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Innovation Policies: Roadblocks to Establishing Sustainable Pharmaceutical Innovation Policies

Doris Estelle Long[1]

INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH, AND PHARMACEUTICALS, Chap.29 (Routledge Press 2021) (co-eds. Srividhya Ragavan and Amara Vanni)

Twenty-five plus years ago, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [2] changed the norms in international protections for pharmaceutical innovations[3] by assuring that such protections would not only be increased, but would also be established as part of a country's *trade* policy. The stronger protections

[1] Professor Emeritus of Law, Former Director of the Center for Intellectual Property, Privacy and Information Security Law, UIC John Marshall Law School; President, Doris Long Consulting; Screenwriter/Producer, VeraKen Productions. I would like to thank Srividhya Ragavan and Amaka Vanni for allowing me to share my views on some practical efforts that I believe can help make public access to medicine a reality. I would also like to thank all those individuals who have graciously given of their time to discuss and debate these issues with me in connection with a documentary Sri and I are making on the impact of trade policy on access to medicines for all socio-economic levels, including the middle class. As always, any errors belong solely to me.

[2] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

[3] Michael Lanthier *et al*., *An Improved Approach to Measuring Drug Innovation Finds Steady Rates of First-in-class Pharmaceuticals, 1987–2011*, 32 HEALTH AFFAIRS, 1433 (2013). I believe that the three-tier innovation classification set forth by Lanthier *et al.* in their article may be useful in determining the appropriate level/type of competitive regulation to assure adequate public access. It divides new molecular entities ("NMEs") into three innovation categories – "(1) whether an NME was the first drug approved in its class; (2) whether it was a therapeutic advance within an existing drug class; or (3) whether it was an addition to a drug class, providing only modest additional benefit relative to other drugs." But for purposes of this chapter, unless specifically identified to the contrary, I am using the term "innovation" and its variants to include all three Lanthier classification categories.

required by TRIPS under both patent[4] and data-exclusivity[5] regimes have become subjects of increasing concern over their adverse impact on the fundamental human right to reasonable access to medicines for all.[6] In 2000, less than *six* years after TRIPS was established, the United Nations Sub-Commission on the Promotion and Protection of Human Rights specifically identified patent protection for pharmaceuticals as creating "apparent conflicts between the intellectual property rights (IPR) regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, [specifically the right to health] on the other."[7] Unfortunately, while the trade policies of TRIPS, in particular its strong protection for IPR in the pharmaceutical sector, continue to drive health costs upwards,[8] potential regulatory doctrines aimed at reducing those costs often remain underutilized or ineffective despite the recognition in TRIPS, Article 8(2) that "appropriate measures" can be taken "to prevent the abuse of IPR by right holders . . . or the resort to practices which unreasonably restrain trade."[9] The need to resolve this issue, to assure both rapid innovation and reasonable access on a socially just basis to the treatments that result from such innovation, has become even more pressing as deaths at the time of publication of this chapter continue to soar from the COVID-19 global pandemic.

This chapter will briefly examine seven "roadblocks" that hinder creation of effective competitive regulatory mechanisms for controlling pharmaceutical prices, and ultimately capping global pharmaceutical profits in a manner supporting socially just, sustainable

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[4] TRIPS, *supra* note 2, at Art. 27 (1) ("patents shall be available for any inventions, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application") (emphasis added).

[5] *Id*. at Art. 39(3) (requiring protection against the "unfair commercial use" of data, including clinical test data, for "pharmaceutical and agricultural chemical products which utilize new chemical entities" where such data is required to be submitted to the government to secure marketing approval"). For a detailed exploration of the interrelationship between intellectual property, including patents, trade secrets (data exclusivity), and trademarks, and access to medicine, see WORLD HEALTH ORG., WORLD TRADE ORG., & WORLD INTELLECTUAL PROP. ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATIONS: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (2013) [hereinafter TRILATERAL REPORT ON ACCESS TO MEDICAL TECHNOLOGIES].

[6] *See, e.g*., International Covenant on Economic, Social and Cultural Rights, art. 12(1), Jan. 3, 1976, S. Treaty Doc. No. 95–19, 993 U.N.T.S. 3 ("The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the *highest attainable standard* of physical and mental health.") (emphasis added); UN Resolution Adopted by the General Assembly on September 25, 2015, The 2030 Agenda for Sustainable Development, A/Res/ 70/1, Goal 3.8 (October 21, 2015) ("Achieve universal health coverage, including … access to quality essential health-care services and access to safe, effective, quality and *affordable* essential medicines and vaccines for all.") (emphasis added).

[7] Sub-Commission on Human Rights Res. 2000/7, *Intellectual Property Rights and Human Rights*, ESCOR, Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg,, U.N. Doc. E/CN.4/Sub.2/Res/2000/7, ¶2 (2000).

[8] *See infra* Part I C *"*Abuses" of the TRIPS Protection Regime" and materials cited therein.

[9] TRIPS, *supra* note 2, at Art. 8(2); *see also id.* at Art. 40 (2) ("Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices *or conditions* that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.") (emphasis added).

innovation. I use the term "competitive regulatory mechanisms" in its broadest sense—to include all attempts to regulate price and access, allowing either greater price competition within the pharmaceutical sector and/or greater access to affordable medicines. For purposes of this chapter, these competitive mechanisms include reducing the likelihood of improvidently granting patents covering innovations that lack the requisite inventiveness,[10] establishing limitations on a patent holder's exclusive rights,[11] such as through compulsory licenses[12] granted when protected drugs are not "reasonably available" on the domestic market,[13] and efforts to increase competition by removing competitive access barriers for generics, biosimilars, and gray market imports.[14] This chapter explores seven currently existing "roadblocks" in efforts to create such mechanisms and suggests potential avenues to overcome them with the goal of creating *sustainable* innovation with a strong social justice component to strengthen access to medicines, while still providing the necessary R&D support that *rational* protection of IPR in pharmaco-medical innovations can provide.[15]

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[10] *See*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 566 U.S. 66 (2012), and discussion *infra* Part II A regarding recalibration of the patent system to reduce improvidently granted patents under "Roadblock One."

[11] TRIPS, *supra* note 2, at Art. 28(1)(c), Art. 28(1)(b) (these rights include the right to prevent unauthorized third parties from "making, using, offering for sale, selling, or importing" a patented product, and from "using, offering for sale, selling or importing," products "attained directly by" a patented process).

[12] *See id.* at Art. 31(f) (allowing compulsory licenses where the use is "authorized predominantly for the supply of the domestic market of the Member authorizing such use"); *Id.* at Art. 31bis (allowing compulsory licenses for export to "eligible countries," that lack sufficient manufacturing capacity to supply their domestic needs).

[13] *See* The Patent Act § 84(1), No. 39 of 1970, INDIA CODE (1998) (requiring "enhancement of a known efficacy" for new use patents) and discussion *infra* Part II A regarding patent law recalibrations for "new uses" under "Roadblock One."

[14] *See* Medicines and Related Substances Act 90 of 1997 § 15C (S. Afr.) (providing for gray market imports for pharmaceuticals) and discussion *infra* Part II B(ii) regarding Gray Market Reform under "Roadblock Two."

[15] I believe patents remain a viable component of a sustainable innovation system, subject to recalibration. They have served an historic, and important source for encouraging private sector pharmaceutical innovation. *See, e.g*., Jayashree Watal & Rong Dai, WTO Staff Working Paper on Product Patents and Access to Innovative Medicines in a Post-TRIPS-Era, Staff Working Paper ERSD-2019-05, at 1 (Apr. 4, 2019) [hereinafter WTO Staff Working Paper] ("Using launch data from 1980 to 2017 covering 70 markets, the study finds that introduction of product patent for pharmaceuticals in the patent law has a positive effect on launch likelihood, especially for innovative pharmaceuticals. However, this effect is quite limited in low-income markets. Also, innovative pharmaceuticals are launched sooner than non-innovative ones, irrespective of the patent regime in the local market."); Karin Timmermans & Togi Hutadjulu, *The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals*, WORLD HEALTH ORGANIZATION [WHO] 8 (2000), [hereinafter ASEAN Workshop Report], https://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf, ("Patents may have positive 'dynamic effects' so far as they foster the development of new products that benefit society."). For a discussion of the required recalibration, see *infra* Part II A regarding suggested patent law recalibrations under "Roadblock One."

Although, the apparently easiest policy solution to combatting high drug costs would be some form of price control achieved through direct price control regulations, caps on patient costs under health care plans, or low-cost compulsory licenses,[16] price regulation alone is not enough. On the contrary, price regulation, without regard to its impact on future R&D funding, is a recipe for disaster. Shorn of rhetorical flourishes, the real issue is to determine the level of return on investment (ROI) sufficient to encourage future innovation by private enterprises, while allowing for reasonably priced deliverables to the public.

As the World Health Organization (WHO) recognized, such regulatory mechanisms are only part of a total strategy for resolving the growing global health care crisis.[17] Yet I believe that unless we create regulatory models for sustainable innovative development—that assure both reasonable access to current medical treatments *and* R&D support for future innovations including, but not limited to, *rational* intellectual property protection for the results of such innovation—we will be unable to craft a global health system post-TRIPS that meets the critical present *and future* health needs of all peoples. This chapter is a modest effort to provide some potential pathways toward that goal.

In Part I, I explore the confluence of factors that has created consistent and pernicious barriers to reasonable access to medicines. Although there are many such barriers, including under-resourced health systems, I focus on those created as a result of skyrocketing prices in the pharmaco-medical sector because of their persistence and the growing recognition that such barriers are not merely a result of socio-economic disparities, but threaten public health policies of even the most developed countries. I contend that the mandatory patent protection of pharmaceuticals required as a result of accession to TRIPS forced countries *as a question of trade policy* to adopt a system that has proven readily subject to industry abuse. This abuse has ultimately resulted in the extension of patent monopolies far beyond the 20-year term required by TRIPS. I explore the scope and practices of abuses that impede price-reductive competition, including evergreening, patent thickets, litigation excesses and non-transparent pricing methodologies and contend that these abuses can be curtailed through effective competitive regulatory mechanisms that include new models for sustainable innovation, with a strong social justice component that reduces or seriously erodes existing access barriers

In Part II, I explore the challenge of creating effective regulatory mechanisms that meet the dual goals of supporting sustainable innovation while reducing existing access

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[16] *See* TRIPS, *supra* note 2, at Arts. 31, 31(bis); Jerome Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. LAW MED. ETHICS 247 (2009); WTO Staff Working Paper, *supra* note 15; Roger Kampf, *Special Compulsory Licenses for Export of Medicines: Key Features of WTO Members' Implementing Legislation*, RSD-2015-07 (July 31, 2015).

[17] *See also* Overall Programme Review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Review Panel Report, WORLD HEALTH ORGANIZATION [WHO] (Nov. 2017), https://www.who.int/medicines/innovation/gspa-review/en/; U.N. Secretary General, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, (Sept. 14, 2016), http://apps.who.int/medicinedocs/documents/s23068en/s23068en.pdf.

barriers. I identify seven overlooked or frequently underappreciated roadblocks that often hamper reform efforts and explore potential solutions, or workarounds tried by diverse countries to combat them. These seven roadblocks are (1) the natural hesitation to start the daunting process of reform for such a complex issue, including patent law recalibration; (2) the adoption of "quick fixes," such as compulsory licenses and grey market imports, without safeguards to ensure necessary continued innovation; (3) lack of transparency in drug pricing methodologies; (4) hidden competitive barriers from unaffiliated regulations, such as those governing school health, that impede accessibility even in the face of patent-based reforms; (5) an unrequited romance with technology that ignores the need to assure that AI does not raise new accessibility barriers; (6) failing to act because purported industry voluntary self-regulation gives rise to an illusion that no further steps are necessary; and (7) the mirage that differential pricing resolves all accessibility challenges. I conclude by stressing the need to begin addressing these seven roadblocks so that access to medicine for all can be ensured as quickly as possible. Removing these roadblocks may not fully remove all access barriers, but it is undeniably a critical first step.