 7, 2023) https://www.hrw.org/news/2023/11/07/draft-pandemic-treaty-fails-protect-rights.

246 Keith Maskus & Jerome Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods,* 7(2) J. Int'l Econ. L. 295 (2004).

247 *See* Laurence R. Helfer, *Regime Shifting in the International Intellectual Property System,* 7(1) Perspectives on Pol. 39 (2009).

248 *See* Laurence R. Helfer & Graeme W. Austin, Human Rights and Intellectual Property Mapping the Global Interface (Cambridge University Press, 2011).

249 Carlos M. Correa & Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?,* South Centre (Nov. 8, 2022), https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf.

250 *See generally* WTO Document WT/MIN(01)/DEC/2, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

Furthermore, the usage of the phrase 'COVID-19 pandemic' instead of just 'COVID-19' appears to be deliberate, implying that the waiver may expire if the disease ceases to be classified as a pandemic, even though the waiver is set to last for five years.[251] In December 2022, the negotiations were essentially over as the WTO members indefinitely extended discussions on whether to expand the waiver to COVID-19 diagnostics and therapeutics.[252]

Thus, there is a need to de-idealize forums that serve as convenient platforms to expand IP rights without adequate and substantive regard for and accommodation of the vulnerable voices of developing nations, and one such forum is the WTO. Christopher May similarly notes, 'the global governance of IPRs in the WTO (at least for the developing countries) is the real problem, foregrounding as it does the 'trade relatedness' of IPRs.'[253]

Furthermore, IP policies should be negotiated independently, not as a part of a package trade or investment deal. Conflating different international regimes, especially those that further private and commercial interests, has the potential to decentralize the voices and diversity of countries and distract policymakers and negotiators from balancing social welfare costs and gains and the domestic socio-economic conditions to protect free trade and foreign investments.[254]

Although realizing this goal would be challenging – as the pharmaceutical patent and knowledge system is embedded in power dynamics and patterns of subordination that dominant stakeholders may be motivated to preserve – it offers the most promising route for understanding and reshaping modern IP structures.[255] While strong IP rights may generally benefit countries with robust and thriving technological industries, they may not be suitable for countries that are net importers of technologies.[256] Indeed, many industrialized nations did not provide extensive IP rights protection, particularly for foreign technologies, during the early stages of their economic development, which allowed for reverse engineering and domestic technological advancement.

iii. Centring 'Flexibility' as a Vital IP Policy Issue

The third and perhaps more profound step is relinking the idea of 'domestic flexibility' and IP rights as it was during the early stages of the development of the Western patent system. The economic

251 *See* Anna Fisher-Pinkert & Sarah Fortune, *We're better off with mRNA vaccines,* Harvard T.H. Chan School of Public Health, https://www.hsph.harvard.edu/news/multimedia-article/were-better-off-with-mrna-vaccines/.

252 Carlos M. Correa & Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?,* South Centre (Nov. 8, 2022), https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf.

253 Lisa Forman, *From the Universal Declaration of Human Rights to a Pandemic Treaty: Will a Right to Medicines Forever be 'Under Construction'?,* 15(3) J. Hum. Rts. Prac. 715–726 (2023).

254 May, *supra* note 19, at 19.

255 Peter K. Yu, *The Non-Multilateral Approach to International Intellectual Property Normsetting, in* International Intellectual Property: A Handbook of Contemporary Research 112 (Daniel J Gervais ed., Edward Elgar Publishing, 2015).

256 Carys J. Craig, *Critical Copyright Law & the Politics of 'IP,' in* Research Handbook on Critical Legal Theory 301 (Emilios Christodoulidis et al. eds., Edward Elgar Publishing, 2019).

and cultural imperatives of many nations are different and stronger IP regimes only make sense once a certain level of technological capacity has been achieved. Non-industrialized countries (non-ICs) should be given more domestic policy space to craft their IP policies to suit their level of development. As Assafa Endeshaw rightly observes, 'the extant literature on the nature, forms, and impact of IP does not distinguish between the roles of non-ICs and ICs in IP lawmaking. It tends to jumble them together as if the state of economic and technological development of nations matters little to the forms and scope of the IP law they adopt.'[257] Thus, the diversity of nations should be central to IP policy by allowing for domestic legislative flexibility.

During the early 19th century, as explained in part 1 of this article, domestic policymakers had significant freedom to shape patent policies, which led to divergent laws across nations. The US, Germany, and France, for example, granted patents for different terms, while others like the Netherlands had varying initial terms based on the invention's nature. Countries like Switzerland, the Netherlands, and Japan refrained from granting patents for a considerable time, and the US didn't recognize foreign technologies for over six decades. Italy engaged in 'knock-off' productions until 1978, without facing immediate foreign sanctions. This liberty also extended to the recognition of pharmaceutical products and processes.

During this era, generic drug companies in developing countries could copy patented medicines and compete globally. This policy flexibility allowed indigenous firms to absorb innovation and knowledge from abroad and industrialize. For example, by the 1990s, Indian generic manufacturers offered some of the lowest prices worldwide.

This legislative liberty was undermined by the TRIPS Agreement. Charles McManis states that 'the field of international intellectual property law underwent a tectonic shift with the promulgation of the [TRIPS Agreement].'[258] It transformed the international patent system,[259] by transferring the pharmaceutical patent norm-setting from the domestic domain to the international level as well as elevating the significance of trade law in the patent system.[260] As other commentators note, '[t]he TRIPS Agreement represented a sea change in the international regulation of [intellectual property rights]'.[261]

The outcomes are now entry barriers for generic companies and limited generic versions of medicines/vaccines as we witnessed during the COVID-19 pandemic. The rationale behind 'domestic flexibility' is based on the fact that there is a need for the recognition of the disparities

257 R. Sherwood, *The TRIPS Agreement: Implications for Developing Countries,* 37 IDEA 491 (1997).

258 Assafa Endeshaw, *The Paradox of Intellectual Property Law-Making in the new Millennium: Universal Templates as Terms of Surrender for non-industrial Nations; Piracy as an Offshoot,* 10 Cardozo. Int'l & Compar. L. 47–77 (2002).

259 Charles R. McManis, *Teaching Current Trends and Future Developments in Intellectual Property,* 52 St. Louis Univ. L. J. 855, 856 (2008).

260 Peter K. Yu, *The Second Transformation of the International Intellectual Property Regime,* in Global Intellectual Property Protection And New Constitutionalism: Hedging Exclusive Rights 1 (Jonathan Griffiths & Tuomas Mylly eds., Oxford University Press, 2021).

261 James Gathii & Cynthia Ho, *Regime shifting of IP law making and enforcement from the WTO to the international investment regime,* 18(2) Minn. J. L. Sci. & Tech. 429, 444 (2017).

in technological developments between industrialized nations and low-income countries in the IP norm-making process. While industrialized nations are typically net exporters of technologies with a robust economy that can support expensive drugs, the opposite is often true for low-income countries. Low-income countries theoretically require sufficient policy space to manage knowledge goods to promote domestic industrialization and public health. Such policy freedom would theoretically facilitate the cross-pollination of ideas and regional technology/health security and promote local industrialization.

The IP experience of some East Asian countries during earlier stages of their development is quite instructive. They adopted weak IP systems, which freed up foreign technologies for domestic consumption and industrialization. Nagesh Kumar notes, 'the East Asian countries, viz., Japan, Korea and Taiwan have absorbed a substantial amount[s] of technological learning under weak IPR protection regime[s] during the early phases [of economic development]. These patent regimes facilitated the absorption of innovation and knowledge generated abroad by their indigenous firms. They have also encouraged minor adaptations and incremental innovations on the foreign inventions by domestic enterprises.'[262]

Britain and the US adopted the same strategy when they were 'developing countries.' Commenting on the early IP policies of Britain and the US, Dru Brenner-Beck states that 'former pirate activities [of these countries] strongly contributed to the development of the infrastructure and technical capacity necessary to ensure that the touted advantages of intellectual property protection actually materialize.'[263]

It is only fair that the same advantage be extended to low-income countries (beyond the least developed countries) to further their industrialization efforts. As Ha-Joon Chang rightly states, 'It seems unfair to ask modern-day developing countries to behave to a standard that was not even remotely observed when the now-advanced countries were at the similar, or even more advanced, stages of development.'[264] This approach ensures that the social welfare costs of protecting essential knowledge goods do not outweigh the social welfare benefits and empowers less affluent nations to decolonize their knowledge economy by providing IP protection for only products and processes that genuinely warrant protection given their local context and for the requisite duration. For instance, a flexible system based on product-specific terms may offer a more balanced approach to the patenting of pharmaceutical products and processes.[265] A flexible patent term would take into account different patented products and processes. As F.M. Scherer notes, a good patent policy 'would tailor the life of each patent to the economic characteristics of its underlying invention through a flexible system of compulsory licensing, under which the patent recipient

262 Frederick M. Abbott et al., International Intellectual Property in an Integrated World Economy 4 (4th ed., Wolters Kluwer Law & Business, 2019).

263 *See* Nagesh Kumar, *Intellectual Property Rights, Technology and Economic Development,* 38(3) Econ. & Pol. Wk. 209–25, 216 (2003), http://www.epw.org.in/show Articles.php?root=2003&leat=01&filename= 53 91&filetype=pdf.

264 Dru Brenner-Beck, *Do as I Say, Not As I Did,* UCLA Pacific Basin L. J. 84, 115 (1992).

265 Ha-Joon Chang, *Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues,* 2(2) J. Hum. Dev. 287, 293 (2001).

bears the burden of showing why his patent should not expire or be licensed at modest royalties to all applicants three or five years after its issue.'[266]

This flexible patent term would provide domestic policymakers more leeway to determine the length of a drug patent based on relevant factors such as utility, sunk costs, and social costs, thereby preventing the creation of unnecessary monopolies, especially in the Global South, where generics/researchers need faster access to these technologies to produce lower cost products.

The inadequacy of a fixed patent term becomes evident when considering secondary patenting of drugs, where a pharmaceutical company makes only an improvement or repurposes an existing drug without incurring significant R&D costs. Under such circumstances, the company is also entitled to a fixed twenty-year term even though it could recoup its R&D costs and make profits within five years. The non-discriminatory patent term structure of the TRIPS Agreement has the potential to generate unnecessary deadweight losses with detrimental effects on access to medicines.

Centring 'flexibility' in the IP policy praxis would also allow domestic players to prioritize international human rights commitments (for example, the right to health and medicines) over economic policies and corporate profits. For instance, authoritative legal and political interpretations of the right to health under international and regional law treaties have identified access to medicines as a critical element of this right, but the rigidness of the IP system may limit the ability of states to protect the right.[267] Lisa Forman notes, '…multiple general comments of the UN Committee on Economic, Social and Cultural Rights (CESCR or the Committee) have definitively read access to medicines into the right to health and other ICESCR rights. The primary locus for reading medicines into the right to health is found in General Comment 14 issued by CESCR in 2000, which offered a foundational definition of the right to health and of the scope and nature of the entitlement and duties it creates. The CESCR indicates that the right to health places concrete obligations on governments to assure access to accessible, affordable, and good quality health care, with essential medicines identified as part of a state's most essential and core obligations under this right.'[268]

Peter Yu notes, '(t)his principle of human rights primacy helps address the continued tensions and conflicts between the protection of human rights and the non–human rights aspects of intellectual property rights.'[269] For example, Resolution 2000/7 of the United Nations Sub-Commission on the Promotion and Protection of Human Rights reminded governments 'of the primacy of human rights obligations over economic policies and agreements.'[270]

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266 F.M. Scherer, *Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation,* 62 Am. Econ. Rev. 422, 422–23 (1972).

267 *Id.* at 427.

268 Lisa Forman, Basema Al-Alami, & Kaitlin Fajberm, *An Inquiry into State Agreement and Practice on the International Law Status of the Human Right to Medicines,* 24(2) Health & Hum. Rts. 125 (2022).

269 Lisa Forman, *From the Universal Declaration of Human Rights to a Pandemic Treaty: Will a Right to Medicines Forever be 'Under Construction'?,* 15(3) J. Hum. Rts. Prac. 715–26 (2023).

270 Yu, *supra* note 259, at 3.

In the meantime, low-income countries need to critically reflect on how to effectively utilize the international patent system and TRIPS flexibilities to serve their national economic interests and technological needs. Currently, it appears that IP laws in many developing countries primarily exist to demonstrate compliance with international obligations to satisfy the prying eyes of powerful Western states. Instead of being implemented to serve local interests.[271] For instance, numerous African countries have thriving agri-based industries, including coffee, cotton, cocoa, and textile sectors producing traditional attire, as well as entertainment industries. It would be beneficial for such nations to devise and implement IPRs that specifically cater to these niche markets and domestic strengths. Thus, emphasizing IPRs such as copyrights, trademarks, and geographical indications would be valuable in this context.

This can be achieved by improving the institutional and administrative framework of these rights. For instance, IP offices and institutions in low-income countries should be properly staffed with development experts and other qualified officials and integrated with other relevant government departments or agencies. The experts would ordinarily understand the importance of balancing between individual and collective interests. Existing IP rules should be interpreted and implemented in a way that furthers the IP bargain, and not just the rent-seeking activities of the traditionally dominant players.

Overall, the analysis in this section exposes the enduring legacies of colonialism, the complex political and economic dynamics shaping intellectual property norms, and the varying interests in the IP norm-making process. It further shows the structural flaws within the pharmaceutical knowledge economy; a system that inherently neglects the local realities of developing nations and underscores how the market approach is inequitable in financing a public good; the system fails to differentiate between high-income and low-income countries. Additionally, the section highlights the power dynamics of global IP norm-making processes, which disproportionately favour a select group of affluent actors while disregarding the right to health and the well-being of impoverished populations.

While it remains a subject of intense debate whether low-income countries would fare better without the existing IP system or an improved IP system as discussed, considering other intersecting local challenges like corruption, inadequate infrastructure, and limited social resources, historical conceptions of the patent system and their impact on the development of nations highlights the need to reexamine the prevailing market-oriented knowledge regime, which has failed to adequately consider public welfare in the dissemination of protected technologies. To the extent that patents and other associated rights restrict competition and limit generics from entering the market in due time for the benefit of low-income countries, they are likely to have the effect of keeping prices artificially high, limiting generic competition, and undermining domestic innovation, which will make it more difficult for countries to respond speedily to health crises. The current system creates

271 UNHCR, *Intellectual Property Rights and Human Rights: Sub-Commission on Human Rights Resolution 2000/7* (Aug. 17, 2000) E/CN.4/Sub.2/RES/2000/7, ¶ 3.

a situation where drugs may exist but cannot be widely accessed because they are either expensive or not sufficiently available in the market due to the activities of big market players.[272]

Moreover, when low-income nations allocate their limited resources towards expensive patented medicines for one disease, fewer resources are available in healthcare budgets overall for other pressing development needs. If patents (including the other supplementary protections like trade secrets, data exclusivities, and patent linkages) are meant to serve the public welfare, then the patent bargain should arguably be structured in a way that encourages the affordability and accessibility of essential medications regardless of location. A good starting point is to consider the historical idea of domestic flexibility within the IP policy regime. Thus, the patent regime should aim not just for efficiency but also fairness and equity.

IV. Conclusion

The conceptualization of the patent system has undergone various stages of transformation, particularly in balancing private and public interests. As discussed in the previous sections of this article, the early philosophical underpinnings of the patent system allowed for a fruitful international exchange of ideas, and countries showed reluctance to grant patents to pharmaceutical products. The knowledge system was flexible, and countries adopted different policies that suited their level of development. This contributed to the industrialization of now-developed nations. When non-Western nations arrived on the global scene after gaining independence from formal colonialist structures, they also enjoyed the liberty that this system provided. They structured their pharmaceutical policies in a way that furthered their local and technological interests, leading to the production of cheap generic versions of drugs in countries like India.

However, the enactment of the TRIPS Agreement shifted the norm-making process from the domestic to the international level and notably elevated private rights above public interests. Despite the presence of exceptions within the Agreement, their effectiveness has been limited due to political pressures, complexities, and the continued expansion of private rights in various forums. The inequities in drug and vaccine access experienced during recent public health crises like the HIV/AIDS and COVID-19 pandemics have highlighted the stark imbalance in the production and distribution of patented technologies, with life-saving vaccines being priced exorbitantly and inaccessible in low-income settings. This new regime, bolstered by the TRIPS Agreement, contrasts with the early stages of patent regime development, during which IP rights were viewed as tools to advance public objectives, and in cases where these rights failed to meet such standards, they were revoked in some countries.

This article argues for an epistemological reconstitution of the IP norm-making process by outlining a non-exhaustive three-step approach: an understanding of the political and economic dynamics involved in the global IP norm-making processes, democratizing the IP norm-making processes, and centring the norm of 'domestic flexibility' in this exercise. This integrated approach aims to provide

272 B. Naomi, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century,* 34 Geo. Wash. Int'l L. Rev. 191–222 (2002).

policymakers in low-income communities the liberty to structure their patent system to suit their level of development and public health needs, which involves encouraging generic competition,[273] and reimagining the law to embrace multiculturism and social welfare.[274]

Policymakers in low-income countries should be empowered to address the distributional implications of patent rights and accommodate non-traditional perspectives on knowledge creation, ownership, and management.[275] Primary patents may not entirely be the problem in this context, but secondary patents and other supplementary protections such as trade secrets, data exclusivities, and patent linkages on non-active elements of drugs/vaccines continue to limit generic producers. The current approach that idealizes the global harmonization of IP rules, which has led to increasing expansion of IP rights, disregards the historical evolution of the patent system and how industrialized nations initially conceptualize it. It sustains the power dynamics in the IP law-making process that has insulated it from democratic restructuring despite empirical studies identifying the various social welfare costs.

273 *Id.* at 401.

274 *See* Anjali Vats & Deidre A. Keller, *Critical Race IP,* 36(3) Cardozo Arts & Ent. 735, 788 (2018).

275 *See* Walter Mignolo, *Epistemic Disobedience, Independent Thought and Decolonial Freedom,* 26 Theory, Culture & Soc'y 1 (2009).

276 *See* Vats & Keller, *supra* note 273, at 795.