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ACCESS TO MEDICINES AND PHARMACEUTICAL PATENTS: FULFILLING THE PROMISE OF TRIPS ARTICLE 31BIS

Ezinne Miriam Igbokwe & Andrea Tosato***

Abstract

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) is one of the cornerstones of the World Trade Organization (WTO). TRIPS requires all WTO member countries (Members) to adopt minimum standards for the protection of intellectual property (IP). This international treaty is highly controversial. Its critics claim that TRIPS imposes a wealth transfer from poorer Members (net IP importers) to richer ones (net IP exporters). Its supporters maintain that trade between developing and developed economies cannot thrive without an internationally-harmonized IP framework. The most contentious issue has long been the impact of the TRIPS patents regime on access to medicines.

Our Article contributes to this debate by illuminating an oft-overlooked facet of TRIPS: Article 31bis. Enacted following the Doha Declaration of 2001, this provision was designed to enable Members with inadequate manufacturing capabilities to import patented pharmaceuticals produced by generics manufacturers under an export compulsory license (ECL) issued by another Member. Initially welcomed with enthusiasm, ECLs have enjoyed minimal success.

We propose an explanation for the current fallow state of Article 31bis and suggest approaches to fulfill its promise. First, we identify and analyze the factors that deter Members from making recourse to ECLs. Second, we posit that, under current law, pooled procurement is the only viable avenue to exploit ECLs and elucidate pathways for Members to pursue this strategy. Third, we advance the view that TRIPS reform is necessary to unlock fully the potential of Article 31bis. We proffer targeted amendments to enhance the flexibility and economic viability of ECLs, detailing the ways in which these revisions would bolster the flow of patented pharmaceuticals from the Global North to the Global South.

The Covid-19 pandemic has reawakened public opinion to the glaring disparity in access to medicines worldwide. It has also exposed the unprecedented extent to which production capacity for mRNA vaccines, antivirals, monoclonal antibodies and other life-saving medicines is concentrated in a small number of wealthy countries. It can only be hoped that this realization will spark the impetus to reform Article 31bis.

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Many thanks to Professors Daniel J. Gervais, Paul Torremans, Christopher S. Yoo, and Polk Wagner for their suggestions and observations.

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INTRODUCTION

The attainment of equipoise between access to medicines¹ and pharmaceutical patents is as desirable as it is arduous.² Throughout the 20th century, lawmakers across the world struggled to balance stimulating the development of new medical inventions through the patent system with ensuring that citizens have affordable access to life-enhancing treatments.³ Their efforts yielded a broad spectrum of diverse solutions, which reflected the underlying heterogeneity in social, political and economic realities. At one end lay jurisdictions with privatized healthcare systems and unrestricted patentability for pharmaceuticals;⁴ at the other, countries with universal public healthcare coupled with a complete bar on medical patents.⁵ In between lay a veritable galaxy of intermediate positions, typically blending partially-subsidized healthcare with narrow protection of pharmaceutical patents.⁶

Compulsory licensing of patents⁷ was often a fundamental tessera in these complex mosaics.⁸ Shaped by a rich history, compulsory licenses (CL) share a common core across all jurisdictions: they are a form of permission that a government grants to a public or private entity to exploit the subject matter of a patent without the consent of the patent holder.⁹ CLs constitute a meaningful exception to the proprietary nature of patents. They loosen a patentee's otherwise complete control over the commercialization of the protected invention.¹⁰

In their struggle to reach equilibrium between access to medicines and pharmaceutical patents, countries relied on CLs in different ways. Some utilized them purely as a remedy to chastise patentees that charged excessive prices or artificially constrained supply. Other jurisdictions went a step

¹ In this Article, we use the words "pharmaceuticals" and "medicines" synonymously.

² The body of scholarship analyzing the interface between patent protection for pharmaceutical inventions and access to medicines is vast. *See generally* ELLEN F.M. 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2016); VALBONA MUZAKA, THE POLITICS OF INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES; Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions*, 10 J. INT. ECONOMIC LAW 921 (2007); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005).

³ *See infra* notes 91-103 and accompanying text.

⁴ *See infra* notes 92-93 and accompanying text.

⁵ *See infra* note 101-103 and accompanying text.

⁶ *See infra* notes 93-101 and accompanying text.

⁷ In this Article, we abbreviate the phrases "compulsory licensing of patents" and "patent compulsory licenses" referring to "compulsory licensing" and "compulsory licenses" respectively.

⁸ *See infra* notes 95, 116-120 and accompanying text.

⁹ *See infra* notes 94-115 and accompanying text.

¹⁰ *See generally* Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461 (2011); Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047 (2009).

further. They enacted special regimes that facilitated the issuance of CLs for medical patents, with the declared intent of expanding access to medicines and stimulating local biochemical manufacturing capabilities.¹¹

Crucially, towards the end of 20th century, the policy choices made by countries to balance access to medicines and medical patents evolved from a domestic matter into a bone of international contention.¹² “Developed countries”¹³ which granted far-reaching patents for pharmaceutical inventions increasingly called for worldwide adoption of protection levels aligned with their own, bemoaning international drug piracy and free riding.¹⁴ “Developing countries”¹⁵ resisted these demands. They retorted that refusing to award medical patents or liberally subjecting them to CLs was entirely within their sovereign prerogative. They maintained that their priority was safeguarding access to medicines for their citizens, rather than protecting the revenue streams of foreign pharmaceutical companies.¹⁶

This impasse was broken with the birth of the World Trade Organisation (WTO)¹⁷ and the annexed Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁸ In return for tariff-free access to the agricultural and commodities markets of developed countries, developing countries accepted that all WTO Members (Members) would be bound to incorporate the intellectual property (IP) minimum standards articulated by TRIPS into their domestic law.¹⁹ Crucially, this treaty mandates patent protection for all types of technical inventions, including pharmaceutical

¹¹ See *infra* notes 114-115 and accompanying text.

¹² See *infra* notes 123-132 and accompanying text.

¹³ Though almost never precisely defined, the developed/developing countries dichotomy is commonly used by international organizations, including the WTO, the United Nations and the World Bank. Throughout this Article, the expression “developed countries” is used to refer to “high income” countries as defined by the World Bank Atlas Method. Coextensively, see the expression “developing countries” is used as an umbrella term to encompass “upper-middle income”, “lower-middle income” and “low income” countries, as defined by the World Bank Atlas Method. See World Bank, *How Does the World Bank Classify Countries?* (World Bank) <https://datahelpdesk.worldbank.org/knowledgebase/articles/378834-how-does-the-world-bank-classify-countries>.

¹⁴ See generally Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89 (1993). See also JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 88–90 (providing a detailed analysis of the free-riding concerns linked to pharmaceutical patents).

¹⁵ See *supra* note 13.

¹⁶ See generally Gutterman, *supra* note 14; A. Samuel Oddi, *The International Patent System and Third World Development: Reality Or Myth*, 1987 DUKE L.J. 831, 831–37 (1987).

¹⁷ See Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter WTO Agreement].

¹⁸ See 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].

¹⁹ See *infra* notes 133-149 and accompanying text.

products and processes.²⁰ Softening this bright-line rule, TRIPS includes “flexibilities” that Members can utilize to curtail the rights of patentees,²¹ including the possibility of issuing CLs.²² However, Article 31²³ imposes limitations on their scope and duration, and specifies that CLs must be “predominantly” for the supply of the market of the issuing Member.²⁴

The TRIPS regime for medical inventions and CLs attracted vehement criticisms, with some commentators going so far as to call it “structural violence”.²⁵ The Global North was accused of foisting its law upon the Global South,²⁶ establishing a “neo-colonial” international trade law framework that would coerce formally sovereign, but economically dependent, developing countries to recognize and enforce the property rights of developed countries.²⁷ In this novel legal order, medicines would be unaffordable for the world’s poor, condemning them to suffer from curable illnesses. These voices grew louder during the HIV/AIDS global epidemic, when a critical defect in this framework emerged, with painful consequences.²⁸

Prior to TRIPS, developing countries would procure unavailable or unaffordable patented pharmaceuticals from jurisdictions in which they were abundantly and cheaply available either because they were subject to a CL, or not patented at all.²⁹ TRIPS abruptly precluded these avenues by rendering pharmaceutical patents mandatory throughout the WTO and barring the export of products manufactured under CLs.³⁰ Under this treaty, the only option for Members seeking to lower prices or increase the supply of a patented medicine was to issue a CL to a domestic manufacturer, instructing them to provide the required pharmaceutical. However, if no local producer possessed the necessary infrastructure and know-how, issuing such a CL would be futile.³¹ As TRIPS was gradually implemented across the WTO, it became evident that the combined effect of its patent and compulsory

²⁰ See *infra* notes 169-182 and accompanying text.

²¹ See *infra* notes 183-186 and accompanying text.

²² See *infra* notes 188-204 and accompanying text.

²³ In this Article, the term “Article” refers to the Articles of TRIPS.

²⁴ See *infra* note 200 and accompanying text.

²⁵ See Amaka Vanni, *Lessons from COVID-19 for Medicines Access*, in INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES 484 (Srividhya Ragavan & Amaka Vanni eds., 2021). See *infra* notes 205-207 and accompanying text.

²⁶ The terms Global South and Global North are used in various ways in social sciences. In this Article we use these terms borrowing from Alfred López “What defines the global South is the recognition by peoples across the planet that globalization’s promised bounties have not materialized, that it has failed as a global master narrative. The global South also mark seven celebrates, the mutual recognition among the world’s subalterns of their shared condition at the margins of the brave new neoliberal world of globalization”; see Alfred J. López, *Introduction: The (Post) Global South*, THE GLOBAL SOUTH 1 (2007).

²⁷ See Andreas Rahmatian, *Neo-Colonial Aspects of Global Intellectual Property Protection*, 12 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 40 (2009). See *infra* notes 205-207 and accompanying text.

²⁸ See *infra* notes 216-218 and accompanying text.

²⁹ See *infra* notes 211 and accompanying text.

³⁰ See *infra* notes 212-213 and accompanying text.

³¹ See *infra* notes 211 and accompanying text.

licensing regimes was to markedly reduce access to patented medicines for Members without domestic pharmaceutical production capabilities.³²

At the WTO Doha Ministerial Conference of 2001, Members recognized this issue and agreed that it necessitated an “expeditious solution”.³³ Following two years of labored negotiations, Article 31*bis* was born.³⁴ This provision engenders a mechanism that, by way of exception to Article 31, enables a Member with insufficient pharmaceutical manufacturing capabilities to import patented medicines supplied by a generics drugs producer operating under an export compulsory license (ECL) issued by another Member. At the time of its adoption, lawmakers, non-governmental organizations (NGO) and commentators welcomed this treaty amendment as a sorely-needed revision of the TRIPS compulsory licensing framework.³⁵ There were high hopes that ECLs would evolve into powerful tools for developing countries in their endeavors to deliver adequate access to medicines for their citizens. Moreover, the collaborative nature of this novel legal device was praised for forging a solidaristic pathway through which the Global South might benefit from the know-how and technological advancements of the Global North.³⁶ Regrettably, this optimism has slowly faded, as only one ECL has been issued and successfully executed over the past two decades.

This Article investigates the current fallow state of Article 31*bis* and proposes strategies to fulfill its promise. The rationale for this enquiry is twofold. First, access to medicines continues to be a struggle in many developing countries. Though great strides have been made in making pharmaceuticals for HIV/AIDS and other deadly illnesses more readily available worldwide, patented treatments for cancer, diabetes, hepatitis, and many other chronic diseases continue to be expensive and hard to access. Members without developed pharmaceutical production capabilities are owed an explanation for the continued failure of ECLs.

Second, the SARS-CoV-2³⁷ (Covid-19) pandemic has illuminated an often-overlooked transformation that has unfolded over the past two decades. Therapeutic biological products (biologics), such as mRNA vaccines, monoclonal antibodies and chimeric antigen receptor T (CAR-T) cells, have become the gold standard, if not the only treatment for a growing number of illnesses.³⁸ The manufacturing capabilities essential to produce biologics are

³² See *infra* notes 217-218 and accompanying text.

³³ See *infra* notes 221-223 and accompanying text.

³⁴ See *infra* notes 226-229 and accompanying text.

³⁵ See *infra* notes 220-245 and accompanying text.

³⁶ See *infra* notes 246-248 and accompanying text.

³⁷ See Alexander Gorbalenya et al., *The Species Severe Acute Respiratory Syndrome-Related Coronavirus: Classifying 2019-NCoV and Naming It SARS-CoV-2*, 5 NATURE MICROBIOLOGY 536 (2020).

³⁸ The Public Health Services Act, 42 U.S.C. § 262(i) (defining a biological product as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of

fundamentally different from those for conventional chemical drugs.³⁹ Even among developed countries, very few have adequate production infrastructure for these types of pharmaceuticals.⁴⁰ In this context, ECLs could become a potent weapon to buttress access to biologics internationally, if they were to operate as originally intended.

This article makes two primary contributions to the existing body of scholarship on Article 31*bis*. First, it analyzes the factors that might be responsible for the underutilization of ECLs and pinpoints those that create the most substantial obstacles. Diverging from a view held by numerous scholars, activists and NGOs, we contend that governmental and corporate interferences, albeit not entirely immaterial, do not currently constitute a substantial obstacle to the utilization of ECLs under Article 31*bis*.⁴¹ In similar vein, we refute the widely-propounded notion that domestic laws and free trade agreements materially hinder recourse to ECLs.⁴² We posit that the primary flaws undermining Article 31*bis* are the complexity of its procedural dimension and, above all, its inability to offer an economically viable proposition to generic medicines manufacturers. Regarding the former, we highlight the onerousness of the mandatory information disclosures demanded of Members that seek to utilize export compulsory licensing. We equally criticize the excessive rigidity of the Article 31*bis* requirements designed to prevent pharmaceuticals produced under ECLs from being diverted away from their intended beneficiaries and sold into developed markets.⁴³ Regarding the latter, we submit that the body of rules under consideration lumbers prospective pharmaceutical producers with unnecessary costs, makes it harder for them to achieve economies of scale and excessively exposes them to litigation risk from patentees.⁴⁴

As its second contribution, this article proffers actionable interventions to realize the full potential of ECLs. We advance the view that, under current law, pooled procurement constitutes the most effective strategy to overcome the economic challenges undermining ECLs. We highlight that, in determinate circumstances, Article 31*bis*(3) allows multiple Members to aggregate their demand for a patented pharmaceutical and thus afford interested generics manufacturers a better chance to attain the levels of production needed for profitability.⁴⁵ This is followed by an exposition of our thesis that reform of the current legal framework is required to maximize the latent opportunities of ECLs. We assess both the merits and viability of a

arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”).

³⁹ See *infra* note 332 and accompanying text.

⁴⁰ See generally Erwin A. Blackstone & P. Fuhr Joseph, *The Economics of Biosimilars*, 6 AM HEALTH DRUG BENEFITS 469 (2013); Carlos Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, SOUTH CENTRE POLICY BRIEF No. 57 9 (2019).

⁴¹ See *infra* Part III.A.

⁴² See *infra* Part III.B.

⁴³ See *infra* Part III.C.

⁴⁴ See *infra* Part III.D.

⁴⁵ See *infra* Part IV.B.

broad range of alternative interventions. We conclude that radical revisions either to the entire TRIPS patent regime or Article 31, albeit hypothetically effective, would be unlikely to ever attract the political support necessary for their enactment. Instead, we propose targeted amendments aimed at enhancing the flexibility and economic viability of Article 31*bis*, submitting that they would both bolster flows of know-how and patented pharmaceuticals from the Global North to the Global South and stand a chance of garnering the necessary political support.⁴⁶

This Article proceeds in four parts. In Part I, we provide a historical and comparative primer to the right of access to medicines, patent protection for pharmaceutical inventions and compulsory licensing. This is followed in Part II by an analysis of the TRIPS patent regime, compulsory licensing under Article 31, and Article 31*bis*. Here, we bring into sharp relief the “mischief”⁴⁷ that export compulsory licensing was designed to redress and dissect the body of rules enacted for its resolution. In Part III, we investigate the possible causes of the limited utilization of Article 31*bis* and present our thesis that procedural complexities and economic challenges fundamentally undermine the legal device under consideration. Part IV focuses on approaches to fulfill the promise of ECLs both within the confines of current law and through law reform.

I. ACCESS TO MEDICINES, PHARMACEUTICAL PATENTS AND COMPULSORY LICENSING

This Part explores access to medicines, patent protection for pharmaceutical inventions, and compulsory licensing. The aim of this analysis is threefold. First, to highlight the significant extent to which these three topics are intertwined. Second, to chart the evolution of this entanglement over time and across jurisdictions. Third, to expound key concepts that are foundational for the discourse in Parts II-IV. The issues under consideration are viewed through historical and comparative lenses to emphasize the depth and breadth of their roots, and the significance of the international context.

A. Access to Medicines

Access to medicines comprises a public health dimension and an individual rights dimension. An understanding of both is required to fully appreciate the social, legal and economic issues that ensued after the adoption of the TRIPS patent regime and its compulsory licensing framework.

Collective action to promote the well-being of populations has a long

⁴⁶ See *infra* Part IV.C.

⁴⁷ In legal interpretation, a long-recognized approach is to construe statutory provisions in light of the “mischief” or “evil” that the law in question was designed to address. See generally Samuel L. Bray, *The Mischief Rule*, 109 GEO. L.J. 967 (2021).

history.⁴⁸ Ancient Indian, Mayan, and Mycenaean civilizations built sophisticated sewage networks, water conduits and public baths for communal use.⁴⁹ Similarly, illuminated by the teaching of Hippocrates, Ancient Greek city states appointed public physicians to prevent and cure illnesses, establishing a custom that would later be embraced by the Persian, Macedonian and Roman Empires.⁵⁰

Nevertheless, throughout antiquity, the Middle Ages and the Enlightenment, public health initiatives focused exclusively on building infrastructure, preventing contagious illnesses, and palliative care for the sick and elderly.⁵¹ Comparable attention was not devoted to medicines, due to the relative underdevelopment of pharmacology as science.

It was not until the 18th and 19th centuries that public health policies started incorporating medicines. Fledgling nation states discovered that military conquest and industrialization required healthy, growing = populations.⁵² In pursuit of these objectives, several European countries and the United States mandated mass inoculations for smallpox and other contagious diseases.⁵³ These were the first instances of governments grappling with the challenges associated with sourcing, distributing, and administering pharmaceuticals on a large scale.

The 20th century witnessed an unprecedented expansion of public health initiatives, including the socialization of healthcare.⁵⁴ In the years preceding World War I, several countries started introducing social insurance for the least privileged members of society.⁵⁵ This solidaristic approach to healthcare slowly permeated Europe, Japan and the USSR during the 1920s and 1930s, spreading worldwide after World War II.⁵⁶ Between the 1950s and 1990s, most developed and developing countries, with the conspicuous exception of the United States, established publicly-subsidized systems aiming to provide “all individuals and communities with the health services they need without

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⁴⁸ On the history of public health see generally Christopher Hamlin, *The History and Development of Public Health in Developed Countries*, in OXFORD TEXTBOOK OF GLOBAL PUBLIC HEALTH 19 (Roger Detels et al. eds., 6th ed. 2015); Than Sein, *The History and Development of Public Health in Low- and Middle-Income Countries*, in OXFORD TEXTBOOK OF GLOBAL PUBLIC HEALTH 37 (Roger Detels et al. eds., 6th ed. 2015); JOHN TOBIN, THE RIGHT TO HEALTH IN INTERNATIONAL LAW 14–51 (2012); DOROTHY PORTER, HEALTH, CIVILIZATION AND THE STATE: A HISTORY OF PUBLIC HEALTH FROM ANCIENT TO MODERN TIMES (1999); GEORGE ROSEN, A HISTORY OF PUBLIC HEALTH (1958).

⁴⁹ See generally PORTER, *supra* note 48, at 10–23; ROSEN, *supra* note 48, at 1–5.

⁵⁰ See generally PORTER, *supra* note 48, at 18–23; ROSEN, *supra* note 48, at 6–26.

⁵¹ See generally PORTER, *supra* note 48, at 23–45; ROSEN, *supra* note 48, at 26–100.

⁵² See generally PORTER, *supra* note 48, at 45–61; ROSEN, *supra* note 48, at 107–66.

⁵³ See Arthur Boylston, *The Origins of Inoculation*, 105 J. R. SOC. MED. 309 (2012); ROSEN, *supra* note 48, at 161–65.

⁵⁴ See generally PORTER, *supra* note 48, at 61–147; TOBIN, *supra* note 48, at 37–39; Hamlin, *supra* note 48; Sein, *supra* note 48.

⁵⁵ See generally PORTER, *supra* note 48, at 96–128 (focusing on Germany, France, Sweden and England).

⁵⁶ See generally Hamlin, *supra* note 48; Sein, *supra* note 48.

suffering financial hardship”⁵⁷ (“universal health coverage”).⁵⁸ Notably, the adoption of the universal health coverage model coincided with the meteoric rise of pharmacology. As governments assumed an expanding role in the delivery of health care, chemical drugs and biologics became irrevocably paramount to the treatment of illnesses.⁵⁹ In this novel scientific environment, access to medicines was cardinal for the success of the universal healthcare systems of each country.

During the second half of the 20th century, alongside its mounting relevance in the public health sphere, access to medicines acquired an ulterior dimension as an individual right. In international law, it flourished as a derivative human right, stemming from the rights to life and health.⁶⁰ The right to life lies at the heart of every major international human rights convention,⁶¹ and has been deemed *jus cogens* both by courts and commentators.⁶² The prevailing view is that this human right obliges

⁵⁷ The World Health Organization defines “universal health coverage” as “all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course”; see [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)).

⁵⁸ See generally Rafael Lozano et al., *Measuring Universal Health Coverage Based on an Index of Effective Coverage of Health Services in 204 Countries and Territories, 1990–2019: A Systematic Analysis for the Global Burden of Disease Study 2019*, 396 THE LANCET 1250 (2020).

⁵⁹ See generally Hamlin, *supra* note 48; Sein, *supra* note 48.

⁶⁰ See generally Niels Petersen, *The Right to Life, International Protection*, MAX PLANCK ENCYCLOPEDIA PUB. INT’L L. (June 2019), available at <https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e841>; HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES (2008); Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT’L L.J. 325 (2003).

⁶¹ For example, the Universal Declaration of Human Rights art. 3 G.A. Res. 217A, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 10, 1948) (“everyone has the right to life, liberty and the security of the person”) [hereinafter UDHR]; the International Covenant on Civil and Political Rights art. 6(1), adopted Dec. 19, 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 (“Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”) [hereinafter ICCPR]; American Convention on Human Rights art. 4, Nov. 22, 1969, O.A.S.T.S. No. 36, 1144 (Every person has the right to have his life respected.).

⁶² For a judicial example of the right to life being recognized as *jus cogens*, see Street Children Case (Morales v. Guatemala), Judgment of Nov. 19, 1999 Inter-Am. Ct. H.R. (Ser. C) No. 63, 139, available at http://www.corteidh.or.cr/seriecing/seriec_63_ing.doc. See also Paul W. Gormley, *The Right to Life and the Rule of Non-Derogability: Peremptory Norms of Jus Cogens* in THE RIGHT TO LIFE IN INTERNATIONAL LAW 120, 122 (Bertrand G. Ramcharan, ed. 1985) (describing the right to life as the “most fundamental human right”); Karen Parker, *Jus Cogens: Compelling the Law of Human Rights*, 12 HASTINGS INT’L & COMP. L. REV. 411, 431–32 (1989) (providing an overview of the right to life as *jus cogens*). The Vienna Convention on the Law of Treaties, art. 53 describes *jus cogens* “a peremptory norm of general international law ... accepted and recognized by the international community of states as a whole as a norm from which no derogation is permitted.” Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, 340, 8 I.L.M. 679, 692.

countries not merely to abstain from depriving people of their life arbitrarily, but also to actively take steps to enable individuals to survive and live with dignity.⁶³ From this premise, the conclusion that the right to life includes a right to access life-saving medicines followed syllogistically, as soon as pharmaceuticals became essential to survive illnesses. For example, the Human Rights Committee that monitors the enforcement of the International Covenant on Civil and Political Rights⁶⁴ has implied that the right to life enshrined in Article 6(1) of this treaty encompasses access to life-saving medical treatments.⁶⁵ Similarly, the Inter-American Commission on Human Rights admitted a case in which the petitioners argued that El Salvador's refusal to purchase essential HIV/AIDS medicines had violated their right to life under Article 4 of the American Convention on Human Rights.⁶⁶

The international human right to health has provided an even stronger platform for the development of access to medicines as a derivative human right.⁶⁷ Numerous international law instruments expressly recognize a right to health.⁶⁸ Mirroring the interpretive trajectory of the right to life, the right to health has been construed ever more broadly to include access to all forms of treatments, including medicines.⁶⁹ For example, Article 12 of the International Covenant on Economic, Social and Cultural Rights states that individuals have a right to "the highest attainable standard of physical and mental health" and requires signatory countries to take the necessary steps for "the prevention, treatment and control of epidemic, endemic ... and other

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⁶³ See HESTERMEYER, *supra* note 60, at 116–17; Yamin, *supra* note 60, at 330–32; BERTRAND G. RAMCHARAN, *THE RIGHT TO LIFE IN INTERNATIONAL LAW* 1–33 (1985). *Contra* see Frank Przetacznik, *The Right of Living as a Basic Human Right*, 6 SRI LANKA J. INT'L L. 203, 586–587, 603 (1994) (arguing in favor of a narrow interpretation of the right to life).

⁶⁴ See *supra* note 61.

⁶⁵ See *The Right to Life*, U.N. GAOR Human Rights Comm., 37th Sess., Supp. No. 40, at Gen. Comment No. 6, §§ 1–5, U.N. Doc. A/37/40 (1982); See also Concluding Observations of the Human Rights Committee: Peru, TT 13, 15, U.N. Doc. CCPR/C/79/Add.72 (1996). See HESTERMEYER, *supra* note 60, at 116–17; Yamin, *supra* note 60, at 331–32.

⁶⁶ See *Odir Miranda v. El Salvador*, Case 12.249, Report No. 29/01, Inter-Am. C.H.R., Annual Report 2000, OEA/Ser./L/V/II.111, Doc. 20 Rev. (2001), available at <http://hrlibrary.umn.edu/cases/29-01.html>.

⁶⁷ The body of scholarship expounding the human right has grown mightily over the past decade; see generally TOBIN, *supra* note 48; HESTERMEYER, *supra* note 60, at 83–84.

⁶⁸ For example, see UDHR, *supra* note 61, art. 25 ("Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including ... medical care"); International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3 (adopted Dec. 16, 1966) art. 12 ("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. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: ... The prevention, treatment and control of epidemic, endemic, occupational and other diseases") [hereinafter ICESCR]. For an exhaustive list see HESTERMEYER, *supra* note 60, at 83.

⁶⁹ See Yamin, *supra* note 60, at 336–41 (providing an exhaustive analysis of this trajectory).

diseases".⁷⁰ In providing the authoritative interpretation of this provision, the Committee on Economic, Social and Cultural Rights, expressly specified that it includes a right to access "essential drugs"⁷¹ of appropriate quality, in sufficient quantities, and without discrimination.⁷²

Both bolstering and resonating with these international law developments, during the second half of the past century, access to medicines was increasingly recognized as an individual right in domestic laws. The national constitutions and primary legislations of many countries have gradually incorporated individual rights to health and healthcare that include access to pharmaceuticals required for a dignified standard of living.⁷³ Moreover, these rights are often directly justiciable, with individuals entitled to take legal action against their governments if they fail to adequately cater to their health needs, including when they are denied medicines.⁷⁴

Thus, over the course of the 20th century, public health and human rights laws increasingly demanded that countries ensure access to medicines for their citizens. The approval, procurement, distribution, and affordability of pharmaceuticals inexorably became fundamental priorities of national governments. In the years preceding the negotiations that resulted in the birth of WTO and TRIPS, this issue was felt with mounting acuity in developing countries, bringing unprecedented attention to the patent protection of pharmaceuticals, and CLs.

B. Patents and Pharmaceutical Inventions

Patent law grants a person a time-limited, exclusive right to exploit economically a technical invention within a determinate territory, in return for a complete disclosure of its inner workings.⁷⁵ Throughout history, diverse

⁷⁰ ICESCR, *supra* note 68, art 12.2(c).

⁷¹ General Comment 14: The Right to the Highest Attainable Standard of Health, U.N. Comm. on Econ., Soc. & Cultural Rts., 20th Sess., 12, U.N. Doc. E/C.12/2000/4 (2000) [hereinafter General Comment 14]. The ESCR Committee defined the notion "essential drug" by referring to the WHO List of Essential Drugs. This list is updated regularly by the WHO. The current version is available at <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>.

⁷² General Comment 14, *supra* note 71, para 12.

⁷³ See generally Courtney Jung et al., *Economic and Social Rights in National Constitutions*, 62 AM. J. COMP. L. 1043 (2014); Jody Heymann et al., *Constitutional Rights to Health, Public Health and Medical Care: The Status of Health Protections in 191 Countries*, 8 GLOB PUBLIC HEALTH 639.

⁷⁴ See generally Lawrence O. Gostin et al., *The Legal Determinants of Health: Harnessing the Power of Law for Global Health and Sustainable Development*, 393 THE LANCET 1857 (2019); ALICIA ELY YAMIN & SIRI GLOPPEN, LITIGATING HEALTH RIGHTS: CAN COURTS BRING MORE JUSTICE TO HEALTH? (2011).

⁷⁵ See generally PETER S. MENELL ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 2020 VOL. I PERSPECTIVES, TRADE SECRETS AND PATENTS: VOL I PERSPECTIVES, TRADE SECRETS AND PATENTS, ch. III.

normative justifications have been offered as the basis of patent protection.⁷⁶ At present, lawmakers and courts worldwide have predominantly embraced the utilitarian view that the purpose of this branch of commercial law is to incentivize research, development and marketing of inventions for their economic and societal welfare benefits.⁷⁷

The birth of modern patents is typically linked to the English Statute of Monopolies of 1623.⁷⁸ This law sparked the evolution of patents from arbitrarily-awarded sovereign privileges to statutory property rights conferred pursuant to a regulated, administrative process.⁷⁹ The patent custom travelled across the Atlantic⁸⁰ and bloomed upon the branches of the first federal US Patent Act of 1790, shortly after the ratification of the Constitution.⁸¹ Most European countries, as well as Russia and Japan, followed suit, creating their own patent regimes in the following century.⁸² Though these laws were not entirely homogenous, their policy aims and key tenets were aligned.⁸³

During the 19th century, the growth of transnational trade prompted inventors increasingly to seek patent protection in multiple jurisdictions. Such attempts were often unsuccessful due to substantive and procedural

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⁷⁶ See Giuliano G. Castellano & Andrea Tosato, *Commercial Law Intersections*, 72 HASTINGS L.J. 999, 1040–41 (2021) (describing the different normative bases that have been suggested by legal scholars for the patent system).

⁷⁷ See generally David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 181–84 (2009); Mark A. Lemley, *Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 993–94 (1997).

⁷⁸ Statute of Monopolies 1623, 21 Ja. 1, c. 3 (Eng.), available at <http://www.legislation.gov.uk/aep/Jal/21/3/contents>. See Chris Dent, "Generally Inconvenient": *The 1624 Statute of Monopolies as Political Compromise.*, 33 MELBOURNE UNIVERSITY LAW REVIEW 415 (2009).

⁷⁹ For an analysis of this transformation across jurisdictions see generally Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 1)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 697 (1994); Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 2)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 849 (1994); Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 3)*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 771 (1995).

⁸⁰ Under English law, North American Colonies were classified as non-English holdings of the Crown and not parts of the kingdom. The Crown alone dictated the laws applicable to these overseas territories; statutes of Parliament and English common law did not extend to them *de jure*. For an analysis of the influence of English law on the American patents system see generally Frank D. Prager, *A History of Intellectual Property from 1545 to 1787*, J. PAT. OFF. SOC'Y 711 (1944).

⁸¹ See generally Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790*, 25 AIPLA Q. J. 445 (1997).

⁸² See generally Zorina B. Khan, *Study Paper 1a Intellectual Property and Economic Development: Lessons from American and European History*, LONDON: COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 9 (2002);

⁸³ This picture emerges lucidly from a variety of studies into the historical trajectory patent law; see generally 1 STEPHEN PERICLES LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 19–27 (1975); SAM RICKETSON, THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY: A COMMENTARY ¶ 1.17 (2015).

obstacles, as well as outright discrimination against foreigners.⁸⁴ To curtail this international fragmentation, governments endeavored to negotiate a multilateral treaty that would harmonize the granting of patents across jurisdictions. These efforts yielded the Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention).⁸⁵

The Paris Convention simplified and standardized the process for obtaining patents across borders by introducing the principle of national treatment,⁸⁶ and the right of priority.⁸⁷ However, this treaty did not meaningfully harmonize substantive patent law. Despite holding numerous revision conferences throughout the 20th century,⁸⁸ signatory countries were never able to bridge their differences on key issues, such as which types of inventions should be patentable, the requirements they should satisfy for protection, the breadth of the rights awarded to patentees, the duration of the protection term, and the type of remedies available for infringement.⁸⁹ It should be noted that the Paris Convention did not require its signatories to grant patents for medical inventions, nor did it harmonize compulsory licensing.⁹⁰

Absent mandatory international standards, countries maintained heterogenous rules on patentable subject matter throughout the 20th century. This disharmony was especially noticeable in the ambit of medical inventions.⁹¹ The United States had a longstanding tradition of granting

⁸⁴ See generally RICKETSON, *supra* note 83, ch. II–III.

⁸⁵ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 303 [hereinafter Paris Convention].

⁸⁶ This principle provides that nationals of a Paris Union country are entitled to be treated, in other countries of the Paris Union, in the same way as those countries treat their own nationals. See generally RICKETSON, *supra* note 83, ¶ 9.16-9.65.

⁸⁷ Typically, national patent systems provide that a patent can be granted only if the invention in question is not already in the public domain. The Paris Convention, art 4 provides that “any person who has duly filed an application for a patent ... in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority” for a period of 12 months from the date of filing of the first application. See generally *Id.* ¶ 10.01-10.138.

⁸⁸ Following the original Paris Convention of 1883, signatory countries agreed to convene periodic meetings to further harmonize industrial property law. These revision conferences were held in Rome (1886), Madrid (1890), Brussels (1897-1900), Washington (1911), the Hague (1925), London (1934), Lisbon (1934) and Stockholm (1967). See *Id.* ¶ 4.01-4.25, 10.46-10.48 (providing an exhaustive analysis of the this revision conference).

⁸⁹ See generally *Id.* ¶ 9.01-9.65; see also Andrea Tosato, *Secured Transactions and IP Licenses: Comparative Observations and Reform Suggestions Secured Transactions Law in the Twenty-First Century*, 81 LAW & CONTEMP. PROBS. 155 (2018) (highlighting the divergences across jurisdiction in the use of IP licenses as collateral).

⁹⁰ See Paris Convention, *supra* note 85, art. 5A (“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”).

⁹¹ See generally GRAHAM DUTFIELD, *THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY, 1880-2020*, ch. 9 (2020) (for an exhaustive

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patents both for pharmaceutical products and processes.⁹² In addition, patentees' rights were further reinforced by the fact that federal law only provided for the issuance of CLs to remedy antitrust violations and for governmental use.⁹³ Western European countries, Japan and Canada similarly offered patent protection for medical inventions, albeit with lesser intensity.⁹⁴ For example, France, Canada, and the United Kingdom enacted both process and product patents for pharmaceuticals, yet subjected them to compulsory licensing mechanisms that diluted the exclusive rights of patentees by enabling generics manufacturers to develop competing products.⁹⁵

Taking a different approach, a broad and diverse group of countries, including Argentina, Austria, Egypt, Greece, India, Spain, and Turkey, only granted patents for pharmaceutical manufacturing processes.⁹⁶ In these jurisdictions, inventors could obtain protection for techniques used to

historical account of the role of IP law in biomedicine); Jean-Paul Gaudillière, *How Pharmaceuticals Became Patentable: The Production and Appropriation of Drugs in the Twentieth Century*, 24 HISTORY AND TECHNOLOGY 99 (2008).

⁹² See generally Graham Dutfield, *The Pharmaceutical Industry, the Evolution of Patent Law and the Public Interest: A Brief History*, in EMERGING ISSUES IN INTELLECTUAL PROPERTY 109, 122–24, 135–46 (Guido Westkamp ed., 2007) (providing an extensive historical account of pharmaceutical entrepreneurship and pharmaceutical patents in the United States).

⁹³ On the history of compulsory licensing in the United States, see *infra* Part I.B.

⁹⁴ See generally Dutfield, *supra* note 92, at 147–49 (documenting the history of the United Kingdom and European continental countries); Joel Lexchin, *Pharmaceuticals, Patents, and Politics: Canada and Bill C-22*, 23 INTERNATIONAL JOURNAL OF HEALTH SERVICES 147 (1993) (detailing Canada's legislative trajectory); Akihiko Kawaura & Sumner J. La Croix, *Japan's Shift from Process to Product Patents in the Pharmaceutical Industry an Event Study of the Impact on Japanese Firms*, 33 ECONOMIC INQUIRY 88 (1995) (expounding Japan's legislation on pharmaceutical inventions).

⁹⁵ See generally Maurice Cassier, *Brevets pharmaceutiques et santé publique en France: Oppositions et dispositifs spécifiques d'appropriation du médicament entre 1791 et 2004*, ENTREPRISE ET HISTOIRE 29–47 (2004) (detailing the history of pharmaceutical patents in France and its compulsory licensing regime); John M. Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection*, 5 PAC. RIM L. & POL'Y J. 237 (1995) (describing the history of New Zealand patent protection for pharmaceuticals and the associated compulsory licensing regime); See Judy Slinn, *Patents and the UK Pharmaceutical Industry between 1945 and the 1970s*, 24 HISTORY AND TECHNOLOGY 191 (2008) (charting the history of UK legislation on pharmaceutical patents and the associated compulsory licensing regime); Lexchin, *supra* note 94 (detailing the history of the Canadian compulsory licensing regime for pharmaceuticals).

⁹⁶ For a complete survey see D. C. Jayasuriya, *Pharmaceuticals: Patents and the Third World*, 22 J. WORLD TRADE 117 (1988) (detailing that, as of 1988, 49 countries did not grant patents for pharmaceutical products, including Argentina, Brazil, Chile, Columbia, Congo, Ecuador, Egypt, India, Indonesia, Mexico, South Korea, Syria and Thailand); Hernan L. Bentolila, *Lessons from the United States Trade Policies to Convert a Pirate: The Case of Pharmaceutical Patents in Argentina*, 5 YALE J.L. & TECH. 57 (2002) (charting the history of Argentinian protection for pharmaceutical inventions before and after TRIPS); See Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 278–90 (2006) (providing a detailed account of Indian patent law and its policy choice to grant only process patents for medicines).

synthesize medicines, but not for the product itself. Competitors could freely produce and sell the same pharmaceutical, provided they obtained it through an alternative manufacturing process. Still differently, a small group of countries, including Brazil and Ecuador, completely excluded patentability of pharmaceutical inventions regardless of whether they involved a product or a process.⁹⁷

The heterogeneity that characterized the protection of pharmaceutical inventions internationally during the 20th century was not a fortuitous accident of history. Across jurisdictions, lawmakers faced the same challenge of achieving equilibrium between providing access to medicines in adequate quantities and affordable prices to their citizens and stimulating research and development while rewarding pharmaceutical inventors. However, they arrived at profoundly different solutions, as each country took a different view on what constituted a palatable balance, based on their legal, economic, social and political milieu. There was no single recipe suitable for every jurisdiction.

Crucially, this landscape swiftly evolved during the 1980s. Through unilateral, bilateral and multilateral initiatives, the United States and other countries with established pharmaceutical industries mounted a relentless campaign to enhance patent protection for medical inventions worldwide. Canada, Japan and most Western European countries expanded the patentability of pharmaceutical products and processes, while narrowing the breadth of their compulsory licensing systems.⁹⁸ Over the span of eight short years (1985-1993), China pivoted from offering no protection for medical inventions to granting both product and process patents.⁹⁹ Following the dissolution of the USSR, Russia and many Eastern European countries enacted patent regimes that provided ample protection to pharmaceutical inventions.¹⁰⁰

⁹⁷ See generally Kumariah Balasubramaniam, *Pharmaceutical Patents in Developing Countries: Policy Options*, 22 ECONOMIC AND POLITICAL WEEKLY (1987) (providing a broad overview the laws of developing countries that did not protect pharmaceutical inventions); Carolyn S. Corn, *Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution Note*, 9 B.U. INT'L L. J. 71 (1991) (documenting Brazil's pharmaceutical patents stance). It should be noted that Mexico also granted neither process nor product patents on pharmaceutical inventions, until 1991; see generally Kenneth C. Shadlen, *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies*, 42 COMPARATIVE POLITICS 41 (2009).

⁹⁸ See generally Lexchin, *supra* note 94 (charting the history of patent protection for pharmaceutical inventions in Canada); Kawaura & Croix, *supra* note 94 (for a comprehensive analysis of Japan's implementation of product patents for pharmaceutical inventions); BENGT DOMEIJ, PHARMACEUTICAL PATENTS IN EUROPE (2000).

⁹⁹ See generally Xuan Li, *The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India*, 31 THE WORLD ECONOMY 1367 (2008) (detailing this swift evolution under Chinese law).

¹⁰⁰ See generally Elizabeth F. Enayati, *Patent Protection for Biotechnology Inventions in Eastern Europe*, BIO/TECHNOLOGY No. 2, 191 (1994) (detailing the adoption of patent protection for pharmaceutical inventions in Eastern European countries).

Developing countries reacted diversely to political and economic pressures urging them to introduce patent protection for medical process and patent inventions.¹⁰¹ A few, including Mexico, South Korea, Thailand, and Turkey ultimately conceded, in return for preferential regional and international trade links.¹⁰² Most developing countries in Africa, Asia and Latin America, including India and Brazil, resisted such pressures. Their position was that it was their sovereign right not to implement pharmaceutical patents both to foster their domestic biomedical sector and facilitate access to medicines.¹⁰³

By the time TRIPS negotiations commenced, patent protection for medical inventions had become a highly contentious matter in international relations, further compounded by the compulsory licensing disputes that emerged in the context of the Paris Convention.

C. Compulsory Licensing

CLs have a rich history. A primordial form of compulsory licensing for public use can be traced back the Venetian General Patent Law (*Parte Veneziana*) of 1474.¹⁰⁴ Under this law, the Venetian government could “take and use any [patented] device and instrument, with this condition however that no one but the author shall operate it”.¹⁰⁵ Although innovative, the Venetian law never penetrated the borders of other jurisdictions and eventually faded into obscurity, in lockstep with the Serenissima’s economic and military decline.

Three centuries later, another embryonic compulsory licensing scheme surfaced in the South Carolinian Act for the Encouragement of Arts and Sciences of 1784.¹⁰⁶ This law established a common regime for copyrights

¹⁰¹ See generally Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 THE INTERNATIONAL LAWYER 835 (1996) (describing the unilateral, bilateral and multilateral actions spearheaded by the United States); Julio J. Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, World Bank Working Paper Series No. 502, 3–10 (1990).

¹⁰² See generally Lewis, *supra* note 101 (charting the shift in the legislation of these countries); Shadlen, *supra* note 97 (explaining that Mexico chose to introduce patent protection for pharmaceuticals to enhance its trading partnership with the United States and Canada).

¹⁰³ See generally also PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?, ch. 9 (202); Verena Schüren, *Two TRIPs to Innovation: Pharmaceutical Innovation Systems in India and Brazil*, SFB-GOVERNANCE WORKING PAPER SERIES, NO. 37 (2012) (for a detailed analysis of India and Brazil).

¹⁰⁴ This Venetian law is considered to be the first patent statute in history. See Stefania Fusco, *Lessons from the Past: The Venetian Republic’s Tailoring of Patent Protection to the Characteristics of the Invention*, 17 NW. J. TECH. & INTELL. PROP. 301 (2019); Giulio Mandich, *Venetian Origins of Inventors’ Rights*, 42 J. PAT. OFF. SOC’Y 378 (1960).

¹⁰⁵ See Giulio Mandich, *Venetian Patents (1450-1550)*, 30 J. PAT. OFF. SOC’Y 166, 176–77 (1948) (analyzing the history of this Venetian Patent Law)

¹⁰⁶ See South Carolina Statutes at Large (Cooper Edition, 1839), Vol. IV, 618-20.

and patents.¹⁰⁷ Accordingly, patentees were subject to a provision establishing that if a copyright holder “neglected to furnish the public with sufficient editions [of the protected work], or shall sell the same at a price unreasonable” a person could petition a court to obtain a “license to reprint and publish such [work], in such numbers, and for such term, as said court shall judge just and reasonable”.¹⁰⁸ While the Venetian compulsory licensing system permitted government use, the South Carolinian law provided for the first implementation of court-sanctioned CLs between private persons.¹⁰⁹ Be that as it may, the South Carolinian Act of 1784 never bore fruit, as it was swiftly superseded by the Federal Patent Act of 1790. It should be noted that lawmakers drafting this federal statute consciously chose not to introduce CLs. Presented with a Senate amendment proposing a compulsory licensing regime modeled after that in the South Carolinian Act of 1784, the House of Representatives soundly rejected it, following a debate in which CLs were criticized as an intolerable encroachment on patentees’ rights.¹¹⁰

Venetian and South Carolinian antecedents notwithstanding, the first fully-fledged compulsory licensing regime was enacted in the English Patents, Designs, and Trade Marks Act of 1883 (Patents Act of 1883).¹¹¹ Under Section 22 of this law, a persons could petition the Board of Trade to obtain a CL over a patent if the invention in question was not being “worked” in England, or if the “reasonable requirements” of the public were not being supplied, or if the petitioner were trying to exploit an invention derivative of the patented one and was being prevented from doing so due the patentees unwillingness to grant a voluntary license. Providing a fourth ground for compulsory licensing, Section 27(2) established that the government could use a patented invention “for the services of the Crown” on terms determined by the Treasury.¹¹² This compulsory licensing framework had a long-lasting

¹⁰⁷ See BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 119 (1967) (analyzing of this statute and noting that was largely inspired by the Connecticut Copyright Statute of 1783).

¹⁰⁸ See *Id.* at 119–20.

¹⁰⁹ See Francine Crawford, *Pre-Constitutional Copyright Statutes Part I*, 23 BULL. COPYRIGHT SOC’Y U.S.A. 11, 35 (1975) (analyzing the applicable procedural rules and noting that the choice of South Carolinian 1784 Act to extend the rules for copyright to patents engendered numerous difficulties).

¹¹⁰ See William Maclay’s journal entry of April 5, 1790, reprinted in 22 J. PAT. OFF. SOC’Y 352 (1940) at 371; BUGBEE, *supra* note 107, at 143. See also Stefan A. Riesenfeld, *Compulsory Licenses and United States Industrial and Artistic Property Law*, 47 CALIF. L. REV. 51 (1959) (charting the history of compulsory licenses in United States intellectual property federal statutes).

¹¹¹ On the historical origin of compulsory licensing see generally David J. Brennan, *The First Compulsory Licensing of Patents and Copyright*, 17 LEGAL HISTORY 1 (2017) (focusing on Anglo-American law); Oliver Brand, *The Dawn of Compulsory Patent Licensing*, 11 INTELLECTUAL PROPERTY QUARTERLY 216 (2007) (for an exhaustive analysis of compulsory licensing from the *Parte Veneziana* to the English patent law reform of 1883); James Roberts, *Compulsory Licences to Work Patented Inventions*, 6 JOURNAL OF THE SOCIETY OF COMPARATIVE LEGISLATION 82 (1905) (for comparative insights).

¹¹² See The Patents Act of 1883, s. 27(2). Under this statute, for the first time, English

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impact in the United Kingdom¹¹³ and served as a blueprint for many common law,¹¹⁴ and civil law jurisdictions.¹¹⁵

During the 20th century, numerous countries incorporated domestic compulsory licensing mechanisms in their patent laws.¹¹⁶ These regimes diverged significantly. In some jurisdictions, CLs could only be granted on narrow grounds, primarily to redress anti-competitive practices, failure to work, unjustifiably high prices or low production levels. In others, patent legislation liberally provided for the issuance of CLs on broad grounds, including public health, national defense, technology transfers, and environmental protection.¹¹⁷ There were also marked dissimilarities regarding the scope, breadth, and duration of CLs and whether affected patentees were entitled to compensation.¹¹⁸ These differences reflected divergent normative aims. In some jurisdictions, CLs were proffered as exceptional remedies to redress patentees' abuses, whereas in others they were viewed as instruments to loosen patent protection, in active pursuit of public policy aims.¹¹⁹ Conspicuously, several countries liberally subjected pharmaceutical patents to CLs with the aim of increasing access to medicines for their citizens.¹²⁰

This dissonance amongst national compulsory licensing regimes eventually became a contentious international matter, as evidenced by the history of the Paris Convention. In the original treaty of 1883, CLs were not even mentioned.¹²¹ In the revisions that took place up to 1958,¹²² signatory countries agreed without incident that compulsory licensing should be implemented as the default remedy to tackle patentees' abuses, such as

patentees could enforce their exclusive rights against the Crown, albeit subject to the compulsory licensing mechanism in section 27(2). See Brennan, *supra* note 111, at 5–6 (analyzing section 27 of the Patents Act of 1883).

¹¹³ The current British compulsory licensing regime largely replicates that of the Patents Act of 1883. See The Patents Act 1977, c. 37, §§ 48A, 48B, 49–54 (Eng.). See RICHARD MILLER ET AL., TERRELL ON THE LAW OF PATENTS, ch. 17 (19th ed. 2021).

¹¹⁴ For example, the Singaporean *Patents Act* (Singapore, cap 221, 2005 rev ed) § 55 and Australian *Patents Act 1990* (Cth) §§ 133, 135 echoes the provisions of the British Patents Act of 1883.

¹¹⁵ See generally Jarrod Tudor, *Compulsory Licensing in the European Union*, 4 GEO. MASON J. INT'L COM. L. 222 (2012).

¹¹⁶ See Jerome H. Reichman, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America* 10–12 (International Centre for Trade and Sustainable Development 2003); 1 LADAS, *supra* note 83, at 533–35.

¹¹⁷ See Reichman, *supra* note 116, at 10–12; LADAS, *supra* note 83, at 533–35.

¹¹⁸ See Reichman, *supra* note 116, at 10–12; LADAS, *supra* note 83, at 533–35.

¹¹⁹ See LADAS, *supra* note 83, at 533–34 (providing a comparative analysis of compulsory licensing regimes in force between the 1960s and 1975); see Reichman, *supra* note 116, at 11 (providing a historical and comparative analysis).

¹²⁰ See *supra* Part I.A.

¹²¹ See LADAS, *supra* note 83, at 522–27 (charting the history of the provisions of the Paris Convention dealing with compulsory licensing).

¹²² Specifically, the Rome (1886), Madrid (1890), Brussels (1897–1900), Washington (1911), the Hague (1925), and London 1934 revision conferences. See *supra* note 81.

“failure to work”, whereas outright revocations should only be a measure of last recourse.¹²³ It was at the Lisbon Revision Conference of 1958 that, for the first time, divergent national attitudes to compulsory licensing truly came to the fore.¹²⁴ Negotiators discussed whether the Paris Convention should limit the grounds upon which signatory parties could grant CLs, and introduce mandatory procedural and substantive standards.¹²⁵ Following fraught negotiations, a consensus could not be found. A narrow accord was reached for CLs issued to redress “failure to work or insufficient working”.¹²⁶ By contrast, signatory parties retained unfettered discretion for CLs granted on grounds of public interest or to redress abuses other than non-working.¹²⁷

Following the Lisbon Revision Conference, the international community grew increasingly divided in its views on patents and compulsory licensing.¹²⁸ These divergences emerged starkly during the failed Paris Convention revision process of 1980-1984. Seeking easier access to patented inventions, developing countries wanted greater freedom to attenuate patentees’ exclusive rights.¹²⁹ To this end, they proposed that the Paris Convention should explicitly encourage liberal recourse to CLs on grounds of public interest, and the possibility for countries to issue exclusive CLs that would bar the affected patentees from competing with compulsory licensees.¹³⁰ Conversely, developed countries pressed for elevating patent protection standards mandated by the Paris Convention.¹³¹ Regarding CLs, they posited that these instruments were being abused in many jurisdictions to the detriment of foreign patentees. To rectify this mischief, they proposed

¹²³ See generally Reichman, *supra* note 116, at 11; RICKETSON, *supra* note 83, ¶ 10.50.

¹²⁴ This was the seventh revision convention. See *supra* note 88.

¹²⁵ For example, this was the first revisions convention in which it was considered whether patentees subject to a compulsory license should be entitled to monetary compensation. See RICKETSON, *supra* note 83, ¶ 10.51; LADAS, *supra* note 83, at 534–36.

¹²⁶ See Paris Convention Article 5A(4) (Lisbon Revision Conference) “available at <https://wipolex.wipo.int/en/text/287778>; See RICKETSON, *supra* note 83, ¶ 10.51 (providing an extensive commentary of this provisions and the Lisbon Revision Conference more broadly).

¹²⁷ See Reichman, *supra* note 116 (emphasizing that “the conditions governing the issuance of compulsory licenses on general grounds of abuse were liberalized and harmonized with the more permissive rules (or lack of rules) governing compulsory licenses issued on public interest grounds.”).

¹²⁸ This growing chasm is lucidly visible in the informal meetings that were organized by WIPO to promote the revision of the Paris Convention. See WIPO, *General Report adopted by WIPO Coordination Committee, the Paris Union Executive Committee and the Berne Executive Committee*, Administrative Bodies of WIPO and of the Unions Administered by WIPO, WIPO Document AB/V/13, 30 September 1974, Fifth Series of Meetings, Geneva, September 24–30, 1974.

¹²⁹ These proposals were put forward by the “Group of 77” which included (all of Africa, except for South Africa, South America, the Caribbean, and Asia, except for Japan). See RICKETSON, *supra* note 83, ¶ 5.05 (explaining the history of the different state groupings).

¹³⁰ See *Id.* ¶ 5.09-5.11, 10.59-10.63 (describing the proposals presented at the Nairobi (1981) and Geneva (1982, 1984, 1985) Revision Conferences).

¹³¹ These proposals were put forward by “Group B” which comprised the countries of Europe (except for those in the Warsaw Pact) Australia, Canada, Japan, New Zealand and the USA. See *Id.* ¶ 5.05.

breadth and scope limitations for CLs, narrower grounds for issuance, and mandatory compensation for patentees.¹³²

After four years of openly contentious and inconclusive negotiations, countries abandoned all aspirations for a substantive revision of the Paris Convention. Developing and developed countries had reached complete deadlock. Notably, compulsory licensing generally, and CLs for pharmaceutical patents in particular, were flashpoints in this principled disagreement.

II. TRIPS, PHARMACEUTICAL PATENTS AND COMPULSORY LICENSING

Part I described how different jurisdictions assumed diverging approaches to the intricate entanglement of access to medicine, pharmaceutical patents and compulsory licensing. Furthermore, it explained that this heterogeneity caused tension and, ultimately, a stalemate between developed and developing countries by the early 1990s. This impasse was conclusively resolved with the creation of the WTO and the concurrent adoption of TRIPS. This Part expounds this momentous development, describing first the WTO negotiating history and then delving into TRIPS patent rules for medical inventions and compulsory licensing. The aim of this analysis is to explore exhaustively the path that led to the enactment of Article 31*bis*, bringing into sharp relief both the grave defect which this provision was designed to resolve and its manner of operation.

A. From the General Agreement on Tariffs to the World Trade Organization

The WTO is the offspring of the General Agreement on Tariffs and Trade of 1947 (GATT).¹³³ Enacted at the end of World War II, GATT was designed to bolster cross-border commerce among formerly belligerent nations.¹³⁴ Over the subsequent four decades, this international trade agreement blossomed, as countries regularly engaged in rounds of negotiations to broaden its remit.¹³⁵ From its inception, GATT was centered on tangible goods, with IP issues only being considered at the margins.¹³⁶ This changed

¹³² See *Id.* ¶ 5.09-5.11, 10.59-10.63.

¹³³ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

¹³⁴ See generally DOUGLAS A. IRWIN ET AL., *THE GENESIS OF THE GATT 5–97* (2008) (for a history of the creation of the GATT); DANIEL J. GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* ¶ 1.02 (5th ed. 2021).

¹³⁵ See GIUSEPPE LA BARCA, *THE US, THE EC AND WORLD TRADE: FROM THE KENNEDY ROUND TO THE START OF THE URUGUAY ROUND* (2016) (analyzing all the GATT negotiating rounds that preceded the Uruguay Round).

¹³⁶ The GATT addressed IP law issues tangentially, by recognizing that trade restrictions flowing from the application of domestic IPRs regimes – such as blocking imports of goods deemed to be infringing of a patent right – were admissible and lawful. See DANIEL J. GERVAIS, *supra* note 134, ¶ 1.05-1.07.

drastically in the round of negotiations held in Uruguay between 1986-1994 (Uruguay Round).¹³⁷

During the Uruguay Round, countries committed to an ambitious overhaul of the extant GATT framework. It was decided to cover a wide range of trade areas by drafting multiple, parallel treaties that would be developed individually but signed as a single package. Performing a sharp “regime-shifting” maneuver,¹³⁸ a group of developed countries, led by the United States and the European Economic Community, advocated for the inclusion of a treaty on “trade-related aspects of intellectual property rights”.¹³⁹

It was initially agreed that such project should have a narrow scope, only addressing cross-border trade in counterfeit goods. Nevertheless, a “coalition”¹⁴⁰ of developed countries insisted on expanding this agenda significantly. Despite remonstrations from developing countries,¹⁴¹ at the Uruguay midterm review of 1989, it was decided that the IP treaty under development would articulate minimum protection standards for copyright, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits and trade secrets, which signatory countries would be required to implement domestically.¹⁴²

This expanded scope required far broader negotiations. The treatment of medical inventions and CLs immediately emerged as profoundly problematic issues in the patents sphere, heralding the resumption of a long-standing international debate.¹⁴³ Developing countries advocated for the complete or

¹³⁷ The Uruguay Round was the eighth round of GATT negotiations. See generally *Id.* ¶ 1.12-1.29 (providing a detailed analysis of the Uruguay Round negotiations); Charles Clift, *Why IPR Issues Were Brought to GATT: A Historical Perspective on the Origins of TRIPS*, in RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 3, 10–20 (Carlos Correa ed., 2010).

¹³⁸ See Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1 (2004) (defining “regime shifting” as “an attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another”); 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) (who build on the Helfer’s definition and present it as “improving power dynamics by shifting from one regime with a view to directly or indirectly create alternative law or practices that conflict with those in another regime”).

¹³⁹ See Clift, *supra* note 137 (for a detailed history of the negotiations that led to the inclusion of IP issues within the scope of the nascent WTO).

¹⁴⁰ See Sonia E. Rolland, *Developing Country Coalitions at the WTO: In Search of Legal Support*, 48 HARV. INT’L L.J. 483, 485–90 (2007) (for a history of country coalitions in the GATT and WTO).

¹⁴¹ See generally Clift, *supra* note 137, at 15; JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 27–28 (2001) (describing these negotiations from the perspective of the Indian delegation).

¹⁴² The Uruguay Round midterm meetings were held in Montreal (December 5-8, 1988) and continued in Geneva (April 5-8 1989). See WATAL, *supra* note 141, at 27–28 (providing an overview of this meeting and suggesting that developing countries surrendered too much to the demands of developed countries).

¹⁴³ See *supra* Parts I.B-C.

partial exclusion of pharmaceuticals from patentable subject matter, as well as absolute freedom for countries to issue compulsory licenses with minimal or little compensation for patent holders.¹⁴⁴ Conversely, developed countries insisted that medical inventions should be protectable with both product and process patents; moreover, they contended that compulsory licensing should only be permissible in a narrow set of circumstances, subject to judicial review and with adequate compensation for patent holders.¹⁴⁵

This polarization was never fully overcome. After contentious negotiations and numerous drafts, the text presented for final approval largely reflected the stance of developed countries.¹⁴⁶ It required signatories to introduce full patentability for both pharmaceutical products and processes.¹⁴⁷ Regarding compulsory licensing, it provided that each country could freely determine the grounds upon which they granted CLs, yet it imposed mandatory procedural and substantive safeguards for affected patent holders.¹⁴⁸ Ultimately faced with a "take it or leave it" proposition, developing countries begrudgingly accepted that internationally-harmonized, mandatory minimum protection standards for IP, including pharmaceutical patents and CLs, were the price to be paid in return for unconstrained access to the agricultural and manufacturing markets of developed countries.¹⁴⁹

At the Marrakesh Ministerial meeting of 1994, the WTO was born. Protection of IP pursuant to the substantive and procedural standards established by TRIPS had become one of the cornerstones of the new international trade legal order.

B. The TRIPS Framework

The TRIPS Preamble begins with the express acknowledgement that both excessive and inadequate protection of intellectual property rights (IPRs)

¹⁴⁴ For example, see Peru MTN.GNG/NG11/W/45 (27 October 1989) (proposing that pharmaceutical inventions should be excluded from patentable subject matter and that countries should have ample discretion in imposing compulsory licenses, including when the patent is not worked locally, there is insufficient supply, or local exploitation has been suspended).

¹⁴⁵ For example, Canada MTN.GNG/NG11/W/47 (25 October 1989) (pharmaceutical patents for both products and process inventions; compulsory licensing subject formulated as non-exclusive, subject to judicial review, linked to adequate compensation and governed by the national treatment principle), Korea MTN.GNG/NG11/W/48 (26 October 1989) (pharmaceutical patents for both products and process inventions; compulsory licensing allowed only for national defense or public interest or when the invention has not been exploited).

¹⁴⁶ See MTN.GNG/NG11/W/76 (23 July 1990). See also DANIEL J. GERVAIS, *supra* note 134, ¶ 1.22-1.28 (providing a detailed history of these negotiations).

¹⁴⁷ See *infra* Part II.C.

¹⁴⁸ See *infra* Part II.D.

¹⁴⁹ For a contemporary perspective see generally Jerome H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement Symposium: Uruguay Round - GATT/WTO*, 29 INT'L L. 345 (1995); Frederick M. Abbott, *The WTO TRIPS Agreement and Global Economic Development*, 72 CHI.-KENT L. REV. 385 (1996).

distort and impede international trade.¹⁵⁰ This is followed by several paragraphs that, as observed by Daniel Gervais, express the aim of TRIPS to achieve “a series of equilibriums: between intellectual property protection and free trade ... between highly industrialised and developing nations; between the private rights of intellectual property owners and cases where the public interest may trump some aspects of the protection of intellectual property”.¹⁵¹

TRIPS Part I establishes general provisions and basic principles that underpin the whole treaty. For present purposes, Articles 7-8 deserve special attention. The former asserts that IP protection and enforcement “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology” for the benefit of both right holders and users “in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.¹⁵²

In similar vein, Article 8 provides that signatory states may adopt measures for the safeguarding of “public health and nutrition” and promote sectors of vital importance to their socio-economic and technological development.¹⁵³ This provision positively recognizes that Members may introduce measures to prevent right holders from abusing their IPRs.¹⁵⁴ Nevertheless, Article 8 expressly specifies that all such domestic interventions must be consistent with the provisions of TRIPS.¹⁵⁵

Articles 7-8 are declaratory in nature, enshrining key concerns voiced by developing countries during negotiations, particularly regarding patent protection of pharmaceuticals and compulsory licensing. These provisions are significant as they express the legislative intent underlying TRIPS and thus provide a normative reference point for its interpretation.¹⁵⁶ Nevertheless, the significance of Articles 7-8 should not be overstated, as they can be construed as neither establishing actionable obligations for Members to discharge,¹⁵⁷ nor as creating general exceptions allowing Members to dilute the mandatory IP protection standards established by TRIPS.¹⁵⁸

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¹⁵⁰ TRIPS, *supra* note 18, Preamble. See *Australia—Tobacco Plain Packaging*, report of the Appellate Body, document WT/DS435/AB/R and WT/DS441/AB/R, 9 June 2020, at para.6.625 and fn.1599 (describing this statement of the Preamble as “key”).

¹⁵¹ See generally DANIEL J. GERVAIS, *supra* note 134, ¶ 3.13; CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 1–17* (2d ed. 2020).

¹⁵² TRIPS, *supra* note 18, art. 7.

¹⁵³ TRIPS, *supra* note 18, art. 8(1).

¹⁵⁴ TRIPS, *supra* note 18, art. 8(2).

¹⁵⁵ *Id.*

¹⁵⁶ See DANIEL J. GERVAIS, *supra* note 134, ¶ 3.117, 3.130 (remarking that these provisions should be viewed as interpretive tools); CARLOS CORREA, *supra* note 151, at 83–107 (who expressly speaks of the “interpretive function” of these provisions).

¹⁵⁷ See DANIEL J. GERVAIS, *supra* note 134, ¶ 3.117, 3.130; CARLOS CORREA, *supra* note 151, at 83–107.

¹⁵⁸ See DANIEL J. GERVAIS, *supra* note 134, ¶ 3.117, 3.130; CARLOS CORREA, *supra* note 151, at 83–107.

TRIPS Part V includes one of the most significant additions of this treaty to the international IP landscape. Article 64 provides that the GATT “Dispute Settlement Understanding”¹⁵⁹ applies to “the settlement of disputes” arising among signatory states, concerning the enactment and application of TRIPS.¹⁶⁰ One Member may bring an action before the WTO Dispute Settlement Body for alleged failures of another Member to either implement or enforce the IP protection standards imposed by TRIPS.¹⁶¹ This international adjudication mechanism features both soft and formal compliance instruments and is considerably more robust and incisive than any enforcement process associated with the other major, multilateral instruments dealing with substantive IP law.¹⁶²

Lastly, TRIPS Part VI formulates transitional rules designed to facilitate signatory states in their progressive implementation of the substantive regime mandated by this treaty. Under Article 65, developed signatory states were required to comply with TRIPS within one year of the treaty coming into force,¹⁶³ while developing countries were given a five-year time window, with an additional five years to implement product patents, including for pharmaceutical inventions.¹⁶⁴ Coextensively, Article 66(1) afforded ten years to “least-developed country Members”¹⁶⁵ (LDC) to comply with all TRIPS obligations.¹⁶⁶ However, this deadline has been postponed repeatedly over the past three decades,¹⁶⁷ and a new extension has recently been granted until 2034.¹⁶⁸ Article 66(1) embodies the principles expressed in Articles 7-8, by providing jurisdictions in the early stages of their industrial and

¹⁵⁹ See Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994). See generally WORLD TRADE ORGANIZATION, A HANDBOOK ON THE WTO DISPUTE SETTLEMENT SYSTEM (Sep. 2017) [hereinafter WTO DSU Handbook].

¹⁶⁰ TRIPS, *supra* note 18, art. 64.

¹⁶¹ See generally WTO DSU Handbook, *supra* note 159, at 40-47.

¹⁶² See generally DANIEL J. GERVAIS, *supra* note 134, ¶ 3.773-3.777; see also MATTHEW KENNEDY, WTO DISPUTE SETTLEMENT AND THE TRIPS AGREEMENT 40-106 (2016) (for an analysis of the TRIPS compliance instruments).

¹⁶³ TRIPS, *supra* note 18, art. 65(1).

¹⁶⁴ TRIPS, *supra* note 18, art. 65(2)-(4).

¹⁶⁵ In 1971, the United Nations General Assembly endorsed a list of “least developed among the developing countries” as a special group of developing countries characterized by a low level of income and structural impediments to growth and requiring special measures for dealing with those problems. This list has been updated annually and currently comprises 46 countries. See UNCTAD, THE LEAST DEVELOPED COUNTRY REPORT 2021 (2021), available at https://unctad.org/system/files/official-document/lcd2021_en.pdf; UNITED NATIONS DEPARTMENT FOR ECONOMIC AND SOCIAL AFFAIRS, HANDBOOK ON THE LEAST DEVELOPED COUNTRY CATEGORY: INCLUSION, GRADUATION AND SPECIAL SUPPORT MEASURES, (United Nations Fund for Population Activities 4th ed. Dec. 2021).

¹⁶⁶ TRIPS, *supra* note 18, art. 66(1).

¹⁶⁷ See DANIEL J. GERVAIS, *supra* note 134, at 3.792-3.796 (detailing the history of these extensions).

¹⁶⁸ See WTO, *WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034*, available at https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm.

technological development with a loose timeline for the gradual implementation of IP protections.

This provision affords great flexibility to LDCs with regard to pharmaceutical patents. They can tailor their domestic regime in whatever way best suits their socio-economic milieu, electing, for example, not to protect such inventions, or only awarding process patents, or making patentees' rights conditional on local investments. Additionally, even if an LDC chooses to introduce partial or full patent protection for pharmaceutical innovations, they can later revise, suspend or revoke this recognition, as Article 66(1) does not forbid signatory states from lowering protection levels.

C. The TRIPS Patent Regime

TRIPS Part II articulates the protection standards that Members are required to implement in their domestic law for copyright, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits and trade secrets. Patents are covered in Articles 27-34.

The fundamental elements of this body of rules can be summarized as follows. First, signatory states must grant patents for both products and process inventions "in all fields of technology".¹⁶⁹ Pharmaceutical inventions are included without exception.¹⁷⁰ The only admissible exclusions are for inventions that are considered harmful to "*ordre public* or morality",¹⁷¹ as well as "diagnostic, therapeutic and surgical methods, and plants and animals other than micro-organisms."¹⁷²

Second, Article 27 articulates three requirements for an invention to be patentable: novelty, inventiveness and industrial application.¹⁷³ In line with GATT and WTO general principles, discrimination based on the place of invention or production of the patented item or its field of application is expressly forbidden.¹⁷⁴

Third, the minimum term of patent protection must not be shorter than 20 years for all patents.¹⁷⁵

Fourth, signatory states are required to award a bundle of "negative

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¹⁶⁹ TRIPS, *supra* note 18, art. 27(1).

¹⁷⁰ It should be noted that the TRIPS obligation is not absolute. See Cynthia M. Ho, *Should All Drugs Be Patentable: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 323–33 (2015) (examining Canada's and India's restrictive approaches to patentability of pharmaceutical inventions through a narrow interpretation of the utility requirement and notion of eligible subject matter respectively).

¹⁷¹ TRIPS, *supra* note 18, art. 27(2).

¹⁷² TRIPS, *supra* note 18, art. 27(3)(b).

¹⁷³ TRIPS, *supra* note 18, art. 27(1).

¹⁷⁴ TRIPS, *supra* note 18, art. 27(1). See *WTO Canada – Pharmaceutical Patents*, WT/DS114/R (March 17, 2000) 170-171 (distinguishing between "differentiation" and "discrimination" and specifying that "Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.").

¹⁷⁵ TRIPS, *supra* note 18, art. 33.

rights”¹⁷⁶ to patentees that must include the rights to exclude others from making, using, selling or importing the protected invention (product patents)¹⁷⁷ or products obtained through the protected process (process patents).¹⁷⁸ Moreover, signatory countries must allow both the transfer and licensing of these exclusive rights, though no minimum standards are imposed regarding the form and substance of these transactions.¹⁷⁹

The TRIPS protection standards for patents are both substantively higher and less flexible than those enshrined in the Paris Convention.¹⁸⁰ This is especially noticeable regarding the regime applicable to pharmaceutical inventions. The requirement that Members implement both product and process patents in this field of technology stands out as especially disruptive when considering the nuanced landscape which existed prior to the birth of the WTO.¹⁸¹ Nevertheless, TRIPS also includes “flexibilities” that were incorporated expressly to enable Members to craft bespoke patent regimes for their domestic realities.¹⁸²

Pursuant to Article 30, signatory states may forge generally-applicable “exceptions”¹⁸³ to curtail the exclusive rights conferred by patents, as long as they are “limited”, and neither “unreasonably conflict with a normal exploitation of the patent”, nor “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”.¹⁸⁴ Albeit subject to these three requirements, TRIPS does not impose substantive or procedural restrictions on Members, leaving them discretion to introduce any exceptions they deem appropriate. For example, under Article 30, laws may be enacted that permit the otherwise-infringing use of patented inventions for research and experimental purposes (e.g. clinical trials and similar activities that involve a patented invention), private non-commercial reasons, early working, stockpiling, parallel importation (first sale doctrine), and preparation of medicines for personal consumption.¹⁸⁵

Beyond Article 30, TRIPS affords additional flexibility to Members

¹⁷⁶ Black’s Law Dictionary defines a negative right as “A right entitling a person to have another refrain from doing an act that might harm the person entitled.”; see GARNER (ED), BLACK’S LAW DICTIONARY (11th ed. 2019).

¹⁷⁷ TRIPS, *supra* note 18, art. 28(1)(a).

¹⁷⁸ TRIPS, *supra* note 18, art. 28(1)(b).

¹⁷⁹ See Andrea Tosato, *Intellectual Property License Contracts: Reflections on a Prospective UNCITRAL Project*, 86 U. CIN. L. REV. 1251 (2018) (highlighting the absence of an internationally harmonized framework for the licensing, assignment and use as collateral of IP licenses).

¹⁸⁰ See *supra* note 85 and accompanying text.

¹⁸¹ See *supra* notes 86-90 and accompanying text.

¹⁸² See generally Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in FROM GATT TO TRIPS: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996).

¹⁸³ TRIPS, *supra* note 18, art. 30.

¹⁸⁴ *Id.*

¹⁸⁵ See generally ANDREW LAW, PATENTS AND PUBLIC HEALTH 93–94 (2009) (for an exhaustive analysis of all these exceptions).

regarding interventions that impair the rights of individual patent holders. Article 32 accepts that Members have the power to revoke determinate patents, imposing neither substantive nor procedural restrictions on such forfeitures, but for the requirement that patentees are afforded “an opportunity for judicial review”.¹⁸⁶ TRIPS also squarely recognizes that Members may issue CLs, yet establishes detailed conditions for the scope and duration of measures, as well as procedural and substantive safeguards for patentees.

D. The TRIPS Compulsory Licensing Regime: Article 31

The TRIPS compulsory licensing framework was originally enshrined in its entirety within Article 31. This provision was the object of lengthy and difficult negotiations.¹⁸⁷ It spawned the first internationally-harmonized regime for CLs, breaking new ground in an area of patent law that was previously left almost entirely to the discretion of each country.¹⁸⁸ From a socio-political perspective, this was a momentous development in the compulsory licensing dispute between developing and developed countries that had started in the revision conferences of the Paris Convention and continued throughout the Uruguay Round.¹⁸⁹

The key tenets of the Article 31 regime can be summarized as follows.¹⁹⁰ First, CLs can only be granted by governmental bodies, although no restrictions are imposed on their nature, composition or function.¹⁹¹

Second, each application for a CL must be considered “on its individual merits”.¹⁹² This requirement does not preclude Members from enacting laws that establish presumptions in favor of issuing CLs in determinate circumstances,¹⁹³ yet it does exclude “blanket” compulsory licensing.¹⁹⁴

¹⁸⁶ TRIPS, *supra* note 18, art. 32. Notably, this provision does not affect the limitations to patent revocations imposed by the Paris Convention; see I LADAS, *supra* note 83, at 519–38 (for an exhaustive analysis of the rules on patent forfeitures in the Paris Convention).

¹⁸⁷ See *supra* Part II.A.

¹⁸⁸ See *supra* Part I.C.

¹⁸⁹ See DANIEL J. GERVAIS, *supra* note 134, ¶¶ 3.439–3.449 (analyzing the history of this provision and the different drafts considered by negotiating states throughout the Uruguay Round).

¹⁹⁰ The summary provided here does not touch upon Articles 31(k) and (l) dealing with the grant of compulsory licenses to remedy “anti-competitive practices”, and to permit the “the exploitation of a patent . . . which cannot be exploited without infringing another patent” respectively. Compulsory licenses granted on these grounds lie outside the scope of the present enquiry.

¹⁹¹ TRIPS, *supra* note 18, art. 31(a).

¹⁹² *Id.*

¹⁹³ For example, a Member might enact a law establishing that insufficient supply of a patented product at an affordable price is grounds for the granting of a CL, placing the burden on patentees to prove otherwise.

¹⁹⁴ See UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 468 (2005) (explaining that governments cannot grant “blanket authorizations of compulsory licences pertaining to types of technologies or enterprises, but instead should require each application

Third, the lawful grant of a CL is conditional upon the prospective licensee having first undertaken “efforts” to obtain a consensual license from the patentee on “reasonable commercial terms and conditions” and that such efforts were not “successful within a reasonable period of time”.¹⁹⁵ This negotiation requisite does not apply in “circumstances of extreme urgency” or for “public non-commercial use”, though the issuing Member must notify the patent holder of issued CLs without delay.¹⁹⁶

Fourth, the government act awarding a CL must specify its scope and duration and such limitations must legally binding on the licensee.¹⁹⁷

Fifth, Members can only issue CLs that are non-exclusive and non-assignable.¹⁹⁸

Sixth, Article 31(f) specifies that CLs must be “authorized predominantly for the supply of the domestic market” of the issuing country. Notably, this provision does not impose a determinate methodology to quantify such predominance, allowing Members to choose their own measuring parameters; nevertheless, the elasticity of the word “predominantly” is not boundless, making the substance of this restriction unequivocal.¹⁹⁹

Seventh, Members must confer an “adequate remuneration” to patent holders subject to CLs, based on the relevant circumstances and the economic value of the protected invention.²⁰⁰

Eighth, consistently with the rule of law principle permeating the entirety of TRIPS,²⁰¹ Members must ensure that patentees have a right to challenge judicially both the issuance of a CL and the amount of compensation received.²⁰²

Since its adoption, Article 31 has attracted spirited criticism. Commentators have averred that it unjustifiably hinders Members’ sovereign prerogatives to issue CLs to pursue public policy objectives and remedy

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for a licence to undergo a process of review to determine whether it meets the established criteria for the granting of a licence”).

¹⁹⁵ TRIPS, *supra* note 18, art. 31(b). See generally Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents Symposium: The Licensing of Intellectual Property*, 78 U. CHI. L. REV. 71 (2011) (considering the range of possible meanings attributable to “reasonable commercial terms and conditions”).

¹⁹⁶ *Id.*

¹⁹⁷ TRIPS, *supra* note 18, art. 31(c).

¹⁹⁸ TRIPS, *supra* note 18, art. 31 (d)-(e).

¹⁹⁹ See Andrew D. Mitchell & Tania Voon, *Patents and Public Health in the WTO, FTAs and beyond: Tension and Conflict in International Law*, 43 JOURNAL OF WORLD TRADE (2009) (suggesting that predominance may be measured on the basis of diverse parameters); Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, QUAKER UNITED NATIONS OFFICE (GENEVA) (QUNO), OCCASIONAL PAPER 9 (2002) (who tentatively suggests that compulsory licenses under which the domestic market would receive forty percent of the supply, while three foreign markets each individually received twenty percent of the supply might be lawful).

²⁰⁰ TRIPS, *supra* note 18, art. 31(h).

²⁰¹ See TRIPS, *supra* note 18, art. 41(4).

²⁰² TRIPS, *supra* note 18, art. 31(i)-(j).

abusive conduct, by entrenching impregnable safeguards for patentees.²⁰³ We disagree.

It is unquestionable that Article 31 establishes mandatory minimum standards regulating the process for the issuance of CLs, their scope, duration, distribution and remuneration. However, this regime is built on the premise that Members may subject any patent, at any moment in time during its protection term, to a CL, regardless of the nature of the invention and whether it covers a product or a process, including patents on pharmaceuticals. Article 31 does not curtail the grounds upon which a Member may issue CLs in any way, nor does it dictate minimum substantive or evidentiary thresholds for such grants. Furthermore, all procedural and substantive protections for patentees mandated by this provision are built around broad and general standards, such as “reasonable commercial terms and conditions”, “circumstances of extreme urgency”, “purpose”, and “adequate remuneration” that afford ample flexibility in their implementation. In our view, Article 31 unequivocally enshrines into international IP law the principle that CLs are a highly adaptable instrument which countries are free to tailor as broadly or narrowly as they deem appropriate for their domestic socio-economic milieu. It is this ample discretion that constitutes the normative core of the TRIPS compulsory licensing regime, not the relatively narrow safeguards that it affords to patentees.

E. The impact of the TRIPS Patent and Compulsory Licensing regimes on Members lacking pharmaceutical manufacturing capabilities

The creation of the WTO and the advent of TRIPS were highly controversial.²⁰⁴ One view was that developing countries were being forced to implement and enforce high protection levels for IP rights that they would have never introduced otherwise, for the meagre recompense of smoother access to the saturated agricultural and manufacturing markets of the Global North.²⁰⁵ The concern being voiced was that the world’s poor would have

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²⁰³ See 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 (2012); Susan K. Sell, *TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 453–54 (2010–2011); Cameron Hutchison, *Over 5 Billion Not Served: The TRIPS Compulsory Licensing Export Restriction*, 5 U. OTTAWA L. & TECH. J. 43, 63–67 (2008); Bryan C. Mercurio, *Trips, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 223 (2004).

²⁰⁴ See generally Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369 (2006); Frederic M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 WORLD ECONOMY 1127 (2004); CARLOS CORREA, *supra* note 151, at 3–10; SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003); J. Michael Finger & Philip Schuler, *Implementation of Uruguay Round Commitments: The Development Challenge*, 23 THE WORLD ECONOMY 511 (2000); DRAHOS & BRAITHWAITE, *supra* note 103.

²⁰⁵ See generally Scherer, *supra* note 204, at 1127–32; Ruth L. Okediji, *Public Welfare*

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their access to technological inventions and creative works restricted for the economic benefit of IP-rich corporations based in developed countries. Some commentators went as far as describing this new international trade law framework as an inequitable bargain, reminiscent of colonialism.²⁰⁶

The response to these criticisms was that the advent of globalized international trade had made the establishment of internationally-accepted minimum standards for the protection and enforcement of IP rights an absolute necessity to reduce counterfeiting and free-riding.²⁰⁷ Proponents of this view observed that TRIPS had mostly reiterated rules and principles already present in other international IP conventions, with only minor substantive and procedural additions.²⁰⁸ Moreover, they emphasized that the WTO would create a forum for international dispute resolution that would be based on the rule of law, protecting developing Members from overbearing unilateral actions of richer countries.²⁰⁹

Initially conducted in the abstract, this debate soon assumed concrete features in the realm of patents. Historically, countries that sought greater access to unavailable or expensive patented inventions made recourse to compulsory licensing only if there was at least one domestic manufacturer with the necessary infrastructure and know-how to fabricate the invention in question and compete with the patentee. When the necessary means for local production were absent, issuing a CL was a vacuous exercise. In such circumstances, countries looked to foreign markets where the product or process in question was cheaply and abundantly available either due to not being patented (Avenue 1) or because it was subject to a CL (Avenue 2).²¹⁰

In the years following its entry into force, it became apparent that the TRIPS patents and compulsory licensing regimes had the combined effect of rendering both these avenues almost unviable.²¹¹ Article 27 disrupted Avenue

and the Role of the WTO: Reconsidering the Trips Agreement, 17 EMORY INT'L L. REV. 819 (2003); SUSAN K. SELL, *supra* note 204.

²⁰⁶ See generally Rahmatian, *supra* note 27; Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective American Association of Law Schools' Intellectual Property Section's Symposium on Compliance with the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 613 (1996); DRAHOS & BRAITHWAITE, *supra* note 103, at 197–207.

²⁰⁷ See generally Daniel J. Gervais, *TRIPS & Development*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT 13–16 (Daniel J. Gervais ed., 2007); Reichman, *supra* note 149; BANKOLE SODIPO, PIRACY AND COUNTERFEITING: GATT TRIPS AND DEVELOPING COUNTRIES 274–77 (1997).

²⁰⁸ See Daniel J. Gervais, *supra* note 207, at 13–17; Jerome H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade after the GATT's Uruguay Round Symposium: Intellectual Property and Competition Law: Changing Views in the European Community and the United States of America*, 20 BROOK. J. INT'L L. 75 (1993–1995).

²⁰⁹ See generally Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together Symposium: Intellectual Property Law in the International Marketplace: TRIPS Panel Principal Paper*, 37 VA. J. INT'L L. 275 (1997).

²¹⁰ See Abbott, *supra* note 2, at 318–22 (exhaustively describing both these avenues).

²¹¹ See Abbott & Reichman, *supra* note 2, at 923–30.

1. By requiring that all Members implement patents for inventions in all fields of technology, this provision all but eliminated the possibility that a product or process would be patented in one country but not in others.²¹² Synchronously, Article 31(f) almost completely precluded Avenue 2 by mandating that Members could only issue CLs “predominantly” for the supply of their domestic market.²¹³ In contradiction with the objectives articulated in Article 7, the TRIPS patents and compulsory licensing regimes made it harder for Members to access patented technologies in fields in which they had limited manufacturing capabilities.²¹⁴

Critically, this facet of the TRIPS affected developing Members most acutely in respect of medical inventions.²¹⁵ Throughout the 20th century, these countries had overcome their limited or absent manufacturing capacity in this sector by consistently purchasing pharmaceuticals from India, Brazil, Argentina and a few other jurisdictions that either did not recognize patent protection in this field or allowed the exporting of products manufactured under compulsory licenses.²¹⁶ As these Members gradually reformed their domestic patent laws to conform with Articles 27 and 31, this long-established international procurement route for pharmaceuticals began to unravel. Tragically, the ensuing disruption in access to medicines concretized precisely at the time when developing Members were desperately scrambling to obtain the patented drugs necessary to contain the surging HIV/AIDS epidemic.²¹⁷

F. The Doha Declaration and Article 31bis

As the 21st century drew to a close, ever-louder condemnation was levelled at the diminution in access to medicines foisted upon developing Members with limited pharmaceutical manufacturing capabilities by the combined effect of the TRIPS patent and compulsory licensing regimes. Bolstered by swelling support from scholars, activists and NGOs,²¹⁸ a large group of developing Members submitted a proposal to fundamentally recast Articles 27 and 31 at the 2001 Doha Ministerial Conference.²¹⁹ Though this

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²¹² See *supra* notes 169-172 and accompanying text.

²¹³ See *supra* note 199 and accompanying text.

²¹⁴ See *supra* notes 156-158 and accompanying text.

²¹⁵ See Abbott & Reichman, *supra* note 2, at 318–22 (exhaustively assessing the impact of the TRIPS patents and compulsory licensing regimes on Members with limited production capabilities);

²¹⁶ See generally Finger & Schuler, *supra* note 204; Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571 (2009).

²¹⁷ See Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 620–21 (2003).

²¹⁸ On the access-to-medicine movement see *infra* notes 280-282 and accompanying text.

²¹⁹ See Council for Trade-Related Aspects of Intellectual Property Rights, Proposal by

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initiative was resisted by developed Members,²²⁰ it succeeded in mustering unanimous support for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).²²¹ The Doha Declaration recognized the importance of patent protection for medical inventions, but coextensively acknowledged “concerns about its effects on prices”.²²² Concurrently, it reiterated the unfettered sovereign prerogative of Members to grant CLs and their “freedom to determine the grounds” upon which they are issued.²²³ Expressing the key issue at the heart of the Doha Declaration, Paragraph 6 explicitly recognized the difficulties faced by countries with insufficient pharmaceutical manufacturing capacity in “making effective use of compulsory licensing under the TRIPS Agreement” and instructed the TRIPS Council to develop an “expeditious solution” to resolve this problem.²²⁴ This was an explicit admission that the original TRIPS framework governing this issue was flawed.

In 2003, after two years of contentious negotiations,²²⁵ the TRIPS Council duly adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Waiver Decision), in which it instituted a temporary “waiver” allowing WTO

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the African Group, et al., IP/C/W/312, WT/GC/W/450, 4 October 2001 (01-4803), available at <http://www.wto.org>. This proposal featured a two-pronged solution. First, it suggested establishing an official interpretation of Article 30 under which signatory states could introduce an exception to patentees’ rights that would permit the production and export of patented products “to address public health needs in importing Members”. Second, building on the international law notion of “comity”, it proposed explicitly recognizing that WTO Members with adequate capacity were authorized to “give effect” to compulsory licenses issued by other WTO members. See Abbott & Reichman, *supra* note 2, at 935 (providing an extensive analysis of this proposal and suggesting that it would have been superior to Article 31bis).

²²⁰ The Proposal by the African Group was met with stark opposition from the United States and the European Union; see *Id.*; DANIEL J. GERVAIS, *supra* note 134, ¶ 2.75-2.76.

²²¹ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001, ¶ 6, WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration] Paragraph 1 Declaration on the TRIPS Agreement and Public Health No. WT/MIN(0)/DEC/2, 14 November 2001 available on https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. See James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. TECH 291 (2002) (investigating the legal status of the Doha Declaration in international law and suggesting that it would be applied by the DSB as a formal amendment to the TRIPS agreement).

²²² Doha Declaration, *supra* note 221, para. 3 (“We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices”).

²²³ Doha Declaration, *supra* note 221, para. 5

²²⁴ Doha Declaration, *supra* note 221, para. 6 (“we recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”).

²²⁵ See Abbott, *supra* note 2, at 326–40 (explaining that three issues were at the heart of this negotiations: scope of covered diseases, eligible importing countries, and the article(s) of the TRIPS Agreement that would be addressed by the solution).

Members to grant compulsory licenses free from the obligations imposed by Articles 31(f) and (h).²²⁶ In 2005, the WTO General Council adopted the “Protocol Amending the TRIPS Agreement” (the Amendment Protocol) which incorporated the substance of the Waiver Decision into TRIPS via the addition therein of Article 31*bis*, its Annex and the Appendix to the Annex (henceforth the Article 31*bis* System).²²⁷ The Amendment Protocol entered into force in 2017, after ratification by two-thirds of Members.²²⁸

The Article 31*bis* System allows a Member (the Importing State) with “insufficient or no manufacturing capacities in the pharmaceutical sector”²²⁹ to import patented “pharmaceutical products”²³⁰ produced under a compulsory license granted by another Member (the Exporting State). Procedurally, it is structured as a dialogical interaction between an Importing and an Exporting State. At the outset, the Importing State must send a notice to the TRIPS Council. This document is not subject to approval, yet it must contain determinate information, including the name of the pharmaceutical product(s) that will be imported and the “expected quantity” required.²³¹ Moreover, unless the Importing State is an LDC,²³² it must self-certify its lack of capabilities to produce the drug in question domestically,²³³ and confirm

²²⁶ See General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), WT/L/540/Corr. 1 (1 September 2003) [hereinafter the Waiver Decision]. This Waiver is permissible because any requirement of a WTO agreement, including TRIPS, may be waived. See WTO Agreement, *supra* note 17, art. IX(3–4).

²²⁷ See WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641, 8 Dec. 2005. It should be noted that both the Waiver Decision and the Amendment Protocol were adopted subject to two identical Council Chair’s Statements that reflected several key understandings agreed by all Members, including that

²²⁸ This threshold is established by the WTO Agreement, *supra* note 17, art. X (“Amendments to provisions of this Agreement . . . shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it.”). At the time of writing, 107 Members have ratified the Protocol Amending the TRIPS Agreement, while Members yet to do so have until 31 December 2021; see https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

²²⁹ See TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(a)(ii).

²³⁰ See TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 1(a), (defining “pharmaceutical product” as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included”). Notably, this definition neither distinguishes between chemical drugs and biologics nor does it impose restrictions based on the illness being treated.

²³¹ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(c).

²³² TRIPS, *supra* note 18, Appendix to The Annex To The Trips Agreement (“Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector).

²³³ TRIPS, *supra* note 18, Appendix To The Annex To The Trips Agreement (“insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that

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that it has granted, or intends to grant, a compulsory license in accordance with Article 31 for the patented pharmaceutical product in question.²³⁴

Once the TRIPS Council has received the Importing State's notification, the Exporting State can issue an ECL that must still conform with Article 31 but which, crucially, is exempt from Article 31(f) "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)".²³⁵ The terms of this compulsory license must bind the licensee both to manufacture the patented pharmaceuticals in a quantity no greater than that notified to the TRIPS Council and to export all of them to the Importing State.²³⁶ Additionally, these products must be clearly identifiable "through specific labelling or marking", as well as distinguishable through special "packaging and/or colouring/shaping of the products themselves."²³⁷

The Exporting State must promptly notify the TRIPS Council that it has issued the ECL and its terms.²³⁸ Prior to shipment, the licensee must create a website through which it discloses the exact quantities of pharmaceuticals supplied to the Importing State and the markings that render them distinguishable.²³⁹ The Exporting State is required to pay compensation to the patentee subject to the compulsory license in question "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member".²⁴⁰

Notably, a Member is eligible as an Importing State only if it has notified the TRIPS Council of its intention to use the Article 31*bis* System.²⁴¹ As of the time of writing, 37 developed Members had expressly elected either not to do so at all or only in circumstances of extreme urgency.²⁴² These opt-outs were expressed when the Amendment Protocol was adopted, almost as an informal political pact among technologically advanced countries not to use the Article 31*bis* System to encroach upon pharmaceutical patentees'

it has no manufacturing capacity in the pharmaceutical sector; or) ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs").

²³⁴ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(a)(iii).

²³⁵ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(c).

²³⁶ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(b)(i).

²³⁷ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(b)(ii).

²³⁸ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(c).

²³⁹ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(c).

²⁴⁰ TRIPS Art. 31bis(2).

²⁴¹ See TRIPS, *supra* note 1, Annex to the TRIPS Agreement 1(b) defining "eligible importing member" as "any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer".

²⁴² The list of country that have notified the TRIPS Council of their intention to use the Article 31*bis* System is available at https://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

rights.²⁴³ Ironically, the Covid-19 pandemic has exposed the short-sightedness of this accord. As several developed Members confront the inadequacy of their mRNA vaccine production capabilities and struggle to secure sufficient supplies to protect their population, sensitivity towards the plight of patentees appears to have suddenly diminished.²⁴⁴

The nascence of the Article 31bis System was received with excitement.²⁴⁵ Government representatives, activists, and legal scholars welcomed the creation of a compulsory licensing mechanism purposely tailored to enable Members with insufficient pharmaceutical manufacturing capacity to source patented pharmaceuticals from markets with greater technical know-how.²⁴⁶ Equally, there was excitement at the prospect of the Article 31bis System opening a new pathway for greater collaboration between developing and developed Members. More broadly, there was hope that this reform would be the first step towards a more equitable and solidaristic TRIPS.²⁴⁷

Regrettably, this optimism has gradually dissipated as attempts to make recourse to the Article 31bis System have been few and mostly unsuccessful. In 2005, Ghana reportedly considered notifying the TRIPS Council of its intention to import HIV pharmaceuticals, yet ultimately abandoned this attempt and procured the required medications in the open market.²⁴⁸ In 2008, Nepal notified the TRIPS Council that it wanted to import the chemotherapeutic drug erlotinib.²⁴⁹ Natco, an Indian generic pharmaceuticals manufacturer, applied for an ECL to supply Nepal, yet withdrew its application later after it was sued by the local patent holder for infringement. In 2021, in response to the Covid-19 pandemic, Bolivia notified the TRIPS Council of its intention to import 15 million doses of a vaccine patented by Johnson & Johnson and, synchronously, entered into a supply agreement with

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²⁴³ See Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT. ECONOMIC LAW 535, 558–60 (2020).

²⁴⁴ See *Id.* (emphasizing that the Covid-19 pandemic has lucidly revealed how such opt-outs were “ill-considered” and suggesting legal avenues for “opting back in”).

²⁴⁵ See minutes of the special meeting of the TRIPS Council meeting of 30 January 2017, WTO document IP/C/M/84.

²⁴⁶ See *Id.*; see also Abbott & Reichman, *supra* note 2, at 969; S. K. Verma, *The Doha Declaration and Access to Medicines by Countries Without Manufacturing Capacity*, in RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 623 (Carlos M. Correa ed., 2010).

²⁴⁷ See *Id.*

²⁴⁸ See WIPO ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 242 (2d ed. 2020) (describing Ghana’s attempt to make recourse to the Article 31bis System).

²⁴⁹ The pharmaceutical company Roche holds the patent to erlotinib and markets it around the world under the name Tarceva. On Nepal’s attempt to use the Article 31bis see generally *Id.*; Donald Harris, *TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 390 (2011).

Biolyse, a Canadian pharmaceutical manufacturer.²⁵⁰ At the time of writing, Biolyse had lodged an application with the Canadian government for an ECL.²⁵¹ It remains to be seen whether this attempt to use the Article 31*bis* System will come to fruition.

Since its creation, the Article 31*bis* System has been used successfully only once by Rwanda and Canada (the Canada-Rwanda ECL).²⁵² in July 2007, following three years of preparations spearheaded by Médecins Sans Frontières, Rwanda notified the TRIPS Council that intended to import a fixed-dose combination of three HIV/AIDS drugs.²⁵³ Two months later, Canada granted an ECL to Apotex, a local manufacturer of generic pharmaceuticals, and notified the TRIPS Council of this issuance, pursuant to Article 31*bis*. By the end of 2008, after several delays, Apotex exported the agreed medicines to Rwanda.

Eighteen years after its introduction, the extremely limited recourse to the Article 31*bis* System and its low success rate raise questions about its effectiveness in redressing the very flaw it was designed to solve.

III. FACTORS HINDERING THE ARTICLE 31BIS SYSTEM

This Part seeks to determine which factors are responsible for the stagnation of the Article 31*bis* System. This is a topic which has attracted significant attention, spawning a large but fragmented body of opinion. The TRIPS Council has addressed this issue in every one of its annual reviews on the “Special Compulsory Licensing System” since 2006;²⁵⁴ moreover, in

²⁵⁰ See *Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic*, available at https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm

²⁵¹ See *Bolivia signs J&J vaccine deal with a twist - it needs WTO patent waiver*, available at <https://www.reuters.com/world/americas/bolivia-signs-jj-vaccine-deal-with-twist-someone-else-would-make-it-2021-05-11/>.

²⁵² See generally Nicholas G. Vincent, *TRIP-Ing up: The Failure of TRIPS Article 31Bis*, 24 GONZ. J. INT'L L. 1 (2020); Tolulope Anthony Adekola, *Has the Doha Paragraph 6 System Reached Its Limits?*, 15 JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 525 (2020); Carlos Correa, *supra* note 40; Stacey B. Lee, *Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6*, 44 GEO. J. INT'L L. 1387 (2012–2013); Harris, *supra* note 249; Brin Anderson, *Better Access to Medicines: Why Countries Are Getting Tripped up and Not Ratifying Article 31-Bis Note*, 1 CASE W. RES. J.L. TECH. & INTERNET 165 (2009–2010); George Tsai, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration Note*, 49 VA. J. INT'L L. 1063 (2008); Christina Cotter, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries Student Article*, 5 LOY. U. CHI. INT'L L. REV. 177 (2008).

²⁵³ See WIPO ET AL., *supra* note 248, at 243 (for a detailed history of the Canada-Rwanda ECL, including a detailed analysis of Médecins Sans Frontières preparatory work, Rwanda's notification to the TRIPS council, as well as a description of the antiviral drugs in question); Vincent, *supra* note 252, at 19 (providing a detailed description of this composite drug and its formants).

²⁵⁴ For the most recent report, see WTO, *Annual Review of The Special Compulsory Licensing System*, IP/C/86 (11 November 2020).

2010, it held a session for Members to discuss openly implementation issues that might be affecting ECLs.²⁵⁵ The WTO, WIPO and WHO have also candidly acknowledged the inactivity of the Article 31 *bis* System in a jointly-issued report focused on access to medical technologies and innovation.²⁵⁶ Furthermore, academics, activists and NGOs have produced a panoply of diverse theories to account for the lack of success of ECLs. Considered holistically, we find that these sources have identified four broad groups of issues: governmental and corporate interferences, obtrusions caused by domestic laws and free trade agreements, procedural complexities and economic challenges. We now analyze each one in turn.

A. Governmental and Corporate Interferences

Mindful of the contentious past of compulsory licensing,²⁵⁷ commentators have suggested that developing Members do not make recourse to the Article 31 *bis* System, due to fear of retaliation from developed Members and pharmaceutical companies.²⁵⁸ In support of this view, scholars and NGOs have long decried the manner in which the United States Government has historically weaponized Section 301 of the United States Tariff Act 1974²⁵⁹ to pressure and sanction states that they deem not to protect American intellectual property interests adequately.²⁶⁰ Moreover, they point to troubling episodes that have occurred in recent past when developing

²⁵⁵ WTO, *Minutes of Meeting Held In The Centre William Rappard On 2 March 2010*, IP/C/M/61 (1 June 2010) 35-42.

²⁵⁶ See WIPO ET AL., *supra* note 248, at 241–44.

²⁵⁷ See *supra* Part I.C.

²⁵⁸ See Halajian, *supra* note 203, at 1213–15; Harris, *supra* note 249, at 392; Carlos Correa, *supra* note 40.

²⁵⁹ 19 USC §221. Pursuant to this provision, the Office of the United States Trade Representative (USTR) annually prepares a report (the “Special 301” Report) examining how foreign countries protect intellectual property rights. Those that are considered to have adopted laws and practices with an “adverse impact (actual or potential) on the relevant United States’ products” are placed on a “Priority Watch List” and may subject to unilateral trade sanctions. All Special 301 reports are available from Office of the United States Trade Representative (USTR) at <https://ustr.gov/issue-areas/intellectual-property/Special-301>. See generally Judith H. Bello & Alan F. Holmer, *Special 301: Its Requirements, Implementation, and Significance*, 13 *FORDAM INT’L L.J.* 259 (1989); Michael Palmedo, *United States: Unilateral Norm Setting Using Special 301*, in *INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES* 274 (Ragavan Srividya & Vanni Amaka eds., 2021).

²⁶⁰ See Palmedo, *supra* note 259 (offering an exhaustive analysis of the use of Special 301 over the past two decades); Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 *J. INT. ECONOMIC LAW* 51 (2016) (charting the historical development of Special 301 and analyzing a large number of cases in which it was used against developing countries); Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicines*, 7 *JOURNAL OF GENERIC MEDICINES* 309 (2010) (for a historical overview of Special 301 and its use during the first term of the Obama presidency).

Members have issued compulsory licenses.²⁶¹ For example, between 2006 and 2008, Thailand issued compulsory licenses for several patented pharmaceutical products used to treat HIV/AIDS (efavirenz, lopinavir/ritonavir), heart disease (clopidogrel) and cancer (letrozole, docetaxel, erlotinib, and imatinib).²⁶² Without negotiating with patent holders, compensation was a royalty set at 0.5% to 2% of the total sale value.²⁶³ As Thailand provides healthcare to all residents free of cost at the point of access, the government projected that these measures would reduce its costs for these pharmaceuticals by a factor of 10.²⁶⁴

Some developed Members and the affected pharmaceutical companies responded aggressively. In 2007, the United States placed Thailand on its Special 301 "Priority Watch List",²⁶⁵ declaring that "while the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern".²⁶⁶ By way of sanction, the United States barred Thai exports from entering its domestic market on a duty-free basis.²⁶⁷

The European Union had a mixed reaction. On one hand, the European Commission wrote to the Thai government expressing reservations regarding the lawfulness of its compulsory licensing practices,²⁶⁸ on the other, the European Parliament passed a resolution expressing support for developing

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²⁶¹ 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., 2020) (recounting the pressure that developed countries and pharmaceutical corporations directed at South Africa in 1997, Brazil in 2001, Malaysia in 2003, Indonesia in 2004, and several others, in response to compulsory licensing initiatives).

²⁶² These drugs were efavirenz, lopinavir/ritonavir, clopidogrel, letrozole, docetaxel, erlotinib, and imatinib. For an exhaustive explanation of Thailand's approach to the grant of these compulsory licenses see Ministry of Public Health and National Health Security Office, *Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand*, February 2007, available at <http://digicollection.org/hss/documents/s18718en/s18718en.pdf> [hereinafter the 'Thai White Paper']. See Abbott & Reichman, *supra* note 2, at 952–53 (for a detailed analysis of these Thai compulsory licenses and the ensuing reaction from states and pharmaceutical companies); Cynthia M. Ho, *Patent Breaking or Balancing: Separating Strands of Fact from Fiction under Trips*, 34 N.C.J. INT'L L. & COM. REG. 371, 411–41 (2009) (providing an extensive legal analysis of these Thai CLs).

²⁶³ Thai White Paper, *supra* note 262, 17.

²⁶⁴ Thai White Paper, *supra* note 262, 11–15.

²⁶⁵ See *supra* notes 259–260 and accompanying text.

²⁶⁶ See USTR 2007 Special 301 Report, 27 available at <https://ustr.gov/sites/default/files/2007%20Special%20301%20Report.pdf>.

²⁶⁷ Reports of the United Nations Secretary-General's High-Panel on Access to Medicines, Promoting Innovation and Access to Health Technologies, (2016) 7 <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> Accessed 19/02/2017, p. 25

²⁶⁸ Letter from Peter Mandelson, E.U. Trade Commissioner to Krirk-krai Jirapaet, Thai Minister of Commerce (July 10, 2007), available at <https://www.keionline.org/wp-content/uploads/mandelson07102007.pdf>

Members that take advantage of TRIPS flexibilities to protect their citizens' right of access to medicines.²⁶⁹ Meanwhile, Sanofi, the patent holder for clopidrogel, threatened to sue the Indian company involved in exporting the pharmaceutical in question into Thailand.²⁷⁰ Even more troubling, Abbott, the patent holder for lopinavir/ritonavir, withdrew an array of new medicines for blood clots, kidney diseases, arthritis, high blood pressure, viral infection and inflammation from the Thai market.²⁷¹ Although this vindictive measure was later reversed, Thai patients suffered unnecessary harm at the hands of a private foreign actor. They were deprived of access to essential treatments, some of which had no alternative, for the duration of the entire dispute.

We agree that compulsory licensing, both under Article 31 and the Article 31*bis* System, are vulnerable to governmental and private retaliatory initiatives, including punitive trade policies and pharmaceutical product withdrawals. Such actions should be condemned unreservedly. They show arrogant disregard for Articles 7-8,²⁷² the flexibilities included in the TRIPS patent regime,²⁷³ the WTO Dispute Settlement Body,²⁷⁴ the Doha Declaration,²⁷⁵ and Article 31*bis*(4) which explicitly prohibits Members not to challenge legitimately-issued ECLs.²⁷⁶ Even worse, these maneuvers encroach upon the national sovereignty of the targeted Members. They constitute a contemptible exploitation of the asymmetrical power relationship that exists between the Global North and the Global South in trade relations.

This notwithstanding, we believe that there is robust evidence to counter the view that the Article 31*bis* System has been scarcely utilized due to the fear of governmental and corporate reprisals. First, the stance of developed Members and pharmaceutical companies towards compulsory licensing has evolved considerably in the years since the adoption of TRIPS, and especially following the Doha Declaration. During the late 1990s and early 2000s, almost every instance of developing Members issuing compulsory licenses for a pharmaceutical product was characterized by political pressure and trade sanctions from national governments, often led by the United States, as well as staunch opposition from patent holders.²⁷⁷

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²⁶⁹ European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, P6_TA-PROV(2007)0353, para 9, available at <http://www.europarl.europa.eu/sides/getDoc.do?Type=TA&Reference=P6-TA-2007-0353&language=EN>.

²⁷⁰ See Abbott & Reichman, *supra* note 2, at 953–54.

²⁷¹ See generally V. Kuek et al., *Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand*, 6 GLOBAL PUBLIC HEALTH 111 (2011) Paul Cawthorne et al., *Access to Drugs: The Case of Abbott in Thailand*. (2007) (for a contemporaneous account of these events).

²⁷² See *supra* notes 156-158 and accompanying text.

²⁷³ See *supra* Part II.B.1.

²⁷⁴ See *supra* notes 182-186 and accompanying text.

²⁷⁵ See *supra* note 221-226 and accompanying text.

²⁷⁶ TRIPS, *supra* note 18, art. 34*bis*(4) ("Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement").

²⁷⁷ See Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health*

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However, over the past ten years, such hostile responses have become infrequent and less intense, while not vanishing entirely.²⁷⁸ Analyzing the conduct of the United States in recent cases, one commentator has gone as far as stating that “its bark is much worse than its bite”.²⁷⁹ This shift has largely been due to the “heroic civil society struggle” of the access-to-medicine movement (A2M).²⁸⁰ Crucially, between 1999 and 2008, the A2M coordinated global awareness campaigns to censure and oppose the retaliatory initiatives directed at South Africa, Brazil, Malaysia, Indonesia and Thailand following their grant of compulsory licenses over pharmaceuticals.²⁸¹ As a result, in all these cases, the patent holders and national governments responsible for these punitive actions received widespread condemnation from the international public, suffered substantial reputational damage and ultimately withdrew their opposition.²⁸²

Second, domestic and export compulsory licensing curtail patentees’ rights in the exact same measure. If there were reluctance to use the Article 31*bis* System due to fear of retaliatory actions, the same would be true for CLs granted to supply the internal market of the issuing country. However, recent empirical evidence shows that Members of all income levels are regularly and effectively making recourse to domestic compulsory licensing for a growing range of patented pharmaceutical products.²⁸³ Son and Lee

Policy: Managing Confrontation with US Firms and Politicians, 29 INTERNATIONAL JOURNAL OF HEALTH SERVICES 765 (1999) (providing an account of the political pressure exercised by the United States on South Africa due to its compulsory licensing policy); Haroon Ashraf, *USA and Brazil End Dispute over Essential Drugs*, 357 THE LANCET 2112 (2001) (analyzing the contrast between United States and Brazil regarding patent protection of HIV/AIDS pharmaceuticals); Ho, *supra* note 262, at 411–41 (detailing the political and corporate pressures encountered by Thailand following the issuance of CLs on several patent pharmaceuticals).

²⁷⁸ See Baker, *supra* note 261, at 302–19 (describing both the progressive shift in stance of developed Members and the increasingly more collaborative attitude of pharmaceutical companies).

²⁷⁹ *Id.* at 306; see also Brook Baker, *Don’t Be Afraid of Compulsory Licenses Despite US Threats: Special 301 Reports 1998–2017 – Listing Concerns But Taking Little Action*, Available at <https://healthgap.org/dont-be-afraid-of-compulsory-licenses-despite-us-threats-special-301-reports-1998-2017-listing-concerns-but-taking-little-action/>.

²⁸⁰ See generally Baker, *supra* note 261; ‘T HOEN, *supra* note 2, at 31–73; Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804 (2008); Susan K. Sell, *Trips and the Access to Medicines Campaign Proceedings of the 2002 Conference - Access to Medicines in the Developing World: International Facilitation or Hindrance*, 20 WIS. INT’L L.J. 481 (2001–2002).

²⁸¹ See Baker, *supra* note 261, at 302–19 (providing numerous bibliographical references to contemporary accounts of the unfolding events); Thomas Owen, *The ‘Access to Medicines’ Campaign Vs. Big Pharma*, 11 CRITICAL DISCOURSE STUDIES 288 (2014); Nathan Ford et al., *The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand*, 363 THE LANCET 560 (2004).

²⁸² See Baker, *supra* note 261, at 302–19.

²⁸³ See Medicines Law & Policy, The TRIPS Flexibilities Database, available at <http://tripsflexibilities.medicineslawandpolicy.org/> [hereinafter the TRIPS Flexibilities Database]; Kyung-Bok Son & Tae-Jin Lee, *Compulsory Licensing of Pharmaceuticals*

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have documented 108 attempts to issue CLs, for 40 different pharmaceuticals products, across 27 countries, between 1995 and 2018.²⁸⁴ These efforts yielded 53 CLs, 18 price reductions, and 16 voluntary licenses, failing to achieve tangible results only in 21 cases. More than half of these attempts involved patented pharmaceuticals for the treatment of HIV/AIDS, yet influenza and cancer medicines have been increasingly subject to CLs over the past decade.²⁸⁵ Between 2018 and 2020, there have been 10 additional applications for CLs, some of which in high income countries, for pharmaceuticals treating HIV/AIDS and cancer, but also opioid overdose, hepatitis C and cystic fibrosis.²⁸⁶ Even more recently, Israel, Russia, and Hungary have issued CLs to increase the supply of pharmaceuticals used to treat Covid-19, with commentators and NGOs actively encouraging other countries to follow suit.²⁸⁷

B. Domestic Law and Free Trade Agreements Obtrusions

The WTO legal order does not preclude Members from entering into multilateral, regional or bilateral free trade agreements (FTA) that introduce

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Reconsidered: Current Situation and Implications for Access to Medicines, 13 GLOBAL PUBLIC HEALTH 1430 (Oct. 2018); Ellen F.M. 't Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL WORLD HEALTH ORGAN 185, 190 (Mar. 2018) (carrying out a comprehensive empirical study on the use compulsory licensing and concluding that “our study shows that TRIPS flexibilities have been used more frequently than is commonly assumed and have proven effective for procuring generic versions of essential medicines, particularly for treating HIV infections”); Son & Lee, *supra* (analyzing available empirical data and concluding that “there have been more attempts to issue compulsory licensing and for more pharmaceuticals, especially for oncology, than previously reported. This means that compulsory licensing that had been devised to cope with the HIV/AIDS pandemic in low-income countries has become a practical measure in several Asian and Latin American countries, even for non-HIV/AIDS medicines.”). See also Eduardo Urias & Shyama V. Ramani, *Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence*, 3 J. INT. BUS. POLICY 367 (2020) (reviewing a large body of empirical evidence and concluding that CLs on pharmaceutical patents yield material price reductions).

²⁸⁴ See Son & Lee, *supra* note 283. These data are consistent with those of the TRIPS Flexibilities Database as well as previous empirical studies; see 't Hoen et al., *supra* note 283; Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MEDICINE (2012).

²⁸⁵ See Son & Lee, *supra* note 283; the TRIPS Flexibilities Database.

²⁸⁶ See The TRIPS Flexibilities Database.

²⁸⁷ See Hilary Wong, *The Case for Compulsory Licensing during COVID-19*, 10 J. GLOB. HEALTH (2020); World Trade Organization, *Patent-Related Actions taken in WTO Members in Response to the COVID-19 Pandemic*, *WTO Working Papers*, No. 2020/12 (2020) available at <https://doi.org/10.30875/fb500072-en> (discussing CLs issued by Israel and Hungary); Médecins Sans Frontières, *Compulsory licenses, the TRIPS waiver and access to Covid-19 medical technologies*, MSF Briefing Document (2021) available at https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf (discussing CLs issued by Israel, Hungary and Russia).

higher IP protection standards than those established by TRIPS (commonly referred to as "TRIPS-Plus"), including restrictions on ECLs.²⁸⁸ Equally, Members are free to enact domestic patent legislation that either directly or indirectly limits ECLs.

Commentators have advanced the view that there is a growing body of domestic laws,²⁸⁹ and TRIPS-Plus FTAs which undermine the Article 31*bis* System.²⁹⁰ Regarding the former, Canada's Access to Medicines Regime (CAMR) has been highlighted as worrisome example.²⁹¹ At the time of its enactment, CAMR was heralded as a regime expressly designed to aid developing countries. Nevertheless, the legislative text imposes restrictions that are not demanded by TRIPS. Notably, it sets the maximum duration of compulsory export licenses to two years.²⁹² Moreover, it circumscribes the

²⁸⁸ As a general proposition WTO rules encourage Members to enter into free trade agreements; see General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994), Article XXIV(4) ("The contracting parties recognize the desirability of increasing freedom of trade by the development, through voluntary agreements, of closer integration between the economies of the countries parties to such agreements."). See generally Pedro Roffe, *Intellectual Property Chapters in Free Trade Agreements: Their Significance and Systemic Implications*, in EU BILATERAL TRADE AGREEMENTS AND INTELLECTUAL PROPERTY: FOR BETTER OR WORSE? 17 (Josef Drexl et al. eds., 2014) (providing an exhaustive survey of FTAs that introduce IP standards above those included in TRIPS).

²⁸⁹ See generally Halajian, *supra* note 203, at 1216; Jillian C. Cohen-Kohler et al., *Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?*, 5 HEALTHCARE POLICY 40 (2010); Amir Attaran, *Why Canada's Access to Medicines Regime Can Never Succeed UNBLJ Forum: Recent Developments in Private International Law*, 60 U.N.B.L.J. 150 (2010); Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT. J. INTELLECTUAL PROPERTY MANAGEMENT (2006).

²⁹⁰ See generally HENNING GROSSE RUSE-KHAN, *THE PROTECTION OF INTELLECTUAL PROPERTY IN INTERNATIONAL LAW* (2016); ERMIA TEKESTE BIADGLEN & JEAN-CHRISTOPHE MAUR, *THE INFLUENCE OF PREFERENTIAL TRADE AGREEMENTS ON THE IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES: A FIRST LOOK* (2011); Hafiz Aziz ur Rehman, *India, TRIPS-Plus Free Trade Agreements and the Future of Access to Essential Medicines*, 19 INFO. & COMM. TECH. L. 267 (2010); Susan K. Sell, *supra* note 203, at 453; Bryan Christopher Mercurio, *Trips-Plus Provisions in Ftas: Recent Trends*, PUBLIC HEALTH LAW & POLICY (2006); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79 (2004).

²⁹¹ Canada was the first country to adopt domestic legislation implementing the Article 31*bis* System. In 2005, it amended the Canadian Patent Act 1985, R.S.C. to include new sections 21.01-21.19. See Act to Amend the Patent Act and the Food and Drugs Act (the Jean Chrétien Pledge to Africa Act), S.C. 2004, c.23. See generally Cohen-Kohler et al., *supra* note 289; Attaran, *supra* note 289; Tsai, *supra* note 252; Paige E. Goodwin, *Right Idea, Wrong Result - Canada's Access to Medicines Regime Notes and Comments*, 34 AM. J.L. & MED. 567 (2008); Elliott, *supra* note 289; Mark D. Penner & Prakash Narayanan, *Amendments to the Canadian Patent Act to Address Drug Access: Is Help on the Way?*, 60 FOOD AND DRUG LAW JOURNAL 459 (2005).

²⁹² See Attaran, *supra* note 289 (highlighting that no other country has introduced such a restriction in their domestic implementation of the Article 31*bis* System); Elliott, *supra*

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pharmaceuticals that may be manufactured under such licenses to those included in a special list (Schedule 1) the amendment of which is subject to a dedicated administrative procedure.²⁹³ Placing an ulterior onus on licensees, the Canadian Patent Act also requires that all medicines produced for export must meet Canadian marketing approval standards, rather than those of the Importing State.²⁹⁴

Regarding TRIPS-Plus FTAs, concerns have been raised about bilateral agreements that directly limit compulsory licensing.²⁹⁵ For example, under the US-Jordan FTA,²⁹⁶ the US-Singapore FTA,²⁹⁷ and the US-Australia FTA,²⁹⁸ signatory states agree to only issue compulsory licenses, both for domestic purposes and when acting as an Exporting State, to address a narrow set of issues: anti-competitive practices of patent holders, public non-commercial use and circumstances of extreme urgency.²⁹⁹ Going even further, the US-Singapore FTA and US-Australia FTA also provide that patent holders cannot be compelled to assist compulsory licensees by having to share “undisclosed information or technical know-how”.³⁰⁰

Equally, TRIPS-Plus FTAs which contain data exclusivity provisions³⁰¹

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note 289, at 107 (criticizing this unnecessary time restriction and highlighting its negative consequences); Goodwin, *supra* note 291, at 578–79.

²⁹³ See Elliott, *supra* note 289, at 100–101 (detailing the political debate that led to this policy decision); Goodwin, *supra* note 291, at 574. 578-579 (emphasizing that no other country has imposed a comparable limitation when implementing Article 31bis); Tsai, *supra* note 252, at 1094–95.

²⁹⁴ See Attaran, *supra* note 289, at 159 (suggesting that this requirement is necessary) Elliott, *supra* note 289, at 103 (expressing a negative view of this requirement).

²⁹⁵ See generally Henning Grosse Ruse-Khan, *Protecting Intellectual Property Rights under BITs, FTAs and TRIPS: Conflicting Regimes or Mutual Coherence?*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* 485 (Chester Brown & Kate Miles eds., 2011); Bryan Christopher Mercurio, *supra* note 290; Carlos M. Correa, *supra* note 290.

²⁹⁶ United States-Jordan Free Trade Agreement Art. 1.2, Oct. 24, 2000, 41 I.L.M. 63 [hereinafter US-Jordan FTA].; see Hamed El-Said & Mohammed El-Said, *TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement*, 10 J. WORLD INTELL. PROP. 438 (2007).

²⁹⁷ United States-Singapore Free Trade Agreement art. 16.7(2), May 6, 2003, 42 I.L.M. 1026 [hereinafter US-Singapore FTA].

²⁹⁸ United States-Australia Free Trade Agreement, art. 17.9(7)(b)(iii), May 18, 2004, 43 I.L.M. 1248 [hereinafter US-Australia].

²⁹⁹ See Gaëlle P. Krikorian & Dorota M. Szymkowiak, *Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine*, 10 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 388, 402–4 (2007) (analyzing the provisions that directly limit compulsory licensing in all major FTAs negotiated by the United States between 1994-2007); Harris, *supra* note 249, at 384–384 (analyzing the reach of TRIPS-Plus FTAs negotiated by the United States).

³⁰⁰ See US-Singapore FTA, art. 16.7; US-Australia FTA, art. 17.9.

³⁰¹ Albeit with differences across jurisdictions, data exclusivity regimes typically provide that safety and efficacy clinical trial data submitted by a patent holder to obtain sale approval by the national authorities of a state cannot be relied upon by competitors for a fixed period of time. See generally Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1 (2009); Aaron Xavier Fellmeth, *Secrecy*,

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have been denounced as detrimental to the Article 31*bis* System.³⁰² For example, the USA-Singapore FTA, US-Jordan FTA,³⁰³ the US-Australia FTA,³⁰⁴ the US-Chile FTA,³⁰⁵ and the US-Morocco FTA³⁰⁶ provide that if a signatory state requires the submission of information concerning the safety and efficacy of a pharmaceutical to authorize its marketing and sale, patentees cannot be mandated to share their own data with compulsory licensees, for a period of time that ranges from three to five years from the date when the patent was originally granted.³⁰⁷

We agree that domestic legislation and multilateral FTAs that directly or indirectly impede the issuance of ECLs are troubling. If the majority of the Members with mature pharmaceutical industries chose this path, the Article 31*bis* System might be rendered dead letter. Nevertheless, in our view, this is not the situation at present and there is encouraging evidence that the international community is moving in the opposite direction. Firstly, almost all Members with advanced pharmaceutical manufacturing capabilities have enacted domestic laws implementing the Article 31*bis* System that do not restrict the grant of compulsory export licenses.³⁰⁸ Even Canada has explored the possibility of reforming its own framework.³⁰⁹

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Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement, 45 HARV. INT'L L.J. 443 (2004); Carlos Maria Correa, *Unfair Competition under the TRIPs Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals Symposium: Public Health and International Law*, 3 CHI. J. INT'L L. 69 (2002).

³⁰² See generally Médecins Sans Frontières, *Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?*, MSF Technical Brief (May 2004), available at <http://www.citizen.org/documents/DataExclusivityMay04.pdf>.

³⁰³ United States-Jordan Free Trade Agreement Art. 1.2, Oct. 24, 2000, 41 I.L.M. 63 [hereinafter US-Jordan FTA].; see El-Said & El-Said, *supra* note 296

³⁰⁴ United States-Australia Free Trade Agreement, art. 17.9(7)(b)(iii), May 18, 2004, 43 I.L.M. 1248 [hereinafter US-Australia].

³⁰⁵ United States-Chile Free Trade Agreement, art. 17.10(b), June 6, 2003, 42 I.L.M. 1026.

³⁰⁶ United States-Morocco Free Trade Agreement, art. 15.10(4), June 15, 2004, 44 I.L.M. 544.

³⁰⁷ See Krikorian & Szymkowiak, *supra* note 299, at 399–402 (analyzing the data exclusivity provisions of all major FTAs negotiated by the United States between 1994–2007).

³⁰⁸ An exhaustive database of the national laws adopted by Members to implement the Article 31*bis* System is available https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm; see generally Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation*, No. ERSD-2015-07 (World Trade Organization (WTO), Economic Research and Statistics Division 2015) (providing a comparative analysis of all the national legislations adopted to implement the Article 31*bis* System up to 2015).

³⁰⁹ See Daniele Dionisio, *Amending Canada's Access To Medicines Regime (CAMR): The New Fate Of Bill C-393*, IP Watch (2011) available at <https://www.ip-watch.org/2011/06/28/amending-canada%E2%80%99s-access-to-medicines-regime-camr-the-new-fate-of-bill-c-393/>. Having passed the Canadian lower house of Parliament, Bill C-393 stalled in the Senate and was not enacted; see Lindsey Amèrica-Simms & Richard Elliott, *Senate Stalling Derails Bill to Fix Canada's Law on Affordable Generic Medicines for Developing Countries.*, 15 HIV/AIDS POLICY & LAW REVIEW 24 (2011).

Secondly, the problematic FTAs negotiated by the United States in the early 2000s were met by a wave of criticism by NGOs, international organizations and scholars, engendering significant public backlash.³¹⁰ In more recent times, the United States has entered into multilateral arrangements negotiated with Peru, Panama, Colombia and South Korea that expressly refer to the Doha Declaration and do not contain direct or indirect restrictions on the granting of compulsory export licenses.³¹¹ In similar vein, the recently ratified United States-Mexico-Canada Agreement (USMCA)³¹² was ultimately stripped of data exclusivity provisions that would have undermined the Article 31*bis* System;³¹³ this is especially significant in light of the fact that the previous North American Free Trade Agreement (NAFTA) contained restrictions on export compulsory licensing.³¹⁴ It should also be noted that FTAs negotiated by the European Union have generally not included restrictions to ECLs.³¹⁵ This is also true of recently multilateral agreements recently signed in by Asian and Oceanian Members, including the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)³¹⁶ and the Regional Comprehensive Economic Partnership (RCEP).³¹⁷

³¹⁰ On the Access-to-medicine movement see *supra* notes 280-283 and accompanying text.

³¹¹ See United States-Panama Trade Promotion Agreement, art. 15.10, June 28, 2007; United States-Peru Trade Promotion Agreement, art. 16.10(2), Apr. 12, 2006; United States-Colombia Trade Promotion Agreement, art. 16.10(2), Nov. 22, 2006. United States-South Korea Free Trade Agreement, art. 18.11 Feb. 10, 2011. See generally Krikorian & Szymkowiak, *supra* note 299, at 402–4.

³¹² Agreement between the United States of America, the United Mexican States, and Canada, Nov. 30, 2018, available at <https://ustr.gov/trade-agreements/free-tradeagreements/united-states-mexico-canada-agreement/agreement-between> [hereinafter USMCA].

³¹³ See Ronald Labonté et al., *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 GLOBALIZATION AND HEALTH 35 (detailing how negotiations in the House of Representative ultimately resulted in the elimination of terms that would have assured ten years of data exclusivity for newly approved biologic medicines).

³¹⁴ See North American Free Trade Agreement Art. 1709(10)(f), United States-Canada-Mexico, Dec. 17, 1992, 32 I.L.M. 289 (1993) (restricting compulsory licenses to the supply of the domestic market of the issuer and not contemplating exceptions to accommodate the Article 31*bis* System).

³¹⁵ See Roffe, *supra* note 288 (noting that the EU has focused on geographical indications in its TRIPS-Plus FTAs, rather than patents and compulsory licensing). The notable exception is the Trade Agreement between the European Union, and its Member States, of the one part, and Colombia and Peru, of the other part, OJ L 354, 21.12.2012, 3–260, introducing a data exclusivity regime with a five-year term under art. 231.2.

³¹⁶ See Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 396–98 (2019) (emphasizing that provisions on strengthening patent protection, as well as data exclusivity were removed from this treaty as soon as the US withdrew from negotiations).

³¹⁷ See Deborah K. Elms, *Getting RCEP across the Line*, 20 WORLD TRADE REVIEW 373 (2021) (detailing the content of this FTA and highlighting the absence of provisions that go beyond TRIPS substantive minima for patent protection).

C. Procedural Complexities

The Article 31*bis* System is governed by a protracted and onerous multi-step procedure, punctuated by detailed requirements.³¹⁸ The Importing State must comply with a series of information disclosure obligations in its notification to the TRIPS Council.³¹⁹ Coextensively, the Exporting State must issue highly-specific compulsory licenses, pay compensation to the affected patentee, and keep the TRIPS Council duly informed.³²⁰ Moreover, the licensee is also required to make public disclosures regarding the manufactured pharmaceuticals.³²¹

Commentators have vigorously contended that the procedural dimension of the Article 31*bis* System is acutely problematic for developing Members, going as far as describing it as a “labyrinth”.³²² As a general criticism, they remark that, when assessed in its entirety, the process is too protracted and demands an unrealistic degree of coordination among parties.³²³ Regarding Importing States, the obligation for non-LDC Members to supply evidence of their insufficient manufacturing capabilities has been singled out as a heavy burden for “an already potentially strapped-for-resources member”.³²⁴ Scholars and NGOs have also denounced the requirement that Importing States specify the exact required quantity of the pharmaceutical in question, not only because this might be a challenging estimation *ex ante*, but particularly because the Article 31*bis* System does not contemplate a renewal or amendment mechanism to increase supply of the imported product after an ECL has been granted.³²⁵

Still sharper criticisms have been levied at the procedural burdens imposed on Exporting States and licensees. The prerequisite to negotiate with patent holders before an ECL can be issued³²⁶ has been decried as a likely source of significant delays, especially when multiple patentees are

³¹⁸ See *supra* notes 229-244 and accompanying text.

³¹⁹ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(a).

³²⁰ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(b)(i)-(ii).

³²¹ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(b)(iii).

³²² See Baker, *supra* note 217, at 655; See generally Vincent, *supra* note 252; Carlos Correa, *supra* note 40; Halajian, *supra* note 203, at 1202-4; Harris, *supra* note 249; Verma, *supra* note 246; Cohen-Kohler et al., *supra* note 289.

³²³ See Carlos Correa, *supra* note 40; Baker, *supra* note 217, at 655.

³²⁴ See Vincent, *supra* note 252, at 22.

³²⁵ See Carlos Correa, *supra* note 40, at 3; 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); Lee, *supra* note 252, at 1402.

³²⁶ This is a consequence of the fact that ECLs issued under Article 31*bis* must comply with the requirements of Article 31, including Article 31(b). See *supra* notes 229-244 and accompanying text. See generally Jillian C. Cohen-Kohler et al., *Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, 3 GLOBAL HEALTH 12 (remarking that this requirement turned out to be especially problematic in the Canada-Rwanda ECL).

involved.³²⁷ Commentators have also expressed strong reservations about the obligation to differentiate products manufactured under an ECL through special colouring and shaping of the pharmaceutical itself.³²⁸ Such alterations are time-consuming, and can often involve a biomolecular investigation of the patented medicine in question to ensure that the generic which is being manufactured has the same bioequivalence and bioavailability.³²⁹

We share the view that the procedural dimension of the Article 31*bis* 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 31*bis* 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.

We are not especially troubled by the information disclosures demanded of Importing States regarding their lack of manufacturing capacity. This condition is easily satisfied through a self-certification which is not subject to approval by the TRIPS Council and that could only be called into question in the unlikely event of a Member contesting its accuracy before the DSB.³³⁰ By contrast, we find that the provisos established to prevent diversion are problematic, due to their lack of flexibility, complexity, and protracted nature. They are in no way calibrated according to the actual circumstances of the case in question, such as the type of pharmaceutical involved, the nature of the illness (acquired, acute, chronic, congenital, genetic or infectious), the market size and purchasing power of the Importing State and whether there is an ongoing emergency. The assumption that permeates these rules appears to be that ECLs immanently and invariably carry an extremely high risk of diversion the avoidance of which is paramount.

It is hard to quantify the measure in which these procedural burdens deter recourse to Article 31*bis*. Nevertheless, it is emblematic that Apotex, the Canadian manufacturer that was involved in Rwanda’s case, has repeatedly pointed to the “complexity of the process” as one of the primary reasons for many delays which afflicted the project and, ultimately, its decision to not

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³²⁷ Carlos Correa, *supra* note 40, at 4; Abbas & Riaz, *supra* note 325, at 40; Vincent, *supra* note 252, at 18.

³²⁸ TRIPS, *supra* note 18, Annex to the TRIPS Agreement, 2(b)ii.

³²⁹ See Baker, *supra* note 217, at 650; Carlos Correa, *supra* note 40, at 9; Abbas & Riaz, *supra* note 325, at 40; Vincent, *supra* note 252, at 18.

³³⁰ See Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work*, 6 J. WORLD INTELL. PROP. 779, 785 (2003) (who observe that “the self-assessment of the available capacity and the subsequent conclusion fall under the exclusive responsibility of the Member itself”).

participate in such initiatives in future.³³¹

D. Economic Challenges

The Article 31bis System is built on the unstated premise that Members with mature pharmaceutical industries harbour a sizeable constituency of manufacturers interested in fulfilling the demand of Importing States. The underlying view appears to be that the international patent system is the main obstacle preventing these producers from entering these markets and that export compulsory licensing will remove this barrier. We believe that these assumptions are flawed in that they underappreciate the economic challenges of these transactions.

First, manufacturing, distributing and selling pharmaceuticals under ECLs is a capital-intensive activity that requires large up-front investment. Production costs are substantial. For chemical-based drugs, research is required to determine the composition of the compound in question and synthesize a stable formulation.³³² In the case of biologics, this reverse-engineering exercise is still more challenging due to the inherent difficulties associated with the creation of biosimilars.³³³ This initial step is followed by the planning and realization of the processes necessary for reliable and quality-consistent manufacturing. Throughout, compulsory licensees must experiment by way of trial and error, as they generally receive no technical assistance from the patentees the invention of which they are replicating. All these operations are time-consuming and expensive.

Regulatory costs are also significant. All pharmaceuticals manufacturers must bear the expenditures involved in obtaining the necessary authorizations from the competent governmental authorities in the jurisdictions in which they want to market and sell their products. For drugs that are molecularly identical to previously-approved patented ones, this process can be relatively painless,³³⁴ by contrast, for biologics, approval of biosimilars can be lengthy

³³¹ Letter from John Hems, Dir., Can.'s Access to Medicines Regime, to Douglas Clark & Brigitte Zirger, Dirs., Apotex Inc. (Jan. 23, 2007), available at https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_apotex_18-eng.pdf; Press Release, Apotex Inc., Second Shipment of Life-Saving AIDS Drugs Leaving for Africa (Sept. 18, 2009), available at <https://www.newswire.ca/news-releases/second-shipment-of-life-saving-aids-drug-leaving-for-africa-538566052.html>.

³³² See generally Prabir Basu et al., *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J PHARM INNOV 30; Pradeep Suresh & Prabir K. Basu, *Improving Pharmaceutical Product Development and Manufacturing: Impact on Cost of Drug Development and Cost of Goods Sold of Pharmaceuticals*, 3 J PHARM INNOV 175.

³³³ See generally Leyre Zuñiga & Begoña Calvo, *Biosimilars: Pharmacovigilance and Risk Management*, 19 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 661 (2010); Simon D. Roger, *Biosimilars: How Similar or Dissimilar Are They? (Review Article)*, 11 NEPHROLOGY 341 (2006); Anoop Misra, *Are Biosimilars Really Generics?*, 10 EXPERT OPINION ON BIOLOGICAL THERAPY 489.

³³⁴ See generally Blackstone & Joseph, *supra* note 40.

and expensive, going as far as requiring clinical trials.³³⁵ Notably, export compulsory licensees may have to cover these outlays twice, if they are required to obtain regulatory approval both in the Exporting and Importing State. In addition, the Article 31bis System imposes its own cost layer. Export compulsory licensees must cover all the expenses associated with anti-diversion obligations, including that of using special packaging, labelling, as well as making information disclosures through a dedicated website.³³⁶ Moreover, they might also be required to pay the "adequate remuneration" owed to patentees under Article 31(h).³³⁷

Second, export compulsory licensees are confronted with a difficult and narrow path to profitability. Typically, Importing States will be developing Members with very low yearly health spending per capita that can only afford low prices for any one pharmaceutical product.³³⁸ This datum significantly narrows the range of pricing strategies that export compulsory licensees can implement to generate the revenues to make the whole endeavour sustainable. In such circumstances, a low-volume, high margin approach will be entirely unworkable. The only viable avenue will be to employ a high volume, low margin strategy.

In theory, the export compulsory licensee would manufacture the patented pharmaceutical product in question in large volumes with the aim of achieving economies of scale;³³⁹ progressively, this would reduce marginal production costs, making it possible to attain a price point that is both affordable for the Importing State and sufficiently profitable for the manufacturer. In practice, however, such a strategy is not always feasible. Crucially, the compulsory licensee will be unable to reach economies of scale if only a small quantity of pharmaceutical products is requested by the Importing State in its notification to the TRIPS Council.³⁴⁰ Similarly, even if economies of scale are achieved, the investments required to produce, distribute and sell the patented pharmaceutical in question may be too great

³³⁵ See generally Steven Simoens & Arnold G. Vulto, *A Health Economic Guide to Market Access of Biosimilars*, 21 EXPERT OPINION ON BIOLOGICAL THERAPY 9 (Taylor & Francis Jan. 2021).

³³⁶ See *supra* notes 229-244 and accompanying text.

³³⁷ See *supra* note 200 and accompanying text.

³³⁸ See World Health Organization, *Global Spending on Health: Weathering the Storm* 2 (2020) (estimating that, in 2018, yearly health spending per capita in low-income countries was \$40, \$115 in lower middle income countries, \$466 in upper middle-income countries and \$3,313 in high income countries).

³³⁹ Economies of scale refers to the phenomenon where the average costs per unit of output decrease with the increase in the scale or magnitude of the output being produced by a firm; see generally Aubrey Silberston, *Economies of Scale in Theory and Practice*, 82 THE ECONOMIC JOURNAL 369 (1972); George J. Stigler, *The Economies of Scale*, 1 THE JOURNAL OF LAW AND ECONOMICS 54, 54 (1958).

³⁴⁰ Notably, under the Article 31bis System, export compulsory licensee can manufacture no more than exact quantity requested by the Importing State; see *supra* notes 229-244 and accompanying text. See Mike Gumbel, *Is Article 31BIS Enough - The Need to Promote Economies of Scale in the International Compulsory Licensing System Notes & Comments*, 22 TEMP. INT'L & COMP. L.J. 161 (2008).

to be recoverable at a price point affordable for the Importing State.

Third, export compulsory licensees face substantial risk to revenue and heavy losses on their investment. Above all, they are extremely vulnerable to patentees lowering the prices of their pharmaceutical products – or even donating them – for the purpose of defending their position in the Importing State’s market. This risk can materialize at any moment in time and the export compulsory licensee has no effective mitigating strategy. This is compounded by the fact that the Article 31*bis* System does not contemplate confidentiality safeguards. The notifications sent to the TRIPS Council by both the Importing and Exporting States are public, effectively providing patentees with all the information necessary to monitor the unfolding of the process and react at the most opportune moment.

It has been suggested that if patentees were to cut prices voluntarily when faced with the prospect of a Member making recourse to Article 31*bis*, this would be a desirable outcome for Importing States.³⁴¹ However, this view overlooks the risk that pharmaceutical manufacturers decline to engage with Article 31*bis* System as a whole, in fear that patentees could undercut their prices at any time.

Export compulsory licensees are also exposed to litigation risk. Patentees can take legal action to challenge the compulsory license granted by the Export State. Even if ultimately unsuccessful, such maneuvers can cause delays and financial stress.³⁴² In like fashion, patentees can promote infringement proceedings against the export compulsory licensee if they have evidence that pharmaceutical products have been diverted away from the Importing State into a different market. Albeit to a lesser degree, ECLs may also be exposed to political instability risk. Military conflict, civil unrest and regime change can either impede the compulsory licensee from generating the revenues necessary to recover its investment or cause the Importing State to default on its obligation to purchase the pharmaceuticals in question.

We believe that the primary reason the Article 31*bis* System has remained largely unutilized to date is that the market conditions that would make a particular ECL economically viable are seldom present. In general, compulsory licensing is an instrument that ontologically has only situational usability. For it to be viable, the compulsory licensee must be in a position to manufacture the patented product and sell it at a price which is lower than that charged by the patentee, but high enough to generate revenues sufficient to cover its costs and make a small profit.³⁴³

The Article 31*bis* System makes achieving this threshold markedly harder. In the context of an expensive industry, its procedural and substantive rules impose significant extra costs, engender idiosyncratic litigation risks

³⁴¹ See Carlos Correa, *supra* note 40.

³⁴² It should be noted that some Members, such as Argentina, have enacted provision pursuant to which an appeal by the patent owner against the grant of a compulsory license does not suspend its immediate execution; see Argentine Patent Law No. 24.481, art. 49. Nevertheless, most Members do not offer such protections for compulsory licensees.

³⁴³ See Cahoy, *supra* note 10, at 481.

and concurrently impede the possibility of achieving economies of scale. For prospective export compulsory licensees that are already in the difficult position of having to deal with Member States with limited purchasing power, these obstacles become all but insurmountable.

Emblematically, representatives of the Canadian generic drugs industry that were involved in the Canada-Rwanda ECL have claimed that they are unwilling to engage with the Article 31*bis* System in the future, due to the quasi-impossibility of operating profitably within its boundaries.³⁴⁴ Echoing this sentiment, a representative of the Indian generic drug manufacturer CIPLA expressed skepticism towards export compulsory licensing, remarking that the economics of this mechanism were unworkable in cases such as that of Rwanda due to its minimal financial resources and small market size.³⁴⁵ In similar vein, Médecins Sans Frontières pointedly criticised the Article 31*bis* System stating that “it . . . ignores the fact that economies of scale are needed to attract interest of producers” and concluded that “without the pull of a viable market for drugs, generics manufacturers will not seek to produce for export”.³⁴⁶

IV. FULFILLING THE PROMISE OF ARTICLE 31BIS

This Part proposes approaches to fulfill the promise of the Article 31*bis* System to furnish Members with an instrument to overcome the strictures imposed by the combined effect of Articles 27 and 31. First, we highlight that ECLs possess unique and unprecedented features which could have a decisive impact for access to medicines in Members lacking pharmaceutical manufacturing capabilities. We posit that it would be unwise for Members to abandon the Articles 31*bis* System in favour of alternative approaches, such as public medicine patent pools and humanitarian aid campaigns.³⁴⁷ From this premise, we expound strategies that Members can pursue within the confines of the current law to circumvent some of the issues that presently undermine ECLs. Thereafter, we consider a broad range of possible reforms to the

³⁴⁴ See Cohen-Kohler et al., *supra* note 326, at 4 (who interviewed executives of Canadian generic drugs manufacturers and found that they had strong reservations regarding the possibility of operating profitably under an ECL. One executive stated “we might end up with a couple of orders, but at the end of the day we won’t make any money out of it, and I’m going to get to a point where someone else comes along, like [NGO], and say “we want this other compound”, I’m not going to be able to develop it, because I’m in business to make money and I can only do so many products.”).

³⁴⁵ See IP Watch, *WTO ‘Paragraph 6’ System For Affordable Medicine: Time For Change?* available at <https://www.ip-watch.org/2016/11/14/wto-paragraph-6-system-affordable-medicines-time-change/> (reporting that the head of government affairs at Indian generic drug company Cipla observed that “the amount of drugs supplied in the 2 years was lower than the amount Cipla produces per month.”).

³⁴⁶ See Médecins Sans Frontières, *Review of the Canadian Access to Medicines Regime – Submission to the Government of Canada* (24 January 2007), available at https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_msf_11-eng.pdf.

³⁴⁷ See below Part IV.A.

Article 31bis System, starting with surgical interventions aimed at progressively augmenting the flexibility and efficiency of the extant TRIPS architecture and venturing as far as fundamental revisions to the structure of this treaty to enable free flow of patented pharmaceuticals from the Global North to the Global South.

A. *The unique potential of the Article 31bis System*

The fallow state of the Article 31bis System has not gone unnoticed. Commentators have posited that ECLs have been an unsuccessful experiment that was condemned to failure by the limitations imposed by developed Members.³⁴⁸ They propose that both human and financial resources should be concentrated instead on obtaining cheap voluntary licenses from patentees,³⁴⁹ bolstering medicine patent pools,³⁵⁰ and arranging humanitarian aid campaigns,³⁵¹ as these avenues have proven far more fruitful in supporting developing Members in their struggle to provide satisfactory public health standards to their citizens including access to medicines.

We fully recognize and welcome the successes achieved through these pathways over the past decade, especially in the fight against the global HIV/AIDS epidemic. Nevertheless, we believe that it would be a mistake to jettison the Article 31bis System and discard ECLs entirely. First, voluntary licensing, medicine patent pools, and humanitarian aid campaigns are inextricably dependant on the collaboration and goodwill either of patent holders or of third-party organizations. By contrast, having access to an effective export compulsory licensing framework enables Members to take

³⁴⁸ See generally Halajian, *supra* note 203; Vincent, *supra* note 252; Harris, *supra* note 249.

³⁴⁹ See generally Brook K. Baker, *A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines Symposium: In Honor of Hope Lewis: International Law, Local Justice: Human Rights Transformed*, 10 NORTHEASTERN UNIVERSITY LAW REVIEW 694 (2018).

³⁵⁰ The most notable example is the Medicines Patent Pool (MPP) established by UNITAID in 2010. The MPP negotiates licenses with HIV medicines patent holders and then enters into sub-licensing contracts with generics manufacturers that agree to manufacture, distribute and sell low-cost, high-quality treatments in underdeveloped regions. See generally 'T HOEN, *supra* note 2, at 73–76 (for a detailed analysis of the history and track record of the MPP); Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. LJ 291 (2012). Similarly, the WHO has recently created the Covid-19 Technology Access Pool (C-TAP) to enable voluntary licensing of IP rights linked to treatments for Covid-19; see World Health Organization, *Operationalising The Covid-19 Technology Access Pool (C-Tap) A Concept Paper*, available at https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true.

³⁵¹ See Rachel Silverman et al., *Tackling the Triple Transition in Global Health Procurement*, CENTER FOR GLOBAL DEVELOPMENT (2019) (analyzing data showing that aid campaigns coordinated by NGOs and corporations finance over 40% of health expenditure in developing countries); Baker, *supra* note 261, at 300–305 (analyzing the Pfizer donation program and other similar initiatives).

action unilaterally, on their own terms.

Second, pharmaceutical patent holders are far more likely to make concessions, including price reductions, transfer of know-how, and voluntary licenses if they are confronted by the spectre of compulsory licensing.³⁵² For Members that cannot rely on domestic compulsory licensing while their pharmaceutical industries are developing, this tactic is only available if the Article 31*bis* System is perceived as a functioning mechanism rather than a hallow threat.

Third, empirical evidence reviewed in Part III showed that Members with established medicinal production capabilities are regularly using domestic compulsory licensing to obtain access to otherwise unobtainable patented medicines. A corollary of this data is that voluntary arrangements with patent holders and aid programs are not always viable or convenient. In such cases, ECLs are the only option for Members without a developed domestic pharmaceutical industry.³⁵³

Fourth, historically, compulsory licensing has been an inward-looking instrument that countries deployed either to curtail patentee conduct disruptive to local markets or to promote domestic policy aims. The Article 31*bis* System aspires to add a new dimension to this legal device, expanding and transforming its functional profile. ECLs are intended to equip Members with a tool the reach of which crosses borders, despite the territorial nature of the patent system. They embody a solidaristic mechanism designed to allow developing countries to benefit from the technological prowess of foreign pharmaceutical industries at affordable prices. Though it is undeniable that Article 31*bis* has not yet borne fruit, the ambitious idea at its core holds great promise. It should not be abandoned due to a flawed implementation. We believe that instead, efforts should be made to maximize the potential of the Article 31*bis* System.

B. Pooled Procurement Strategies

Part III.D highlighted that economic challenges are one of the key factors undermining the Article 31*bis* System. In particular, one of the primary obstacles faced by prospective export compulsory licensees is achieving economies of scale due to the typically small market size of Members eligible to be Importing States. We believe that the TRIPS legal framework presents

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³⁵² See Urias & Ramani, *supra* note 283 (reviewing a vast body of empirical evidence and concluding that a compulsory licensing event is likely to reduce the price of the affected patented drugs); Beatrice Stirner, *Learning from Practice: Compulsory Licensing Cases and Access to Medicines*, 1 PHARMACEUTICAL PATENT ANALYST 555 (2012) (highlighting the impact of compulsory licensing in lowering drug prices); see also Reed F. Beall et al., *Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement*, 34 HEALTH AFFAIRS 493 (2015) (highlighting that there is a risk for compulsory licensing to yield “suboptimal value when compared to the alternative of international procurement ... when used by low-income countries to manufacture medicines locally.”).

³⁵³ See *supra* notes 283-287 and accompanying text.

latent opportunities to countervail this issue through pooled procurement strategies. Two approaches warrant close consideration.

First, Article 31bis(3) establishes that a Member participating in a customs union or a free-trade association, half the membership of which is comprised of LDCs, can export unreservedly any patented pharmaceutical which it has manufactured or imported under a compulsory license throughout this economic area.³⁵⁴ This is a meaningful exception to the restriction imposed by Article 31(f),³⁵⁵ with the declared aim of “harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products”.³⁵⁶

Article 31bis(3) has substantial implications for export compulsory licensing. By virtue of this provision, rather than having to act separately, Members party to an eligible trade agreement can notify the TRIPS Council jointly and express their intent to import a determinate pharmaceutical in the quantity required for their collective need.³⁵⁷ By pooling their demand, Importing States can present a more palatable risk-reward proposition for prospective licensees by offering better economies of scale, and, in turn, reducing marginal production costs to a level that renders a high-volume-low margin business strategy viable.

Beyond its effect on the economic dimension of export compulsory licensing, as suggested first by Abbott and Reichman,³⁵⁸ Article 31bis(3) can be leveraged to improve significantly the position from which Members participating in eligible regional trade arrangements negotiate with pharmaceutical patent holders. Imagine that a group of states, half of which LDCs, entered into a multilateral treaty designed to eliminate all duties and non-tariff barriers affecting the commerce of pharmaceutical and medical equipment. Consider further that this international law instrument provided

³⁵⁴ See TRIPS, *supra* note 18, art. 31bis(3) (“where a developing or least developed country WTO Member is a party to a regional trade agreement ... at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question”). It should be noted that the customs union or trade agreement in question must comply with Article XXIV of the GATT 1994 and the Decision on Differential and More Favourable Treatment, Reciprocity, and Fuller Participation of Developing Countries, 28th November 1979 (L/4903, BISD 26S/203).

³⁵⁵ See *supra* note 199 and accompanying text.

³⁵⁶ TRIPS, *supra* note 18, art. 31bis(3) (“With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products”).

³⁵⁷ See TRIPS, *supra* note 18, Appendix to The Annex To The Trips Agreement note 4 (“Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.”).

³⁵⁸ See Abbott & Reichman, *supra* note 2, at 973–76 (discussing extensively the potential benefits of organized pool procurement at a regional level).

that its signatories agreed to the creation of a regional entity to which they conferred the necessary powers to organize the procurement of pharmaceuticals and issue ECLs on their behalf. Pursuant to governmental instructions, this regional entity would negotiate directly with pharmaceutical patent holders to source the required medicines to satisfy the demand of the entire trading bloc. Article 31bis(3) would decisively strengthen the bargaining position of the regional entity in question in these interactions, as patentees would be aware that failure to reach an acceptable voluntary agreement would likely lead to one of the following two scenarios.³⁵⁹

Firstly, if one of the countries had the necessary manufacturing capabilities to produce the pharmaceutical product in question, it would issue a domestic compulsory license with the aim of supplying all other countries party to the trade agreement. Secondly, if the required technology and know-how were not present in any one of the countries involved in the regional trade agreement in question, the regional entity could notify the TRIPS Council, triggering the Article 31bis System on behalf of the whole trading bloc.³⁶⁰ Confronted with such prospects and provided that the offered terms were not beneath their marginal costs, patent holders would likely prefer striking a deal with the regional entity, as they would at least preserve their presence in the region, secure market share and increase their good will and trademark visibility.

We believe that Article 31bis(3) holds great promise, and that it has not received the attention it deserves. Only recently have Members party to eligible regional trade agreements begun to explore its possibilities with conviction. For example, the Southern African Development Community (SADC)³⁶¹ has recently developed an interest in exploiting Article 31 and 31bis through regionally pooled procurement, as evidenced in its Pharmaceutical Business Plan 2013-2017 and more recently with the creation of its Pooled Procurement Services System for pharmaceuticals.³⁶² The East

³⁵⁹ See *Id.* (arriving at this same conclusion).

³⁶⁰ See *supra* note 357.

³⁶¹ Originally stemming from the Southern African Development Co-ordination Conference of 1980, the SADC is a regional economic community founded in 1992 and consisting of 16 countries: Angola, Botswana, Comoros Islands, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia, and Zimbabwe; see Consolidated Text of the Treaty of the Southern African Development Community (adopted 17 August 1992, last amended 21 October 2015) available at https://www.sadc.int/files/5314/4559/5701/Consolidated_Text_of_the_SADC_Treaty_-_scanned_21_October_2015.pdf.

³⁶² See Ellen F.M. 't Hoen et al., *Patent Challenges in the Procurement and Supply of Generic New Essential Medicines and Lessons from HIV in the Southern African Development Community (SADC) Region.*, 11 J. PHARM. POLICY PRACT. (2018) (detailing the efforts of the SADC and highlighting that the SADC Pharmaceutical Business Plan 2015–2019 expressly proposes to “utilise the paragraph 6 system (Doha Declaration) or article 31 bis of the TRIPS Agreement to facilitate local production for export; or importation for re-exportation within SADC as a regional bloc.”); Chikosa Banda, *Intellectual Property and*

Africa Community (EAC)³⁶³ has similarly striven to establish a regionally pooled procurement mechanism for some time,³⁶⁴ although it has only latterly taken more resolute steps in this direction.³⁶⁵

Unfortunately, these encouraging steps have not generated meaningful progress to date. Members involved in these regional trade agreements have struggled to institute and operate an entity responsible for pharmaceutical procurement on their behalf. It can only be hoped that, in the wake of the Covid-19 pandemic, these initiatives will gain momentum.³⁶⁶ Some encouraging early evidence has been seen in a recent agreement signed by Cabo Verde, Comoros, Guinea-Bissau, Madagascar, Mauritius, São Tomé and Príncipe and Seychelles, with the aim of jointly procuring drugs and vaccines to improve quality of and access to medicines.³⁶⁷

Having recognized the inherent value of Article 31*bis*(3), it should also be acknowledged that this provision has an intrinsic ceiling. The condition restricting the scope of application of this provision to regional trade agreements half the membership of which is comprised of LDCs sharply restricts its reach. At present, only multilateral trade arrangements involving Members in Sub-Saharan Africa satisfy the requirement in question.

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Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region Symposium: Clinical Trials and Access to Essential Medicines in African Countries, 31 MD. J. INT'L L. 44 (2016) (detailing reforms across SADC members aimed at exploiting Article 31*bis*).

³⁶³ Originally founded in 1967, the EAC in its present incarnation was founded in 1999. It is a regional economic community consisting of 6 countries: Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. See Treaty Establishing the East African Community, Nov. 30, 1999, 7 AFR. INT'L L. 421, 2144 U.N.T.S. 255.

³⁶⁴ See Treaty Establishing the East African Community, *supra* note 255, art. 118, ("Partner States undertake to: (a) expressing take joint action towards the prevention and control of communicable and non-communicable diseases and to control pandemics and epidemics of communicable and vector-borne diseases ...; (c) develop a common drug policy which would include establishing quality control capacities and good procurement practices").

³⁶⁵ See generally Hiiti Sillo et al., *Coming Together to Improve Access to Medicines: The Genesis of the East African Community's Medicines Regulatory Harmonization Initiative*, 17 PLOS MEDICINE (describing the African Medicines Regulatory Harmonization (AMRH) Initiative). In addition to the AMRH project, the EAC introduced a legal common market protocol in 2019 that provides a non-discrimination clause for public procurement among member states; see generally Omolo Joseph Agutu & Eurallyah Akinyi, *The National Treatment Rule and the Regulation of Public Procurement under the East African Community Common Market Protocol*, 5 JOURNAL OF CORPORATE AND COMMERCIAL LAW AND PRACTICE 115 (2019).

³⁶⁶ For a description of the regional response to Covid-19 in Africa see generally Samuel Ojo Oloruntoba, *Unity Is Strength: Covid-19 and Regionalism in Africa*, 56 THE INTERNATIONAL SPECTATOR 56 (Routledge Apr. 2021); Abbott & Reichman, *supra* note 243, at 550–58 (positing that pooled procurement strategies could play a crucial role to overcome the Covid-19 pandemic in Africa).

³⁶⁷ See World Health Organization, African Island States Launch Joint Medicines Procurement Initiative, 29 September 2020, available at <https://who-africa.africa-newsroom.com/press/african-island-states-launch-joint-medicines-procurement-initiative?lang=en>.

Members in Latin America, the Caribbean, the Middle East and South-East Asia which would equally benefit from the demand aggregation mechanism afforded by Article 31*bis*(3) are precluded from accessing it due to the absence of a sufficient number of LDCs in these regions.³⁶⁸ This is particularly lamentable when considering that some of these geographies already have regional procurement entities in operation such as The Organization of Eastern Caribbean States' Pharmaceutical Procurement Scheme (OECS-PPS), and the Gulf Cooperation Council Group Purchasing Program.

Second, even for Members not party to regional trade agreements within the scope of Article 31*bis*(3), there are pooled procurement strategies that might be pursued to maximize the potential of the Article 31*bis* System. TRIPS does not preclude Members from engaging the Article 31*bis* System in unison. Acting as a *de facto* consortium, a group of countries could contemporaneously but separately notify the TRIPS Council of their intention to import a particular patented pharmaceutical product. Leveraging their joint demand, these Members could then bargain collectively and offer terms that would be more likely to attract prospective licensees. A material shortcoming of pooled procurement strategies falling outside of the perimeter of Article 31*bis*(3) is that each individual Importing State would be barred from re-exporting the drugs in question. Nevertheless, this hurdle could be overcome through careful *ex ante* planning on the part of each participant in these consortia. In areas such as Latin America, where there are almost no LDCs but many economies with limited pharmaceutical manufacturing capabilities, coordinated recourse to export compulsory licensing could muster significantly greater bargaining power than a single Member acting alone.

C. Law Reform

The preceding discourse has suggested that, in determinate circumstances, pooled procurement strategies can enable Members to overcome some of the economic obstacles that impede the extant Article 31*bis* System. Nevertheless, these are mitigating strategies. It is inescapable that the current body of rules is deficient. We believe that for ECLs to fulfill their promise, law reform is required.

In the first instance, the procedural dimension of the Article 31*bis* System should be radically recalibrated. The normative aim guiding this intervention should be to rebalance the current fixation on preventing diversion and verifying the eligibility of the Importing State with equivalent, if not greater, attention to simplicity, flexibility and expeditiousness. When notifying the TRIPS Council, rather than having to specify the exact quantity of pharmaceuticals required *ex ante*, Importing States should be allowed to state an indicative range. Moreover, they should have the option to amend their notification *ex post* to increase the previously-specified total, provided that

³⁶⁸ See *supra* note 165.

their situation of need persists.

The application of Article 31(b) to the compulsory licenses granted by Exporting States should also be reconsidered. Under this provision, prospective licensees must make “efforts” to obtain a voluntary license from patentees “on reasonable commercial terms and conditions” for a “reasonable period of time”, before a compulsory license can be lawfully granted. The ratio of these preconditions is rooted in the assumption that the ensuing production will enter the issuing country’s domestic market, where the prospective compulsory licensee will be in competition with the patentee. However, the prerequisites under consideration suit neither the aims nor the dynamics of the Article 31*bis* System. Reflecting the aims of the Doha Declaration, the objective standard for the Article 31(b) negotiations should be revised from “reasonable commercial terms and conditions” to “terms and conditions that reflect the humanitarian, social and economic circumstances of the Importing State”. In similar vein, mindful of the lengthy multi-step nature of the Article 31*bis* System procedure, the prescribed time limit for negotiations should be reduced from a “reasonable period of time” to a “brief” one.

In similar vein, the obligations imposed on the export compulsory licensee to prevent diversion of the manufactured pharmaceuticals should also be reconfigured. Moving away from the current rigid set of measures, the Article 31*bis* System should introduce a flexible standard. Exporting States should be allowed to grant compulsory licenses which prescribe anti-diversion countermeasures appropriate to the actual circumstances of each case. Such a rule would allow for a scalar approach. The onus placed on export compulsory licensees would be minimal, when the risk of diversion is low due to, for example, the pharmaceutical in question being in scarce demand in developed markets, or difficult to smuggle owing to its storage and conservation profiles. By contrast, if the risk of diversion were elevated, the Exporting State would be at liberty to prescribe more onerous monitoring duties, extending across production, transport and distribution. This elasticity would open the door to innovative and cost-efficient technological solutions – including NFC chips, GPS tracking and distributed ledgers – rather than meagre reliance on coloring and shaping of products, as well as packaging.

Lastly, pooled procurement should be facilitated and further incentivized within the Article 31*bis* System. The current requirement that confines the operation of Article 31*bis*(3) to regional trade agreements half the current membership of which is comprised of LDCs is extremely restrictive. A different threshold should be set with sensitivity not just for LDCs but also developing Members, as these countries often lack pharmaceutical manufacturing capacity, especially for biologics. Pooled procurement outside of Article 31*bis*(3) should also be facilitated. When an Importing State notifies the TRIPS Council of its need for a pharmaceutical product, other Members should be allowed to join their request at any point in time by sending their own notification. Such an adhesion mechanism would greatly reduce coordination challenges and perhaps give rise to a snowballing effect,

with a growing number of Members incrementally summing their demand and, in turn, rendering the transaction more appealing for prospective licensees.

An alternative approach to buttress the flow of patented pharmaceuticals from the Global North to the Global South might involve reforming the TRIPS patent regime, rather than the Article 31*bis* System. The most direct avenue would be to recast fundamentally the legal treatment governing the export of patented medicines. Members could agree to modify Article 30, instituting a mandatory limitation to the rights of patentees whereby the production of a patented pharmaceutical for the purpose of distributing it into the market of a Member without manufacturing capacity would be positively qualified as a non-infringing activity. Arguably, such a rule would be consistent with the general conditions set in Article 30(1) for patent rights "exceptions", as it would be "limited", and neither "unreasonably conflict with a normal exploitation of the patent", nor "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".³⁶⁹ An amendment of this nature would require all Members to adopt this rule within their domestic legal order. Marking a stark departure from current law, it would completely unshackle flows of patented pharmaceuticals from Members that have developed manufacturing capabilities towards those that do not.

A less drastic approach would involve Members agreeing to an authoritative interpretation of Article 30 through a TRIPS Council Decision.³⁷⁰ This declaratory act would clarify that it is consistent with the TRIPS patent regime for Members to enact into their domestic patent laws limited carve outs that prevent patentees from taking action against persons who produce patented pharmaceuticals to export them to Members without manufacturing capacity. This reform would not mandate that Members adopt this exception, yet it would make this possible for those that so desired.

A still-narrower intervention would be for Members to amend TRIPS by eliminating Article 31(f). More restrained than the preceding options, this excision would not introduce an exception designed to allow generally unrestricted export of patented pharmaceuticals. Rather, it would only allow this activity within the confines of the TRIPS compulsory licensing regime. Accordingly, a manufacturer in a developed Member that wanted to export a patented drug to another Member without the consent of the patentee would have to obtain a compulsory license, abiding by all the procedural and substantive requirements under Article 31.

³⁶⁹ See *supra* notes 176-180 and accompanying text.

³⁷⁰ WTO Agreement, *supra* note 154, art. IX(2) ("The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1, they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members.").

Setting aside the legal implications for importing Members,³⁷¹ the crucial problem shared by all these prospective interventions is that they are unlikely to ever attract the necessary political support. Similar proposals were considered extensively in the months preceding the Doha Declaration, and especially during the lapse of time between the Doha Declaration and the Decision.³⁷² Developed Members never showed any genuine interest in endorsing the compression of pharmaceutical patentees' rights that such interventions would entail.³⁷³ Considering that both TRIPS modifications and authoritative interpretations equally necessitate the support of three-fourths of all Members to be approved by the WTO, it is highly improbable that such profound revisions of Articles 30 and 31 will occur in the foreseeable future.

Thus, it is our view that it would be pragmatic to concentrate efforts on reforming the Article 31*bis* System, as developed Members would find it difficult to reject such initiatives, given their ostensible commitment to its success.

CONCLUSION

The original TRIPS framework contained a crucial flaw. It sharply curtailed access to patented medicines for some of the world's most vulnerable populations. In the 2001 Doha Declaration, the TRIPS Council contritely acknowledged this failing and resolved to rectify it. Their solution was the creation of export compulsory licensing through the Article 31*bis* system. Regrettably, this novel instrument has failed to deliver on its promised outcomes.

In this Article, we have contended that this is due neither to governmental and corporate interferences, nor conflicting national laws and international treaties. Though not insignificant, these factors are not determinative. Our view is that the Article 31*bis* System is impaired by suffocating procedural and substantive requirements that deter both Members and pharmaceutical

³⁷¹ For Members interested in importing pharmaceuticals manufactured abroad, these three reform approaches would present unproblematic, identical scenarios. If either the pharmaceutical in question were not patented in their jurisdiction or the domestic patentee consented, there would be no need to enact special measures to allow such imports. Similarly, no interventions would be required if the jurisdiction in question recognized a first sale doctrine pursuant to which patentees' rights are exhausted following lawful manufacture and export of a patented product under a compulsory license issued in another country. Members would have to issue a parallel compulsory license authorizing import only if the pharmaceutical in question were protected by a patent in their jurisdiction, the relevant patentee opposed inbound flows and their rights could not be deemed exhausted under the applicable first sale doctrine.

³⁷² See Abbott, *supra* note 199 (providing an exhaustive analysis of a range of possible TRIPS reforms involving Articles 30 and 31 that would address the issue highlighted in the paragraph 6 of the Doha Declaration).

³⁷³ See Abbott, *supra* note 2 (detailing the negotiations that followed the Doha Declaration and explaining how the current Article 31*bis* System emerged following developed Members rejecting reform proposals that would have fundamentally recast Articles 30 and 31).

manufacturers from making recourse to ECLs.

Despite acknowledging the severity of these defects, we believe that the Article 31*bis* System nevertheless holds great potential. Rather than being dismissed unceremoniously, it should be revised through targeted interventions to address its current shortcomings. Within a reformed framework, ECLs could cut across the territorial boundaries of the patent system and enable developing countries to draw on the technology and know-how of developed pharmaceutical industries at affordable prices. Such a seed of solidarity is rarely, if ever, sown in the domain of international intellectual property law. Given time and care, it may yet blossom.

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