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Access to Medicine and TRIPS Agreement: A Historiographic Mapping of the Tradescape

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Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights[1] (TRIPS Agreement) is the most wide-ranging and influential multilateral treaty to date in the field of intellectual property (IP). Sweeping in scope, it established a global minimum standard for the protection of IP. For many developing countries, however, the TRIPS Agreement prescribed a higher standard than previously allowed in their national laws such as longer terms, broader rights, and fewer exceptions to the scope of rights. While innovation and trade remained the larger objective, the World Trade Organization's (WTO) global patent prescription largely created a privileged societal class with access to lifesaving medication, distinguishing them from those excluded from access to available medications. Patent protection as mandated by the TRIPS Agreement was the distinction that caused the morphing of lifesaving medication into a luxury, and thus, is an integral part of the discussion on access to medication. This decade witnessed an elevated interest over the role of patents in the context of pharmaceutical innovation and its effect on access to medication.

Patents are currently perceived, however unfairly, as *the* woe affecting pricing and as a tool thwarting access to lifesaving medication. While the effect of pharmaceutical pricing remains a significant question in the United States (US), pricing and other policies remain as subjects of a larger access to medication debate globally.[2] Over time, patents have evolved into a strategic business tool, which, in turn, resulted in a slow but steady downgrading from its touted position of being the unique economic prescription to kick-start innovation. As such, the rhetoric of innovation, which long served as a platform to nestle "patents," was being challenged within many countries and in many industries. From the US, the traditional flag-holder unfurling the benefits of patents, to developing countries such as India, which is a relatively newer graduate of the trade regime,[3] the role of patents has become a subject for scrutiny. In all, the TRIPS Agreement exacerbated the access to lifesaving pharmaceuticals into a global concern from what was essentially a poor country issue.

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[1] *See* TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 3 (1995) [hereinafter TRIPS Agreement].

[2] In 2016, as the debate on price of pharmaceuticals became an important election issue in the United States, the fact that patents contribute to such an increase in price came into the limelight. For example, in January 2016, the US News reported that 50 Democratic members of the House, led by Rep. Lloyd Doggett, D-Texas, urged government agencies to consider diluting or diminishing the exclusive rights over patents on pharmaceuticals. *See* Kimberley Leonard, *Can the Government already Control Drug Prices*, US NEWS (Jan. 11, 2016), http://www.usnews.com/news/articles/2016/01/11/congressional-democrats-urge-nih-to-act-on-drug-prices. Similarly, in 2016, Sen. Bernie Sanders and Rep. Elijah Cummings sought more information about the price increases for *Iclusig*, a drug used to treat chronic myeloid leukaemia which was priced at $199,000 for a year's worth of treatment. *See Sanders, Cummings Send Letter on ARIAD's Staggering Price. Increases* (Oct. 20, 2016) available at https://bit.ly/2ETma5B

[3] *See, e.g.,* Srividhya Ragavan, *Of the Inequals of Uruguay*, 274 MARQ. INTELL. PROP. L. REV. 10 (2006) (on India's process patent regime and its graduation into the TRIPS patent regime).

The year 2020 marks the 25th anniversary of the TRIPS Agreement and thus presents an opportune moment for critical appraisal from diverse perspectives. The past 25 years have been marked by debates between those that want to limit the Agreement's scope with those that crave to expand it. On the one hand, the HIV/AIDS crisis of the late 1990s and early noughties underscored the limitations of the TRIPS Agreement leading to the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),[4] which epitomizes an attempt to ameliorate these limitations. The emerging economies of Brazil, India, Russia, and China – which initially approached the TRIPS negotiation as weaker participants and importers of patented technology,[5] have morphed into key players of the policy, equitable innovation, and the access debates seeking limits to the scope of the TRIPS Agreement. Meanwhile, goaded by a quest for expanding private property rights, the US and the European Union (EU) fervently sought to expand the scope of and encourage patents.

The year 2020 also represents a confluence of factors that has elevated the imminence of the access debate in the context of the TRIPS Agreement. The fetish for encouraging patents notwithstanding, inflated prices within the US and the EU made lifesaving medication inaccessible for patients while simultaneously increasing health-care spending as a percentage of the Gross Domestic Product (GDP). Meanwhile, multilateral, plurilateral, and mega-regional trade agreements have ratcheted up the standards of IP protection beyond those stipulated by the TRIPS Agreement. Consequently, transnational civil society networks continue to play key roles in reframing the narrative surrounding patents. Amidst this, the WTO slipped into an existential crisis from a whining US, crying foul at all trading partners while creating protectionism locally in the name of 'America First'; stalemate in the Dispute Settlement Body (DSB); an inflow of talent capital that has merged borders but raised social issues; a realization within the developed world that 'free trade isn't free' but represents competition from hitherto unknown quarters of the world; and from the growing global trade tensions disrupting traditional theories of innovation. Amidst this, as the coronavirus gripped the globe, the WTO in crisis forcibly reconciled the power of public health to increase or impede trade.

This juncture is appropriate for analyzing the historical trajectory of the global struggles to access to medication. The analysis would complement the current paradigm shift with preference to a realistic approach to enable access to medication over an ideologically normative and inflexible approach. An inclusive approach rather than an exclusive solution can result in sustainable access to medicine. The analysis below provides a backdrop by classifying the struggles for access to medication discussions into generational questions, using the various chapters to weave three eras of medicine access struggles into the dialogue.

The *tradescape*: An analysis of structures and actors

The tumultuous *tradescape,* which references the landscape of the trade regime, provides the background and hopes to outline a historiographic mapping of the struggles of diverse actors for access to medicine rupturing established global structures over three generations. The historiographic mapping traces the changes in the patent discourse terrain by analyzing the metamorphosis of IP ideology, particularly patents. In doing so, this book captures the different

[4] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].
[5] FREDERICK M. ABBOTT ET AL., EMERGING MARKETS AND THE WORLD PATENT ORDER (2014), 5.

sets of actors such as states, transnational business corporations, civil society groups, and the (re)framing of patent discourses within and among these actors.

Our intergenerational analyses of the legal issues surrounding the access to medicine question provides an insight into the *structures* within which the actors have operated along with the dynamic relationship between *structures and actors.* The term structure, as used in this book, refers to the economic system within which various actors operate. The influence of structures over the behavior of actors and in turn, the influence exerted by actors over structures eventually caused generational shifts in the debate on the role of patents, trade, and access to medication. The book examines the influences over established global protocols, national and international agreements, and state and non-state entities. In doing so, we acknowledge that the history of patent harmonization discourse is a story of dynamic actors, whose interactions with established structures continue to shape the global patent regime.

Patents and the global neoliberal economy synthesis

The mercantile economic system of 18th-century Europe enabled competitive advantage by embracing patents to incentivize innovation.[6] Importantly, the norm is that nation-states have exerted – and will continue to exert – key influence over policies that results in international structures in the form of treatises and institutions. Thus, the 18th-century structures were instrumental in kick-starting transnational commerce that inspired international regimes such as the Paris Convention for the Protection of Industrial Property.[7] However, the beginnings of the contemporary structure can be attributed to the deepening of the neoliberal ideal, which led to the uneasy marriage of IP with trade, generating a new set of actors (for example, corporations) whose actions have had historical impact.

The expansion of the neoliberal trading system increased the value of information and knowledge, which in turn, proportionally increased the value of IP and vice versa.[8] Soon, higher IP standards became the preferred norm for developed nations to gain competitive advantage in the international market. It precipitated a renewed structure in the form of the WTO with a propensity to move towards stronger enforcement and more vested interests to propel IP into a newer *avatar* armed with the trade enforcement mechanism, which devalued humane influences. Susan Sell, in explaining the influence these neoliberal structures exert on actors along with the development of highly protectionist global IP standards, notes that "structures help to identify the significant agents

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[6] Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part II),* 76 J. PAT. & TRADEMARK OFF. SOC'Y, 852 (1994) [hereinafter Walterscheid Part II]; Thomas M. Mesbesher, *The Role of History in Comparative Patent Law*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 594, 602 (1996).

[7] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as revised at the Stockholm Revision Conference, July 14, 1967, 828 U.N.T.S. 305 [hereinafter Paris Convention]. In particular, the Great Exhibition of 1851, which promised to "unify the industrial products of all civilised peoples on earth in a comparative display" necessitated an overarching transnational structure monitored by an international organization as a means to reduce imitation. This and subsequent patent congresses formed parts of the drafts of Paris Convention eventually paving the way for international IP regulatory structures such as the WIPO, whose weak enforcement precipitated the move to a different structure with stronger enforcement mechanism. *See* Margrit Seckelmann, *From the Paris Convention (1883) to the TRIPS Agreement (1994): The History of the International Patent Agreements as a History of Propertisation?*, 14 JOURNAL DER JURISTISCHEN ZEITGESCHICHTE, 51 (2013); JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 56 (2004); Seckelmann, *supra* note 7, at 59.

[8] BRAITHWAITE & DRAHOS, *supra* note 7, at 61, noting that transnational business corporations wanted the ability to locate their production anywhere in the world but have the assurance that their IP will be protected. They pushed the IP regime to be part of a multilateral trade agreement to ensure global coverage.

in any particular context and also shapes preferences."[9] These structures, she adds, "alert us to whose preferences are likely to matter, not just in the domestic context, but in the international arenas."[10] In this respect, the neoliberal structure in the US, propelled by competitive markets, economic expansionism, and monopolistic accumulation became a motivation for economic coercion that enabled private sector actors to pursue extensive IP protections. Importantly, it underscores how law (in this case, IP and international trade law) is deeply implicated in the construction of a neoliberal global political economy.[11]

The emergence of private sector actors who successfully fostered international support characterizes a distinctive aspect of the contemporary trade regime, which naturally strengthened global protection of IP.[12] The distinguishing feature is that powerful nation-states, particularly the US, incorporated the interests of monopolistic transnational corporations to allow public international law to work in a manner that achieves the ends of private corporations, albeit in the name of global trade benefits.[13] However, the consequential emergence of public interest-minded non-state actors resulted in a pushback along the lines of fairer pricing, wider access to, and availability of essential medicines. The emergence of these actors and their impact on the structures resulted in a generational shift, causing the maturation of developing countries – once importers of IP – into informed players invigorating the debate on private versus public. It brought a fresh set of talent capital that has astounded the trade regime. All of the non-state actors, which include civil society, patient groups, and nations on the development spectrum engaged in an unsynchronized challenge to existing structures. In focusing on the participation of these actors and the challenges they posed to the neoliberal capitalist structures, the book underscores the dynamics between the various players to define, particularly how they have altered, the political landscape over which the fight for access to affordable lifesaving medication will continue.

The book is unique in presenting the debates over the impact of patents, trade, and the TRIPS Agreement on access to medicine and how they galvanized non-state and non-business actors, such as nongovernmental organizations and civil society groups, whose roles have been exceptional in the past two decades. The book highlights how the presence of non-state actors "diffused the leverage of asymmetries of power based on political and market forces alone."[14] Importantly, the actors have proffered an alternative framing and understanding of pharmaceutical patent "right" as a public issue as opposed to trade or IP issue. In summary, the book presents how both *structures* and *actors* shift conceptions of the role of IP rights and underscores the emergent controversies over access to medication.

Mapping the historiography of the international patent system

[9] SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW 5 (2003).
[10] *Id.*
[11] Jedediah S. Britton-Purdy et al., *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, Columbia Public Law Research Paper No. 14-657 (Mar. 2, 2020), YALE L. J. (forthcoming).
[12] BRAITHWAITE & DRAHOS, *supra* note 7, at 61; Susan K. Sell, *Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice*, 49 INT'L ORG. 315-349, 320 (1995).
[13] *See generally* Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not- So-Brave) New World Order of International Intellectual Property Protection,* 6 IND. J. GLOBAL LEGAL STUD. 11, 13 (1998), who notes the use of international law by the US to enforce its system of property rights.
[14] John Agada et al., *Globalization of Intellectual Property Rights: Implications of the TRIPS Agreement for Access to HIV/AIDS drugs in Africa*, 46 PROCEEDINGS OF THE AMERICAN SOCIETY FOR INFORMATION SCIENCE AND TECHNOLOGY 1-11, 9 (2009).

In the historiography of the evolution of patents, early influences of nation-states were important actors playing a critical role in motivating the creation of the multilateral trade system that currently impacts access to medication issues. Historically, actions of nation-states were influenced by social and economic factors which resulted in the evolution of patent laws specifically fashioned to nurture national development. For example, patents were used as a tool for innovation and to retain immigration in Venice, the earliest state where patents originated.[15] Similarly, patents were introduced to attract foreigners and support domestic industrialization in Britain, another important state actor, by "stimulating the local production of both raw materials and a wide variety of manufactured goods previously imported from abroad."[16] In the US, patent provision was introduced to promote science and technology.[17] Arguably, in their earliest instance, patents were disconnected with the ideals of global trade but meant to foster local industrialization[18] and as part of an effort to further national objectives. Thus, early patent regimes embraced a developmental approach to achieve national economic self-sufficiency.

Just as local economic realities dictated early patent development, bad economic times disfavored patents. In fact, patent development in the West has been remarkably acquiescent to symmetrical social and economic influence. For example, the end of the 1860s – which coincided with the beginning of economic depression in Europe and North America – saw a growing anti-patent feeling in the West.[19] Thus, the consequent economic depression and political upheavals by the financial crisis in 1873 were credited as key factors in the dissatisfaction towards patents.[20] This dissatisfaction grew, according to Ragavan, because patented products become accessible to even fewer people than during normal economic times.[21] There was also dissatisfaction against patents in European countries such as the Netherlands and Germany.[22] For instance, Marks Langs notes that the economic recession in Germany created uncertainty among politicians and fueled anti-patent sentiments among proponents of free trade.[23] Similarly, in the Netherlands, Eric Schiff asserts that as "free trade movement was gaining momentum in the country, patents came to be seen as a form of protectionism and impediment to trade."[24] Thus, even in countries where patents were seen as beneficial to domestic development, lack of access to what was considered a privilege necessitated a restraint in their use. Whenever the patent regime was considered as not achieving its aim of producing public benefit, it arguably led to a general anti-patent perception. Interestingly, the access to medication discourse of the last two decades, and significant developments in the pharmaceutical and bioscience fields in developed countries, have resulted in a re-emergence of the dissatisfaction toward patents.

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[15] Skilled artisans and artists were granted two-year monopoly rights, while tax breaks were granted to skilled workers by the city-state. The Venetian system influenced patent evolution in Europe.

[16] Walterscheid Part II, *supra* note 6, at 879.

[17] In the US, as in Venice and England, the general sentiment was to establish a patent regime that would result in national economic benefits. Thus, patent policies were historically meant to achieve national objectives and were instituted with an appreciation of the importance of addressing welfare considerations.

[18] SRIVIDHYA RAGAVAN, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES 17 (2012).

[19] *Id.* at 20.

[20] RAGAVAN, *supra* note 18, at 20.

[21] *Id.* at 27.

[22] ERIC SCHIFF, INDUSTRIALIZATION WITHOUT NATIONAL PATENTS: THE NETHERLANDS, 1869-1912; SWITZERLAND, 1850-1907 19 (1971); Petra Moser, *Patents and Innovation: Evidence from Economic History*, 27 JOURNAL OF ECONOMIC PERSPECTIVES, 26 (2013).

[23] Markus Lang, *The Anti-Patent Movement Revisited: Institutional Change and Cognitive Frames in Nineteenth-Century Germany*, SSRN ELECTRONIC JOURNAL, 7 (2010).

[24] SCHIFF, *supra* note 22, at 26.

Rise of multilateralism: From Paris Convention to TRIPS Agreement

From nation-states, multilateral organizations represent another set of actors contributing to the global patent evolution. Indeed, multilateralization resulted in a system wherein "global" objectives of the trade regime gained priority over national objectives. Local national realities were consequently relegated to tertiary consideration. Historically, the first strides towards multilateralism began in 1883 when the Paris Convention was ratified. The goal of this first multilateral agreement was to enhance IP protection in foreign jurisdictions by replacing the fragmented reciprocal arrangements among European powers.[25] The Paris Convention allowed flexibility in its interpretation in national laws as long as such interpretation applied to both nationals and foreigners and did not contravene any provisions of the Convention.[26] This legislative freedom created heterogeneous global patent rules wherein countries adopted different standards of industrial property protection.[27] Even though the Paris Convention was seen by many, including legal scholars[28] and developing countries,[29] as favorable to developed countries, it was still regarded by certain countries, such as the US, as insufficient. This was because it did not have any enforcement mechanism and its provisions were flouted by many countries. It eventually resulted in the creation of the World Intellectual Property Organization (WIPO) in 1967, which helped to further promote worldwide awareness of IP rights.[35] Even though the principle of national treatment still applied,[30] developed countries were concerned about insufficient IP protection and enforcement in developing countries. These concerns as well as the structure of the WIPO, particularly weak enforcement mechanisms, compelled a move towards stronger enforcement structures.

*The birth of generic*s *and new actors*

The growth of multilateral IP systems coincided with the growth of generic drugs industries in some developing countries such as India and Brazil. At that time, a high rate of poverty and

[25] The original signatories were Belgium, Portugal, France, Guatemala, Italy, the Netherlands, San Salvador, Serbia, Spain, and Switzerland. The US joined the Convention in 1887. Ecuador, El Salvador, and Guatemala later withdrew from the Convention in 1886, 1887, and 1895, respectively. ULF ANDERFELT, INTERNATIONAL PATENT-LEGISLATION AND DEVELOPING COUNTRIES 69 (1971).

[26] Paris Convention, art. 15.

[27] In Switzerland and Spain, for example, chemical products were not patentable, while France and Italy did not grant patent to pharmaceutical substances. *See* Surendra J. Patel, *Intellectual Property Rights in the Uruguay Round: A Disaster for the South?*, 24 ECONOMIC AND POLITICAL WEEKLY, 980 (1989).

[28] Patel, *supra* note 27, at 982-83; *see also* Rajeev Dhavan et al., *Conquest by Patent: The Paris Convention Revisited*, 32 JOURNAL OF INDIAN LAW INSTITUTE (1990); Edith Penrose, *International Patenting and the Less-Developed Countries*, 83 THE ECONOMIC JOURNAL, 768 (1973); Constantine Vaitsos, *Patents Revisited: Their Function in Developing Countries*, 9 THE JOURNAL OF DEVELOPMENT STUDIES 71-97 (1972).

[29] Brazil was the first country to table discontentment with provisions of the Paris Convention in 1961 and was followed by similar proposals from Bolivia and Argentina. *See* Andrea Koury Menescal, *Changing WIPO's Ways? The 2004 Development Agenda in Historical Perspective*, 8 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY, 761-796, 764-766 (2005); *see also* Peter K. Yu, *Tale of Two Development Agendas*, OHIO NORTHERN UNIVERSITY LAW REVIEW (2009); Patel, *supra* note 27, at 983.

[35] The WIPO emerged from the United International Bureaux for the Protection of Intellectual Property (BIRPI), which itself was formed by the merged Paris Convention and the 1886 Berne Union for the Protection of Literary and Artistic Works (Berne Convention) under a single secretariat in 1893. See Christopher May, *The Pre-History and Establishment of the WIPO*, 1 THE WIPO JOURNAL 16-26 (2009); Debora J. Halbert, *The World Intellectual Property Organization: Past, Present and Future*, 54 THE COPYRIGHT SOCIETY OF THE USA (2007).

[30] The principle of national treatment allows countries to extend to foreign nationals the same rights and legal privileges enjoyed by their own nationals. *See* Paris Convention, art 2.

epidemic diseases burden became an integral part of government's national development objectives.[31] India had the highest priced drugs in the world,[32] and in response, it amended its patent laws in line with its national goals[33] and enacted the Indian Patent Act 1970.[34] The enactment abolished product patents for pharmaceuticals and agrochemicals and only allowed process patents.[35] India also signed an Agreement with the United Nations Children's Fund (UNICEF) to locally manufacture penicillin and other antibiotics, which resulted in the establishment of the Hindustan Antibiotics Limited in 1954 to produce low-cost generic drugs.[36] In Brazil, similar domestic reforms were implemented to ensure availability of reasonably priced drugs. Brazil's Law Number 7.903/1945 removed product patent protection for medicines, food, and chemicals.[37] In 1969 and 1971 respectively, two new amendments enabled Brazil to domestically manufacture pharmaceuticals. [38]

The law reforms in India and Brazil resulted in the establishment of an indigenous pharmaceutical industry, which helped control public health expenditure. For example, within a decade of reforming its patent law, the Indian generic drug sector grew to be one of the biggest GDP generators for the country.[39] By 1991, domestic firms accounted for 70 percent of the bulk drugs production and 80 percent of formulations.[40] Similarly in Brazil, the 10 largest national pharmaceutical companies increased their market share by 10 percent within a decade after the removal of patent products.[41] Peter Drahos, in analyzing this growth, notes that generics drug manufacturers posed a viable threat to the Western pharmaceutical companies that had dominated the international pharmaceutical industry.[42] Feeling the loss of access to developing country markets, Western pharmaceutical cartels lobbied their national governments to secure higher patent standards away from the WIPO through a forum where the large pharmaceuticals players could secure a global IP standard. In light of these concerns and pressures from IP industries, the

[31] RAGAVAN, *supra* note 18; AMAKA VANNI, PATENT GAMES IN THE GLOBAL SOUTH: PHARMACEUTICAL PATENT LAWMAKING IN BRAZIL, INDIA AND NIGERIA (2019).
[32] See Justice N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law*, Sept. 1959 citing the US Senate Committee Kefauver Committee Report headed by Senator Estes Kefauver.
[33] The Ayyangar Report laid the foundation for the Indian patent regime, particularly for its analysis of the adaptability of foreign patent regimes and policy options to address India's national needs.
[34] *See* Patents Act 1970, 27 India A.I.R. Manual 450, § 84 (1979).
[35] *Id.* at § 5.
[36] RAGAVAN, *supra* note 18, at 35.
[37] Law No 7.903/1945; *see also* Bruno Salama & Daniel Benoliel, *Pharmaceutical Patent Bargains: The Brazilian Experience*, 18 CARDOZO J. INT'L & COMP. L. 633, 639-40 (2010); VANNI, *supra* note 31, chapter 4 focuses on Brazil's intersection of the HIV/AIDS program and pharmaceutical patent regime to trace the development of socially conscious patent and pharmaceutical policies; Christopher S. Mayer, *The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?*, 12 TEMP. INT'L & COMP. L. J. 37 (1998); Bermudez and others (n 13) 52.
[38] Law Number 1.005/1971 in 1969 removed food, chemical, and pharmaceutical substances, materials, products, and medicines from the list of patentable materials, while Law Number 5.772/71 in 1971 prohibited the patenting of processes for food, chemicals, and medicines.
[39] While only two indigenous companies were among the top 10 firms in terms of retail sales in 1970, by 1996 this rose to six, and by 2001 it was up to eight. *See* VANNI, *supra* note 31.
[40] Jean Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?*, National Bureau of Economic Research, Working Paper No. 6366 (1998).
[41] GARY GEREFFI, THE PHARMACEUTICAL INDUSTRY AND DEPENDENCY IN THE THIRD WORLD 229 (1983). The Brazilian government enacted policies to attract investments for the creation of a chemical industry to produce specialized chemicals, active pharmaceutical ingredients (APIs), and their intermediates in order to reduce dependency on imported APIs for pharmaceutical and chemical production. *See* VANNI, *supra* note 31.
[42] Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 765-789, 768 (2005).

US moved the issue of IP discussion to the General Agreement on Tariffs and Trade (GATT) – a forum in which it was the single most influential player.[43]

The birth of generics and their success in catering to medicine access not only contributed to more economic productivity by addressing diseases, but also levelled the playing field. This shifted the globe into its next era of access to medication. The foundational pillars of this new era rested on pharmaceutical companies' fear of the generic industry. Previously, and using patents as a tool, pharmaceutical companies had created a new class-based society divided by their ability to access medication. However, the introduction of generics into the market resulted in re-scrambling the class-based access-to-medication system. The fear of transnational pharmaceutical corporations resulting from the emergence of generic industries located in developing countries consequently caused a pushback affecting medicine access.

An uneasy marriage of trade and IP

The pushback from the pharmaceutical industry propelled a proliferation of international norm-setting activities creating new structural mechanisms to achieve harmonization of laws. In the territory of international norm setting, harmonization created legal equality into a system that was naturally comprised of unequal parties with huge variation in economic and bargaining parities.[44]

Meanwhile, much had changed in the 110 years between the Paris Convention in 1883 and the arrival of the TRIPS Agreement in 1994. In 1948, the GATT was created to regulate world trade by reducing tariff, minimizing trade barriers, and boosting economic recovery after the devastation of the Second World War. However, a weak dispute settlement mechanism was cited as the reason for a limited global trade expansion, which in turn triggered calls from various countries, mostly the US, for a more powerful and comprehensive organization.[45] The result was the conception of the WTO, distinguished by its ability to create credible threats and enforce disputes between sovereign members. The ability to enforce disputes through trade sanction was one of the salient features of the TRIPS Agreement, the other being the setting of mandatory minimum standards of protection.[46] The ability to enforce disputes materialized in the form of a dispute resolution mechanism to adjudicate cases of infringement of WTO agreements.[47] The enforcement

[43] Laurence Helfer calls the process of moving international law-making and standard setting from one forum to another as "regime shifting," where state and non-state actors alike shift law-making from one international venue to another. *See* Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L. L. (2004); *See generally* Ha-Joon Chang, *Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues*, 2 JOURNAL OF HUMAN DEVELOPMENT, 287-309 (2001); SELL, *supra* note 9; SELL, *supra* note 12; Drahos, *supra* note 42.

[44] Ragavan, *supra* note 3.

[45] Peter Drahos, *Global Property Rights in Information: The story of TRIPS at the GATT*, 13 PROMETHEUS 6-19, 12 (1995).

[46] TRIPS Agreement, art. 27 includes in the definition of patentable subject matter both pharmaceutical products and process and introduced the concept of non-discrimination in all fields of technology for patent application.

[47] TRIPS Agreement, arts. 63 and 64. Article 64 of the TRIPS Agreement provides for dispute settlement through articles 22 and 23 of the General Agreement on Tariffs and Trade (GATT); *see also* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M, 1125, 1226, 1244 [hereinafter DSU]. Article 6 of the DSU provides for the establishment of a panel at the instance of the complaining party, which is the Dispute Settlement Body. Over the years, various countries have initiated and/or completed dispute settlement procedures relating to the provisions of the TRIPS Agreement. *See* DS50: India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (1996); DS114: Canada – Patent Protection of Pharmaceutical Products (2000); DS170: Canada

mechanism of the WTO addressed one of the main criticisms that the developed nations had levelled against previous international IP regimes. According to Braithwaite and Drahos, one of the US complaints against the WIPO (in addition to the voting rules) was the lack of enforcement of IP.[48] Thus, the dispute settlement mechanism is a direct response to address a lack of credible surveillance in WIPO Conventions and further strengthened the liaison between trade and IP laws in unprecedented ways.

At the Uruguay Round meetings, the US and the European Economic Community (EEC) linked IP issues to the larger international trade framework to ameliorate the Paris Convention deficiency in harmonizing global IP rules.[49] Commentators agree that the move by the US and EEC to include IP as part of the GATT regime created an environment conducive for developed countries to use access to their markets as a bargaining chip.[50] It resulted in establishing a higher standard of IP in the form of minimum benchmarks along with a much-needed enforcement mechanism. Drahos, in analyzing the IP negotiations, notes that the US and the EEC used the threat of denying market access as a means to build the consensus required to shape the content of the TRIPS Agreement text.[51] Further, the nature of cross-negotiations at the GATT allowed for countries to leverage losses in one area into a concession in another. For example, developing countries hoped for elimination or minimization of barriers in agricultural trade as an important trade-off, which never truly materialized. In the end, developed countries were able to push through higher levels of IP in the form of the TRIPS Agreement text. TRIPS proponents believed that the ability of the WTO to generate threats and the enforcement of retaliatory mechanisms compelled sovereign obedience. As shall be seen, it is the signing of the TRIPS Agreement that precipitated the generational debates on medicine access.

Now, 25 years later, a fault line can be traced in the TRIPS regime between developed and developing nations at the interface of IP and access to medication. The structural paradigm of trade and the TRIPS Agreement invigorated the next set of actors, particularly invested developing countries and committed civil societies. For developing countries and civil society groups aligned with the views of developing countries, the TRIPS Agreement mirrored the interests of global corporate actors in developed countries. As a result, it reflected the specific view of IP as uniquely promoted by Western countries, aligned with their transnational corporations and divorced from the harsh realities that plagued the rest of the world. This fault line, as the chapters in the book highlight, weaves a common thread between diverse issues such as definitions of inventiveness, use of compulsory license, patent examination processes, treatment of public health objectives, and legitimate domestic policy on patent law.

HIV/AIDS crisis and the limitations of the TRIPS Agreement

– Term of Patent Protection (2001); DS199: Brazil – Measures Affecting Patent Protection (2001); *see also* MATTHEW KENNEDY, WTO DISPUTE SETTLEMENT AND THE TRIPS AGREEMENT: APPLYING INTELLECTUAL PROPERTY STANDARDS IN A TRADE LAW FRAMEWORK (2016).

[48] BRAITHWAITE & DRAHOS, *supra* note 7, at 566.

[49] A. Jane Bradley, *Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations*, 23 STAN. J. INT'L L., 59 (1987).

[50] Drahos, *supra* note 42, at 769; *see also* SELL, *supra* note 9, ch. 4; Susan K. Sell, *TRIPS: Fifteen Years Later*, 18 J. INTELL. PROP. L. (2011).

[51] Drahos, *supra* note 42, at 774.

As the world globalized and harmonized internationally, one key event showcased the disparities and limitations of the TRIPS Agreement in the context of access to medicine. Widely known as the HIV/AIDS crisis, this issue precipitated the struggle for access to medication. The widespread occurrence of specific diseases associated with an HIV infection that raged through the world in the late 1980s and 1990s, killing millions of people, changed the ground realities. The devastation on the lives of people located in mostly poorer countries as a result of the lack of access to antiretroviral (ARV) medicines emphasized the limitations of the TRIPS Agreement.[52] By 2001 – 20 years after the first HIV/AIDS diagnosis and with more than 2.5 million deaths from AIDS, with the prospect of a profound effect on the productivity of nation-states – the TRIPS Agreement faced an existential crisis.[53]

Unsurprisingly, when the Indian generic drug manufacturer Cipla announced it would sell triple-drug therapy for $350 per patient per year to Médecins Sans Frontières (MSF) and directly to poor nations, several major pharmaceuticals lowered prices,[54] prompting the then United Nations Secretary General Kofi Anan to reaffirm that HIV/AIDS constituted a national security threat and a public health crisis.[55] The HIV/AIDS crisis not only showcased the inflexibility of the TRIPS Agreement but also challenged its structural establishment. The implications of the TRIPS Agreement on public health and the Cipla announcement mobilized support like never before from global non-state actors such as transnational civil society groups and health activists.[56] This phenomenon remains unique to date and the book captures that as part of the global transitions of the medicines access debate. In the US, for instance, groups such as the Consumer Project on Technology (CPTech, now Knowledge Ecology International, or KEI) rallied against the impact of the TRIPS Agreement on drug prices. Medicine access activists such as MSF and the Working Group on Intellectual Property (GTPI), whose positions are captured in the book, initiated campaigns linking the effect of patents on availability and access to medication.[57] In support, multilateral agencies such as the WIPO and the World Health Organization (WHO), and institutions such as the United Nations Commission on Human Rights (UNHCR) raised concerns regarding the impact of the TRIPS Agreement on access to medicines and the resulting implications for health and human rights.[58] Simultaneously, at national levels, various events resulted in amplifying the access to medication debate. For example, 41 pharmaceutical companies in South Africa plus the South African Pharmaceutical Manufacturers' Association filed a lawsuit against the national government for including TRIPS flexibilities into domestic law to increase the affordability and accessibility of medicines. The vocal mobilization of civil society and the media attention from the lawsuit forced pharmaceutical companies to withdraw the suit, thus allowing

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[52] VANNI, *supra* note 31; *see also* ETHAN B. KAPSTEIN & JOSHUA W. BUSBY, AIDS DRUGS FOR ALL (2013).
[53] 2007 World Health Organization HIV/AID Update Presentation, http://www.who.int/hiv/facts/2007_epiupdate_report_fullpresentation_en.pp. According to the WHO, about 35 million people have died from the epidemic from 1988 to 2018. *See Why the HIV Epidemic Is Not Over*, WHO.INT, https://www.who.int/hiv-aids/latest-news-and-events/why-the-hiv-epidemic-is-not-over.
[54] *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, NYTIMES.COM, https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html?module=inline.
[55] *Secretary-General Proposes Global Fund for Fight Against HIV/AIDS and Other Infectious Diseases at African Leaders Summit*, UN.ORG, https://www.un.org/press/en/2001/SGSM7779R1.doc.htm.
[56] *See* Brook Baker, *infra* chapter …. at page
[57] VANNI, *supra* note 31.
[58] Office of the High Commissioner for Human Rights, *Human Rights and Trade* (2003), https://www2.ohchr.org/english/issues/globalization/trade/docs/5WTOMinisterialCancun.pdf.

for the amendment. The consequential alliances of developing countries with civil society activists dominated the efforts to make the global IP regime more equitable.

Importantly, two limitations of the TRIPS Agreement came to the fore. First, the inability of the TRIPS Agreement to address practical difficulties of poorer countries to access medicines by manufacturing generic versions of expensive medications. Second, even if flexibilities were incorporated, a realization that there were countries that lacked adequate manufacturing capacity and that the TRIPS Agreement prevented them from importing generic medications from countries such as India, which had the capacity to manufacture these medications. In response to the first concern, the WTO General Council adopted the Doha Declaration in 2001.[59] The Doha Declaration recognized the gravity of health issues facing many countries and emphasized the autonomy of states to implement and interpret the TRIPS Agreement in a manner supportive of public health.[60] To address the issue of countries without manufacturing abilities, the WTO General Council adopted in August 2003 article 31*bis*, paving the way for importation of low-cost medicines from countries with manufacturing capacity.[61] The amendments also allowed any member country, either acting individually or as a regional grouping, to grant compulsory licenses with a view of exporting pharmaceutical products to countries with insufficient or no manufacturing capacities.[62]

Recent developments buoyed by pharmaceutical industry lobby in developed nations pushed back via trade and investment agreements, resulting in an array of bilateral and plurilateral agreements which became a choice mechanism for building extensive TRIPS-plus IP protection. Thus, trade agreements such as the Trans-Pacific Partnership (TPP) and the proposed Regional Comprehensive Economic Partnership have pushed the bar for higher IP standards. With that, a new set of tools to enhance private property rights emerged. Data exclusivity, patent/marketing approval linkage, third party dispute settlement, and reduced use of flexibilities are all exemplars of the contemporary issues.[63] The emergence of newer issues, structures, and actors propelled a new era with a new set of regulatory compliance standards.

Recent developments and emerging issues

The next generation in the drug debate surprisingly involved developed countries where a steady increase in the price of pharmaceuticals over a decade caused health-care costs to skyrocket, raising sophisticated questions with implications beyond patents. Interestingly, pharmaceutical companies are facing growing condemnation against the background of soaring drug prices, causing governments to become constituencies acting towards the cause of making either medication or health care accessible to citizens. For example, the UK's National Institute for Health and Care Excellence (NICE) recommended against the use of *trastuzumab emtansine* (brand name *Kadcyla*) in the National Health Service (NHS) because of its high price, even though it recognized the efficacy of the drug to treat breast cancer.[64] Similarly, when patient-led campaign

[59] Doha Declaration, *supra* note 4.
[60] *Id.*
[61] Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [hereinafter Decision]; *see also* Doha WTO Ministerial 2001: Ministerial Declarations and Decisions, WTO Doc. WT/MIN(01)/17 (Nov. 20, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm.
[62] *Id.*
[63] See Burcu Kilic, …. Infra chapter (on the work of Public Citizen in free trade agreements).
[64] *Kadcyla too expensive for routine funding on NHS*, NICE (2016), https://www. nice.org.uk/news/article/kadcyla-too-expensive-for-routine-funding-on-nhs.

organization Just Treatment criticized the price of cystic fibrosis drug *Orkambi* manufactured by Vertex Pharmaceuticals, the NHS entered into price negotiations to reduce the cost.[65] In the Netherlands, hospitals started making their own generic versions of expensive medicines to ensure availability of expensive drugs.[66] In France, Médecins du Monde filed a challenge at the European Patent Office against Gilead's *Sovaldi* – used to treat hepatitis C – challenging the cost and patent validity of the drug.[67] The US has been exceptional, where several issues have been raised on the question of pharmaceutical pricing, health-care access, patents, secondary patents, data exclusivity, and more. The practice of inflating the price of off-patent drugs, such as in the case of *Humalog* – a brand of insulin manufactured by Eli Lilly whose patent had expired 75 years ago and whose price nearly tripled between 2002 to 2013 and doubled again since then – raised concerns even among supporters of the Pharmaceutical Research and Manufacturers of America (PhRMA).The biggest game changers were American senators and members of Congress – who evangelized to sympathizers for reducing health-care costs – that became critical of the exorbitant cost of pharmaceuticals.[68]

Particularly in the US, and generally in the West, the evolution of health care into a privilege has proportionally seen an increase in discontentment and considerable challenges against all structural barriers that work to overprotect private capital at a huge public cost. Thus, beginning with the subject of patents and its co-relation to innovation,[69] several issues have brought the health-care access debate to the forefront by raising concerns about secondary patents, the regulatory issues relating to patents, market and data exclusivities, patent linkage, and more, each of which are dealt with in the book. For example, secondary patenting[70] – the practice of filing patents that are minor variants of the parent compound – leads to evergreening by creating a stack of patents, such that the innovator can exercise monopoly even after the first of several stacked patents expires.[71] Such stacking effectively extends monopoly that unfairly delays the entry of generics to the market and raises costs for governments and patients as a result. Secondary patents have been challenged because, while they can increase the number of patents, they do not necessarily reflect the presence of innovation.[72] A report by the advocacy group Initiative for Medicines, Access & Knowledge (I-MAK) discussed that pharmaceutical companies file hundreds of patent applications which are

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[65] *The Global Battle Over High Drug Prices*, THE ECONOMIST, https://www.economist.com/business/2019/05/21/the-global-battle-over-high-drug-prices.

[66] *Dutch join backlash at expensive drugs by making their own*, REUTERS, https://www.reuters.com/article/us-netherlands-pharmaceuticals-insight/dutch-join-backlash-at-expensive-drugs-by-making-their-own-idUSKCN1QP0M4.

[67] *Concerns over high-priced medicines back in the European Parliament*, POLITICO, https://www.politico.eu/article/concerns-over-high-priced-medicines-back-in-the-european-parliament/.

[68] *Patents Under Debate as Pharma Executives Face US Senate Committee*, INTELLECTUAL PROPERTY WATCH, https://www.ip-watch.org/2019/02/27/patents-debate-pharma-executives-face-us-senate-committee/; *It's Time for Pharmaceutical Companies to Have Their Tobacco Moment*, NYTIMES.COM, https://www.nytimes.com/2019/02/24/opinion/drug-prices-congress.html.

[69] Innovation and its …. Book. Cite here…

[70] *See generally* Amy Kapczynski, *The Right to Medicines in Age of Neoliberalism*, HUMANITY JOURNAL (Apr. 26, 2019), http://humanityjournal.org/issue10-1/the-right-to-medicines-in-an-age-of-neoliberalism/; Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE JOURNAL OF LAW & TECHNOLOGY; Bhaven N. Sampat & Kenneth C. Shadlen, *Secondary Pharmaceutical Patenting: A Global Perspective*, 46.3 RESEARCH POLICY 693-707 (2017); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31.2 JOURNAL OF HEALTH ECONOMICS 327-339 (2012).

[71] Srividhya Ragavan, *Drugs, Drugs Everywhere but Just Not for the Poor*, 8 WIPO Journal 41-53 (2016).

[72] FEROZ ALI ET AL., PHARMACEUTICAL PATENT GRANTS IN INDIA: HOW OUR SAFEGUARDS AGAINST EVER-GREENING HAVE FAILED, AND WHY THE SYSTEM MUST BE REFORMED 18 (2018).

used to extend their patent term beyond the 20 years of protection intended under international patent law.[73] This effectively blocks competition, keeps cheaper versions of medicines off the market, and makes medicines harder to access on account of high drug prices. In effect, the world is witnessing a global shift in the access-patent discourse. Previously considered a problem for low-income countries, the issue is a global barrier to public health and trade.

Like secondary patents, the issue of data exclusivity can also work in tandem with the patent regime to add another level of protection. Data exclusivity refers to the practice of protecting clinical trial data submitted to a regulatory body to prove the safety, quality, and efficacy of a new drug.[74] In practical terms, this prohibits the dissemination of clinical trial data to a third party (usually, a generic company), thereby preventing the generic company from relying on the data for its own drug approval. For instance, the US Affordable Health Care for America Act in 2009 extended a 12-year exclusivity period for biologics.[75] When patents are awarded for 20 years, whether the safety data and related information should be independently protected remains an important question. It is more complicated in cases where the underlying patent is found invalid, resulting in the clinical trial data alone preventing a generic drug company from releasing a cheaper version until the data protection period is over, thereby virtually allowing the holder of the invalid patent to monopolize the market for the duration when data protection prevails.

Data exclusivity can also affect the use of compulsory license by requiring the generic manufacturer to seek the patent holder's approval to use the test data separately for marketing approval. In the EU, for instance, depending on whether the originator drug is a chemical or biologic, a generic may not be marketed between 10 to 12 years after the grant of the initial market authorization for the originator product.[76] This forces a generic company to duplicate the clinical trial, the cost of which will be passed on to consumers. The issue of data exclusivity, especially as required under article 39 of the TRIPS Agreement, has been contentious among legal scholars and commentators. For example, Daniel Gervais reads data exclusivity as a mandate in the TRIPS requirement to protect against unfair commercial use.[77] Carlos Correa and Shamnad Basheer, on the other hand, argue that the language of article 39 falls short of what could be recognized as data exclusivity, and that the US position is inconsistent with the TRIPS Agreement.[78] Similarly, Ellen T'Hoen et al believe that the TRIPS Agreement does not oblige countries to confer exclusive rights over data related to marketing approval to the originator company.[79] This book presents these challenges and issues that implicate data exclusivity, patents, and their effect on access to medication.

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[73] INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 2 (2018).

[74] *See generally* Srividhya Ragavan, *The Significance of the Data Exclusivity and Its Impact on Generic Drugs*, 1.1 JOURNAL OF INTELLECTUAL PROPERTY STUDIES 131-141 (2017); Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 8.2 JINDAL GLOBAL LAW REVIEW 241 (2017).

[75] Affordable Health Care for America Act, 155 CONG. REC. H12623, 12784 (Nov. 7, 2009). *See also* Srividhya Ragavan, *The (Re)Newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON LAW REVIEW 1186 (2017).

[76] I-MAK, *supra* note 73, at 3.

[77] DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 545 (Sweet & Maxwell, 4th ed. 2012).

[78] CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 367 (2007). *See also* Carlos Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 72-73 (2002).

[79] Ellen F. M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 JOURNAL OF PHARMACEUTICAL POLICY AND PRACTICE, 2 (2017).

In addition, patent linkage has grown in recent times to pose as a barrier to medicine access. According to Ragavan, patent linkage, which is the tying-in of patent information with data exclusivity, requires the regulatory body to verify if a generic application relates to a patented product. Thus, a government body essentially performs the role of a gatekeeper of private property. This adds another layer of administrative approval, thus operating to further delay the entry of generics.[80] Patent linkage has far-reaching effects due to its widening scope and geographical coverage via free trade agreements (FTAs) and mega-regional agreements. By delaying the entry of generics into markets, patent linkage allows the high prices of originator medicines to remain unrestrained.[81] It is essentially an additional layer that shields the originator pharmaceutical company from competition from generic manufacturers. As Kyung-Bok et al assert, patent linkage facilitates innovator pharmaceutical companies to obtain a de facto injunction against a generic drug company.[82] Such injunctions can delay generic applications for up to 30 months, unless non-infringement or invalidity is established earlier, either by court judgment or patent expiry, during the 30 months.[83]

Overview of the book: Examining three generations of access to medicines debate

The preceding section provides a background of how the TRIPS Agreement can impact public health through trade and productivity. Indeed, the signing of the TRIPS Agreement marks the beginning of a generational debate to access medication. The chapters in the book expand on this conceptual genealogy to delineate the historical trajectory of what we, the editors, term as ***The Three Generations of Global Struggles with Access to Medication***. The section below provides an overview of the chapters discussed in the book.

Part I titled **International Norm Setting and Patent Metamorphosis: First Generation** shows the institutions and actors involved in the metamorphosis of pharmaceutical patents, both at the international and domestic levels. We call it first generation because it details key episodes in the pharmaceutical patent trajectory to tease out how the 'story and dialogue' changed and the new fault lines that have been drawn leading to a notable divergence between IP rights in the pharmaceutical industry and those in any other industry. Consisting of nine chapters, Part I offers an insight into the transformation of pharmaceutical patents and access to medicine interests in respective forums, notably the WTO (*chapter 2*), the WHO (*chapter 3*), the EU and the generic drugs industry (*chapter 4*), FTAs (*chapter 5)*, a case study of the TPP and the US–Mexico–Canada Agreement (*chapter 6*), the African Union (*chapter 7*), and on the Bayh-Dole Act and patenting activity of universities and other nonprofits outside the US (*chapter 8*). The critical observation of the chapters within this section is the confluence of various actors and institutions in the development, framing, and reframing of pharmaceutical patent laws, which has led to the steady ratcheting up of standards and norms in a manner that has made access to medication a luxury.

Following this, Part II titled **State Actions and the Medicines Access Debate: Second Generation** captures the role of state actors and their engagements as part of an emerging and changing global pattern. We call it second generation because it looks at how countries adapted to

[80] Ragavan, *supra* note 75, at 1163-1196; Texas A&M University School of Law Legal Studies Research Paper No. 18-19, 1192.
[81] Kyung-Bok Son et al., *Moderating the Impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States*, 14 GLOBALIZATION AND HEALTH (2018).
[82] *Id.*
[83] *Id.*

the globalization of patents and how their domestic patent law activities changed and continue to change the global narrative on public health and access to medicine. The six case studies in Part II offer insights into the operation and variations of pharmaceutical patent norms in select countries. In doing so, the chapters capture the ground realities as well as policies employed by national governments to improve access. The detailed accounts include a discussion of how industrial and related policies were used to encourage local production and technology transfer in select countries such as in Brazil (*chapter 9*); the introduction and employment of innovative policies to aid the development of the domestic economy and technology originating in China (*chapter 10*); the influence of IP provisions in preferential trade agreements (PTAs) in Canada which have had varying impact on domestic subregions and subpopulations (*chapter 11*); analyses of the landmark Novartis case in India (*chapter 12*) and the "pharmagate" crisis in South Africa, and the effect of these domestic legal disputes on generic pharmaceutical manufacturing landscape and medicine access in both countries, respectively (*chapter 13*); the role of government in using compulsory licenses and their fallout on public health discourse in Thailand (*chapter 14*); and the unilateral norm-setting actions of the US using the Office of the US Trade Representative Special 301 Reports (*chapter 15*). The national studies highlight two important aspects. First, they underscore how a number of emerging markets have risen to challenge existing ideologies on global patent framework; second, how the legal system – including policy makers and the judiciary – play a key role in the interpretation of laws, which can be critical in driving the discourse and dialogue on patent reform and access to medication debates.

Part III of this volume titled **Global Patterns and Emerging Issues: Third Generation** highlights new changes and challengers to the existing framework. Here, focus is on the participation of civil society that brought patent law into the field of activism, the role of the private sector to mobilize the access to medicines issue, and the emergence of new issues which triggered a simultaneous convergence *and* divergence of regulatory standards. We call it third generation because it captures the state of 'flux' due to advances in technology and new threats to global health, which pose new challenges to an already complex system of IP. Analyses in this section include the role of civil society in reframing the narratives surrounding patents and in strengthening the network of civil society participation (*chapter 16*); the firsthand experience of GTPI, a grassroot civil society and patient group in Brazil, in vocalizing access to medicines advocacy and mobilization efforts in Brazil and in other countries (*chapter 17*); and the responsibility of the private sector as regards right to health and access to affordable medicines (*chapter 18*). Within Part III, the last five chapters look at other elements in the evolving global scene that are relevant to the discussions on the TRIPS Agreement and access to medicine. The various issues include the relationship between IP rights and competition law (*chapter 19*); the distinct world of pharmaceutical patents due to the convergence of various domestic regulatory frameworks and actors (chapter 20); discussions on the barriers engendering the creation of effective competitive regulatory mechanisms for controlling pharmaceutical prices (*chapter 21*); how pharmaceutical companies use trademark laws to manipulate consumers to control markets beyond the life of patents (*chapter 22*); the practice of Traditional Medical Knowledge (TMK) and pushback from the pharmaceutical industry to marginalize TMK (*chapter 23*); and how the digital divide can affect access to medicine by exacerbating the inequality in medicine access and availability (*chapter 24*).

COVID-19 and access to medicine: Concluding lessons

If there is a disruptive force that helped reckon with generations of struggle and acknowledge the significance of public health to economic prosperity and trade, it is COVID-19. The pandemic unfurled into the globe quietly but emphatically – stopping trade and economic activity. For a

while, by giving *Remdesivir* an orphan drug status out of turn, the US seemed to struggle to reconcile the idiocy of its IP ideology even as New York state was being halted to an economic stop by COVID-19. In all, the pandemic has raised questions on the viability of the current IP system to foster trade, the role of pharmaceutical innovation, the importance of transfer of technological knowledge and generally, the imminence of access to medicine. It has also forced the globe to address the issue of research and development of new treatments for infectious diseases and readiness for future pandemics. The concluding chapter looks at the COVID-19 pandemic and access to medication debate (*chapter 25*). In revisiting the pharmaceutical patent landscape, it examines how the current IP framework has ceased to be a model for delivering products critically needed to respond to global health emergencies.

In presenting conceptual and policy problems affecting poor nations, as well as the contemporary but comparable health-care access issues of developed countries, the book's distinguishing feature is the diversity of issues discussed. By examining the role of civil society groups, patient organizations, regulatory bodies, and government officials in developed and developing nations and their impact on the various legal structures within which they operate, we believe the book will provide a unique insight into the global debate on patents and access to medication discourse. As scholars committed to the cause, we hope that the theme covered in this book will reverberate globally.