

ARTICLE

THE WTO IS DEAD, LONG LIVE THE WTO: THE LINGERING INTERPRETIVE PROBLEM OF ARTICLE 27.1 OF THE TRIPS AGREEMENT

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ABSTRACT

Amidst populist discontent with the former bipartisan championing of the agenda of free trade liberalization, this article revisits a lingering interpretive problem within one of the key instruments of that agenda—the World Trade Organization’s (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. Having long been a battle ground over patents and public health, the TRIPS has come into renewed controversy in recent years ever since Donald Trump’s refusal to seat new appellate officials to hear cases before its dispute settlement mechanism and even more notably in the wake of rich country opposition to India and South Africa’s request for a waiver of key TRIPS provisions in October 2020 at the height of the COVID-19 pandemic. Specifically, the article revisits Article 27.1’s mandating that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” Having always been regarded as a possible threat to flexibilities allowing deviation from strict patent rights of the kind developing countries have fought so hard to validate to preserve their ability to prioritize public health, the meaning of Article 27.1 remains less than fully resolved. After summarizing the contours and sources of this interpretive problem, the article dissects the one (and only) key WTO dispute touching on its non-discrimination provision. In so doing, it counterposes the

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most common proposed solution to addressing the interpretive problem it poses—of constructing an a priori distinction between unlawful discrimination and lawful differentiation—with actual instances of technology-specific legal and policy choice by countries in the global North during the TRIPS era. In documenting the latent anti-formalism informing such legal and policy choice and juxtaposing it with the stance many of the same countries have taken in the “drugs-for-the developing” world debate, the article offers a broader critique of formalism as a mode of solving interpretive problems in the context of grappling with the norms of free trade liberalization and social provisioning in instruments like the TRIPS.

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I. INTRODUCTION

In its short but highly contentious history, the World Trade Organization (WTO) has seen reports of its demise persistently ebb and flow with the waxing and waning of controversies over the implications of its annex agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹ Hailed in the aftermath of the Cold War by its promoters as an essential add-on to the WTO’s baseline regime of “free trade” liberalization—by fostering and protecting the fruits of innovation through more clearly specifying “property rights” (capable of demanding a market premium for their use)—the TRIPS agreement has been equally long reviled by assorted critics. Pointing out that its provisions have little to do with trade as such, many have observed that the TRIPS embodies the increasing reliance of high-income countries on the proliferation of “IP”—as both concept and reality— and, thus, that it is little more than a means for advancing a political economy of rentierism and incumbent advantage in a phase of capitalism’s history that has seen a general shift away from productive investment and towards financial speculation, asset stripping, and the hardening of a class order premised on austerity for the poor and in-effect public spending on the rich.

Indeed, insofar as the TRIPS has especially portended this shift as a symbol of the re-architecting of international economic law around new avenues of unequal exchange² between the Global

1. See, e.g., Rorden Wilkinson, *The WTO in Crisis: Exploring the Dimensions of Institutional Inertia*, 35 J. WORLD TRADE 397 (2001); Stephen J. Powell & Trisha Low, *Is the WTO Quietly Fading Away? The New Regionalism and Global Trade Rules*, 9 GEO. J.L. & PUB. POL’Y 261 (2011); Markus Wagner, *The Impending Demise of the WTO Appellate Body: From Centrepiece to Historical Relic?*, in THE APPELLATE BODY OF THE WTO AND ITS REFORM 67, 67–90 (Chang-Fa Lo, Junji Nakagawa & Tsai-fang Chen eds., 2020); Ralf Havertz, *The Crisis of the WTO Appellate Body and the Current Trajectory of Neoliberalism*, 8 FRONTIERS POL. SCI. 1 (2026).

2. With a long history, going back before the Prebisch-Singer thesis and the Latin American “dependency school”—often seen as originating in the early post-war era—the thesis of unequal exchange has engendered a large literature, even despite being scorned

North and South (especially by the time one excludes China, with its decidedly mixed institutional approach to development³), it has been controversy over access to medicines that has been the key pivot upon which the fate, or at least, the state of the WTO has seemed to turn. Already leading up to the “Battle of Seattle” that greeted the WTO’s third Ministerial conference in 1999, and that marked the first great moment of civil disobedience against the post-Cold War era’s new world order of free trade liberalization, HIV/AIDS activists had relentlessly pursued then U.S. Presidential candidate Al Gore on the campaign trail for his stance on upward harmonization of international patent law and antiretrovirals for populations like those in Africa and Asia. By September 2003, the WTO’s Fifth Ministerial Session at Cancun collapsed as the rift between the developing country bloc and the advanced economies grew into a seeming chasm, in no small part due to the question of

and largely ignored by economists as the neoclassical-Keynesian synthesis cemented itself. As telling as it has been welcome, then, Thomas Piketty’s recent, quite explicit endorsement of the thrust of the theory from the heart of the mainstream has been notable. See Thomas Piketty & Gastón Nievas, *Unequal Exchange and North-South Relations: Evidence from Global Trade Flows and the World Balance of Payments 1800–2025* (World Inequality Lab, Working Paper No. 2025/11, 2025), <https://wid.world/document/unequal-exchange-and-north-south-relations-evidence-from-global-trade-flows-and-the-world-balance-of-payments-1800-2025-world-inequality-lab-working-paper-2025-11/> [<https://perma.cc/4KLY-ZEN9>]. On the key early post-war texts launching or re-launching the tradition of analysis, see RAÚL PREBISCH, *THE ECONOMIC DEVELOPMENT OF LATIN AMERICA AND ITS PRINCIPAL PROBLEMS*, ECLA/UN, U.N. Sales No. 50.II.G.2 (1950). See also H.W. Singer, *The Distribution of Gains Between Investing and Borrowing Countries*, 40 AM. ECON. REV. 473 (1950). For those working in the vicinity of Prebisch and Singer and generally regarded as more closely affiliated with post-war Marxian economic thought, see ARGHIRI EMMANUEL, *UNEQUAL EXCHANGE: A STUDY OF THE IMPERIALISM OF TRADE* (1972) and SAMIR AMIN, *ACCUMULATION ON A WORLD SCALE: A CRITIQUE OF THE THEORY OF UNDERDEVELOPMENT* (1973).

3. On challenges to the World Bank/Gates Foundation-style championing of the record of post-Cold War liberalization once China is removed from the picture, see, for example, Robert H. Wade, *Is Globalization Reducing Poverty and Inequality?*, 32 WORLD DEV. 567, 576 (2004); David Woodward, *Incrementum ad Absurdum: Global Growth, Inequality and Poverty Eradication in a Carbon-Constrained World*, 4 WORLD ECON. REV. 43, 43–62 (2014), <http://wer.worldeconomicsassociation.org/files/WEA-WER-4-Woodward.pdf> [<https://perma.cc/8XTA-C6E8>]; Sanjay G. Reddy, *The Emperor’s New Suit: Global Poverty Estimates Reappraised* 1–22 (Queen’s Coll., Dep’t of Econ., Working Paper No. 53, 2008), <https://www.newschool.edu/social-research/wp-content/uploads/sites/290/2023/03/Reddy-Emperors-New-Suit.pdf> [<https://perma.cc/223K-YYUB>]; Jason Hickel, *Is Global Inequality Getting Better or Worse? A Critique of the World Bank’s Convergence Narrative*, 38 THIRD WORLD Q. 2208, 2208–22 (2017); BRANKO MILANOVIC, *CAPITALISM, ALONE* (2019) (offering one of the most notable dissents from the World Bank convergence story, particularly given that Milanovic’s famed “Elephant Chart” became emblematic of turn-of-the-millennium convergence claims).

access to medicines. Coming only two years after the Fourth Ministerial had yielded the storied “Doha Declaration”⁴—with its provisions on “the TRIPS agreement and public health” meant to confirm that member countries’ obligations under the former would not cut into their ability to tend to the latter, the collapse at Cancun was the first step toward a generalized stalling of the WTO process for much of the next decade.

Fast forwarding into the present, the WTO has remained mired in controversy. By 2016, the media was filled with talk about U.S. President Donald Trump’s “populism”-based turn away from liberalization.⁵ This turn of events could have surprised only those incapable of appreciating the gap between great power rhetoric about “free trade” and the shifting imperatives that actually tend to drive the formulation, let alone the application, of the norms of the international system.⁶ Key to this has been the (ultimately, largely symbolic) tariffs on China during Trump’s first administration and, of course, the more intensified tariffs during his second administration.⁷

Of course, this strand of free trade liberalization’s troubles has bled across a “polarized” America’s divides in part through President Joe Biden’s intervening administration’s shared, and—compared to the 2016-20 Trump regime—significantly expanded, trade war against China.⁸ The Biden administration’s intervening years also cemented a turn away from free trade liberalization

4. World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

5. Peter Baker & Ana Swanson, *Trump Authorizes Tariffs, Defying Allies at Home and Abroad*, N.Y. TIMES (Mar. 8, 2018), <https://www.nytimes.com/2018/03/08/us/politics/trump-tariff-announcement.html> [<https://perma.cc/HUL4-7PVZ>]; Phil Gramm & Mike Solon, *Trump, Tariffs and the Protectionist Temptation*, WALL ST. J. (Mar. 23, 2018), <https://www.wsj.com/articles/trump-tariffs-and-the-protectionist-temptation-1521844770> [<https://perma.cc/34TP-B3EW>].

6. See Baker & Swanson, *supra* note 5; Gramm & Solon, *supra* note 5.

7. See Baker & Swanson, *supra* note 5; Gramm & Solon, *supra* note 5.

8. See, e.g., Anshu Siripurapu & Noah Berman, *Is Industrial Policy Making a Comeback?*, COUNCIL ON FOREIGN RELS. (Sep. 18, 2023), <https://www.cfr.org/backgrounders/industrial-policy-making-comeback> [<https://perma.cc/9XT2-ZER7>]; Mariana Mazzucato & Sarah Doyle, *Biden’s Incomplete Industrial Policy*, FOREIGN AFFS. (May 6, 2024), <https://www.foreignaffairs.com/bidens-incomplete-industrial-policy> [<https://perma.cc/4D46-WLXK>]; Adam Tooze, *Great Power Politics: What Was Bidenomics?*, LONDON REV. BOOKS (Nov. 7, 2024), <https://www.lrb.co.uk/the-paper/v46/n21/adam-tooze/great-power-politics> [<https://perma.cc/TA8J-ALLL>].

through a return to industrial policy in the United States, albeit one that has always looked more like a confused effort to revive Keynesian stimulus policies toward the end of symbolically championing selective areas of manufacturing while trying to secure the advantages of American capital over areas where it currently can scarce compete with global counterparts.⁹

At the same time, controversies at the level of the WTO have constituted a less visible strand of continuity across the now two Trump and intervening Biden administrations' steady release of the post-Cold War rhetoric of free trade liberalization. These have included the ongoing fallout—already from the 2016-20 years—of President Trump's refusal to seat new appointees (essentially, judges) to the appellate body of the WTO's dispute settlement institutions. However, the more significant continuity is likely to be found in and around the latest eruption over access to medicines and the TRIPS—in the context of a proposed waiver of the agreement's provisions as applied to COVID-19 vaccines. Introduced by South Africa and India in 2020, during the first Trump administration, countries in the global south continued doing battle over the waiver proposal—largely without success—with their counterparts in the rich world, the United States included, during Biden's time in office.¹⁰

9. See, e.g., Siripurapu & Berman, *supra* note 8; Mazzucato & Doyle, *supra* note 8; Tooze, *supra* note 8.

10. The waiver proposal was submitted very early amidst the global pandemic in October 2020. It was vigorously opposed by parties including the European Union, the United States, Switzerland, and the United Kingdom for most of the two subsequent years. While there was a shift after the new administration in the United States fleetingly signaled rhetorical support in May 2021, it took another year for President Biden to register actual support for further movement. What followed, in the end, was a version of the waiver that was adopted only on June 17, 2022, and that critics alleged, not unconvincingly, was not only much too late but, less well-known, also proverbially much “littler” than the years of waiting would have led one to hope, much less than the original proposal had argued for. The final waiver was not only limited to COVID-19 vaccines (thus, excluding therapeutics and diagnostics), it also placed key geographic limits on exports between developed countries through the requisite compulsory licensing power the TRIPS provides for; it also eschewed meaningful facilitation of technology transfer, in keeping with the period of extended stonewalling that greeted India/South Africa proposal at the heights of the pandemic, when a key rationale for refusal settled upon the claim—in part, inaccurate and in part a self-fulfilling prophecy—that the waiver would be futile because developing countries could not manufacture their own vaccines anyway. Compare World Trade Organization, Request for a Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669 (Oct. 2, 2020) (proposing broad suspension of TRIPS arts. 1, 4, 5, 7, 8, 31, and 31*bis* for all COVID-

Against the backdrop rehearsed above, it cannot be surprising that the juridical meaning of the TRIPS for access to medicines remains contestable ground. Yet this is not simply because of the agreement's having become a proxy for larger struggles, whether between big pharma and the world's poor, high-income countries and their middle- and especially low-income counterparts, or those who portray drug development as a leading example of the success of incentivizing private ingenuity through property rights and those who instead insist on the centrality of public funding in drug research and development.¹¹ It is also because there remain provisions of the TRIPS, especially around the baseline flexibilities to deviate from strict patent rights that the Doha Declaration was supposed to have fully validated, that constitute interpretive problem areas that are arguably yet to be fully resolved within WTO jurisprudence.

This article revisits one such problem area, concerning the would-be non-discrimination discipline under Article 27.1 of the agreement and its requirement that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."¹² I use the phrase *would-be* because at the heart of this problem is whether, indeed, the excerpted provision of Article 27.1 should be read as a full-fledged non-discrimination norm in the style of the similar such non-discrimination disciplines that form the core of the TRIPS regime—through its most-favored nation and national treatment provisions.

After first reviewing the scope of persisting unclarity surrounding the TRIPS and access-to-medicines question in Part I, the article turns to the negotiating history of Article 27.1 in Part II,

19 medical products), *with* World Trade Organization, Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30 (June 17, 2022) (limiting waiver to vaccines only, excluding therapeutics/diagnostics, and extending LDC transition periods).

11. On the perhaps foundational case for patents in a context like that of pharmaceuticals, see WILLIAM NORDHAUS, *INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE* (1969); Frederic M. Scherer, *The Pharmaceutical Industry*, in *HANDBOOK OF THE ECONOMICS OF INNOVATION* 393–428 (Bronwyn H. Hall & Nathan Rosenberg eds., 2010).

12. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27.1, 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 the TRIPS Agreement].

clarifying how the final version of its would-be non-discrimination provision constituted an amalgamation of several strands of concern that were at play during the drafting process, with the final version of Article 27.1 emerging only abruptly and absent any master intention to construct a sweeping non-discrimination norm. Here, in particular, I focus on the disjointed origins of Article 27.1's "patents shall be available" and "patent rights enjoyable" language as well as how these two would-be objects of discrimination fail to equally well fit the further language specifying ostensibly suspect grounds of discrimination—especially that concerning discrimination based on "field of technology."

In Part III, I then turn to the one (and only) WTO dispute settlement body (DSB) decision involving Article 27.1's ostensible non-discrimination norm—dating from 2000 and pitting Canada against member states of what is now the European Union. In most significant part, here I argue that especially now, so long after the decision, it is misleading to understand the interpretive problem presented by Article 27.1 primarily in terms of existing attempts to formalistically distinguish unlawful discriminatory treatment from lawful differential treatment. More than two decades later, after the fight over TRIPS-flexibilities has so often spilled over into the public arena—most recently in the context of the fight over the patent waiver on COVID-19 technologies—and with developing countries having repeatedly already won recognition for these flexibilities, conjuring invariably underdetermined distinctions between discrimination and differentiation embeds the supposed dilemma Article 27.1 poses more than dissipating it.

Finally, in Part IV, I build on Part III by looking to how actual legal interventions and policy proposals that have been made in the aftermath of the TRIPS have always had to be rationally tailored in a way that defies any broad reading of Article 27.1's ostensible non-discrimination norm. More specifically, in this part I consider how ever since the TRIPS came into force member states in the Global North have repeatedly—and necessarily—tailored technological domain- and context-specific proposals or interventions that thoroughly obviate the very approach to Article 27.1 that would ride roughshod over such rational targeting that have tended to be championed in the pharmaceuticals (and, especially, "drugs-for-the-developing world") context.

II. THE PROBLEM OF INTERPRETING ARTICLE 27.1

A. Overview

According to Article 27.1, the TRIPS agreement mandates as follows:

[s]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.¹³

Across its two halves, Article 27.1's ostensible non-discrimination discipline is situated in the second of its two sentences. While the provision's reference to "place of invention" has always appeared relatively straightforward, the same has been less the case for the other two grounds of "discrimination" it renders suspect. The invocation of "field of technology" is arguably the more interpretively confounding, being both semantically more unusual as a term of art and, as attached to the idea of "patent availability" as an object of suspect discrimination, making for a directive that seems redundant given the way it immediately restates what the first sentence of Article 27.1 mandates. The reference to "whether products are imported or locally produced," on the other hand, has portended controversy less because of any impenetrability to what its terms seem to mean than because of its being an even more unconcealed battleground for the competing priorities of high-income countries and their developing world counterparts/antagonists. (More specifically at issue here were so-called "local working" requirements, a key flexibility with respect to patent rights that low- and middle-income countries naturally wanted to preserve the long-standing ability to make use of under international intellectual property law.)

While I will return to a discussion of negotiating history (and local working requirements) in Part II, for now it is enough to say

13. TRIPS Agreement, *supra* note 12, art. 27.1.

that even though the “field of technology” and “imported or locally produced” language proved controversial as grounds of suspect discrimination for different reasons, they are also hard to separate from one another insofar as the latter made its way into Article 27.1 as a byproduct, of sorts, of the former. The upshot of all of this has been to never have left it very clear if the notion of non-discrimination under Article 27.1 was meant simply to encourage the extension of patent protection to areas like pharmaceuticals and food products that were traditionally omitted from many national patent regimes or, more heavy-handedly, as some kind of blanket prohibition on exceptions to patent rights.¹⁴

*B. Non-Discrimination as a Norm
within the TRIPS/WTO Beyond Article 27.1*

Of course, Article 27.1 is not the only part of the TRIPS that traffics in the concept of non-discrimination. An overarching commitment to the norm is made manifest in Articles 3 and 4 of the agreement and the foundational obligations they set up to

14. In what is likely the best, recent effort to wrestle with Article 27.1, Milhan Ikram Mohamed observes that proponents of the TRIPS were concerned enough with the agreement’s mandating “the inclusion of substantive intellectual property law standards” that would “have to be adhered to by” member states that they inserted Article 27.1’s non-discrimination provision to make up for what they felt were the inadequacies of the TRIPS baseline non-discrimination disciplines of National Treatment and Most Favored Nation status in Articles 3 and 4. *See* Milhan Ikram Mohamed, *Unravelling the Rule Against the Discrimination of Fields of Technology Under the Patent Rules of the TRIPS Agreement* 11–12 (Nov. 2018) (Ph.D. dissertation, University of Cambridge). This is even as he also highlights the lengths to which the agreement was unprecedentedly made to go to include a host of safeguard provisions (as in Articles 7, 8.1. and the Preamble) to counteract the most “severe consequences that were expected by many opponents of the Agreement” with regard to constricting developing countries’ freedom in substantively designing their national patent law regimes. *See id.*

ensure national treatment¹⁵ and most favored nation¹⁶ status between member states. Indeed, these provisions, themselves, echo the nominally equivalent duo of principles for reducing tariff-based barriers to trade under the WTO's 1994 General Agreement on Tariffs and Trade (GATT). There, they are respectively elaborated in Articles III¹⁷ and I¹⁸ of the 1947 GATT, which the 1994 GATT incorporates wholesale.

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15. In relevant part, the National Treatment obligation requires that:
 (1) Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

TRIPS Agreement, *supra* note 12, art. 3.

16. In relevant part, the Most-Favoured-Nation obligation requires that:
 With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member.

Id. art. 4.

17. In most relevant part, the "National Treatment on Internal Taxation and Regulation" provisions of Article III of the GATT 1947 provide as follows:

The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.

General Agreement on Tariffs and Trade art. III, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194, 196 [hereinafter GATT 1947].

18. In most relevant part, the "General Most-Favoured-Nation Treatment" provisions of Article I of the GATT 1947 provide as follows:

With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs

More specifically, under Article 3 of the TRIPS the national treatment obligation seeks to equalize the handling of intellectual property rights vertically within any given WTO member state's national market, regardless of the nationality of the patent holder/seeker. Article 4's most favored nation principle, on the other hand, seeks to equalize treatment horizontally across member states, so that no WTO member can treat nationals of any particular member state differently than they do those of any other.

At first glance, then, Article 27.1's non-discrimination language might be understood as a way of restating the non-discrimination disciplines elaborated in Articles 3 and 4. On this view, the language would simply demand that member states adhere to the national treatment and most favored nation obligations with more specific respect to the "availability of patents" and "the enjoyment of patent rights"; likewise, what reference Article 27.1 makes to distinctions based on place of invention, whether products are imported or locally produced, and "field" of technology might be assumed to comprise even more specific illustrations of how patents/patent rights might fail to be made sufficiently available or enjoyable to non-nationals.

At the same time, there have always been reasons for pause in reading the more peripheral non-discrimination language of Article 27.1 in the above way; together, these make it clear that Article 27.1 was and is something other than a means of extending/exemplifying the principles enunciated in Articles 3 and 4. First, Article 27.1 applies in a more narrow context than Articles 3 and 4: not that of intellectual property rights in general but patent rights in particular. Insofar as it clearly eschews mention of copyrights, trademarks, industrial designs, and geographic indications, therefore, its applicability differs from Articles 3 and 4's in scope and nature.

2 and 4 of Article III, any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

Id. art. I.

Second, with respect to the grounds of suspect “discrimination”—on the basis of place of invention, import status, and field of technology—it elaborates, Article 27.1 is directed not at the national identity of the patent seeker/holder but *product* identity. This is the inverse of Articles 3 and 4 of the TRIPS, the national treatment and most favored nation norms of which are directed at *national* identity rather than *product* identity.¹⁹ Rather than being accidental, moreover, Article 27.1’s way of eschewing a focus on national identity in the manner of Articles 3 and 4 was clearly intentional, since it emulates how the most favored nation and national treatment principles are structured outside of the intellectual property context in Articles I and II of the GATT, where the focus is also on product identity. Indeed, as much was already emphasized during the negotiation of the TRIPS, by the Secretariat of the agreement’s Negotiating Group Council, which pointed out how Article I of the GATT differed from Article 3 of the TRIPS insofar as it assumed national identity to be a characteristic inhering in *goods* entering into trade rather than the parties doing the trading.²⁰

At the same time, nor is Article 27.1’s non-discrimination directive any simple restatement or extension of the *product* identity-based versions of the GATT’s national treatment or most favored nation status norms. For under the GATT’s so-called *like products* doctrine, those principles apply only when other aspects of product identity are “like.” No such doctrine governs whatever norm of non-discrimination Article 27.1 sets up. In fact, the very product features Article 27.1 seems to set up as suspect bases of discrimination—like the “field” of the product’s technology—are ones that would have to be “alike” for Articles I or II of the GATT to apply in the first place. Ultimately, then, it would appear that

19. TRIPS Agreement, *supra* note 12, arts. 3–4.

20. As is stated in the document:

[i]t should be noted that the ‘national treatment’ concept in international intellectual property law differs from that in the General Agreement in that it concerns the treatment given to persons (foreign nationals compared to nationals of the country) whereas the concept in Article III of the General Agreement concerns the treatment given to goods (imported goods compared to domestically produced goods).

Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Provisions on Enforcement in International Agreements on Intellectual Property Rights: Note by the Secretariat, ¶ 8, WTO Doc. MTN.GNG/NG11/W/18 (Feb. 10, 1988).

Article 27.1's non-discrimination language is *sui generis* when compared *either* to the core non-discrimination disciplines of the TRIPS itself or the GATT more generally.

Third, it is hard not to see how it is only Article 27.1 that explicitly invokes the term "discrimination" in laying out its strictures. This too would seem to add to the sense that Article 27.1's strictures should be just as well seen as *sui generis* and context specific. In this respect, one might say that Article 27.1 invokes "discrimination" in a generic sense rather than as a doctrinal term of art.

Fourth and related, even considered purely internal to its own directive, Article 27.1's non-discrimination language would appear to be *sui generis* since it really *cannot* be plausibly understood—as per the seeming possibility rehearsed at the outset of this section—as illustratively extending or exemplifying some more fundamental non-discrimination discipline.²¹ Its references to guaranteeing the "availability of patents" and the "enjoyment of patent rights," for example, reveal themselves to substantially differ from one another in a confounding way on closer inspection.²² The latter turn of phrase, at the very least, appears to be far less straightforward than the former, with whatever it might mean to not discriminate with respect to the "enjoyment of patent rights" presenting at least two problems. The first of these follows from the lack of any definition—whether in the TRIPS itself or any other international intellectual property law agreement—of the term "enjoyment."²³ The second follows from a lack of clarity around what "rights" are meant to be included within the ambit of the "patent rights" that must be "enjoyed" non-discriminatorily. Beyond these difficulties, still others arise when trying to make sense of the "enjoyment" and "making available" language as it is further given specificity through the additional verbiage indicating the ostensible grounds of suspect discrimination; or, rather, this is

21. TRIPS Agreement, *supra* note 12, arts. 3–4.

22. *Id.* art. 27.1.

23. This was a point emphasized by the Panel that decided the only WTO dispute settlement body case touching on Article 27.1. See Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 5.36, WTO Doc. WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada-Pharmaceutical Patents Panel Report*], https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm [<https://perma.cc/2VXZ-BV9K>].

the case at least insofar as that verbiage—like “field of technology”—itself remains undefined.

III. THE MAKING OF ARTICLE 27.1

A. Patent “Availability” and the Dunkel Draft

While the negotiating history of the TRIPS has been well-rehearsed elsewhere,²⁴ in grappling with the lingering lack of certitude around the meaning of Article 27.1 it is worth recounting the story in at least cursory form. This is not the least because as part of a larger treaty apparatus, the TRIPS is meant to be interpreted in accord with the Vienna Convention on the Law of Treaties (“Vienna Convention”), including its provisions making negotiating history a pertinent factor in so doing. As per Article 32 of the Vienna Convention, “recourse to supplementary means of interpretation including preparatory work, inter alia, may be had in order to confirm the meaning resulting from” the application of Article 31, which itself mandates that “a treaty shall be interpreted in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.”²⁵

For the present purposes, the importance of the negotiating history of Article 27.1 is thus to be found in the way it illuminates how the ambiguity of its non-discrimination language follows from what was both a highly contentious and rather ad hoc process of its emergence. Indeed, the final form of Article 27.1’s non-discrimination language was a very late addition to the negotiating process, and as such it fastened together divergent priorities. (For clarity’s sake, it is worth noting that the TRIPS talks were largely completed by early 1991, some three years before the ultimate resolution of the Uruguay Round of negotiations for the WTO more generally with the Marrakesh Agreement of April 1994.)

24. Considerable attention has been given to Daniel Gervais’ helpful treatise. DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 147 (1st ed. 1998). Gervais has been a regular consultant to the OECD and was an official of the World Intellectual Property Organization (WIPO). As a specialist in copyright, he participated in the negotiation of the TRIPS.

25. Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331, 340 (entered into force Jan. 27, 1980) [hereinafter Vienna Convention].

Perhaps what is most striking in early drafts of the text is the lack of any unified intention behind or even necessary connection between the provisions that would later come to appear like the skeleton of a full-fledged non-discrimination discipline—specifying twin objects of suspect discrimination, on the one hand, and a tri-partite division of prohibited bases for such discrimination on the other. Until almost the very end of the negotiating process, in fact, it was only the first object of discrimination—meaning, “the availability of patents”—that came in for any mention, with concern over the second—regarding the “enjoyment” of “patent rights”—simply going unmentioned. Likewise, in the early draft of the agreement prepared for the Brussels Ministerial Conference in December 1990 (the “Brussels Draft”), the obligation to make patents “available” only required agnosticism with respect to a single factor—namely, “field of technology.” Even in this form, moreover, the obligation was qualified by counterpart language that was permissive of member states simultaneously raising the bar for patentability through the new/inventive step/etc. language. As the Brussels draft had it:

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial applications. [Patents shall be available without discrimination as to where the inventions were made.]²⁶

Beyond this reference to “field of technology,” the only other of the three bases of discrimination Article 27.1 calls into question that even obliquely appeared in the Brussels draft was that concerning “place of invention,” albeit here as a concern with “where . . . inventions were made.”²⁷ Even this mention, however, only appeared in the Brussels draft as bracketed—or non-consensus—text and, here once more, only as linked to an obligation to make patents “available” rather than any regarding the “enjoyability” of patent rights.²⁸

26. GERVAIS, *supra* note 24, at 145; Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods: Prepared for the Brussels Ministerial Conference, GATT Doc. MTN.GNG/NG11/W/76 (Nov. 22, 1990) [hereinafter Brussels Draft].

27. TRIPS Agreement, *supra* note 12, art. 27.1.

28. *Id.*; Brussels Draft, *supra* note 26.

All told, then, the Brussels draft presented only a highly circumscribed non-discrimination principle—if it can even be called such a thing—under the rubric of its predecessor provision to the final agreement’s Article 27.1. As Daniel Gervais explains this is unsurprising given that even support for that provision “concern[ed] more directly the United States,” which was the chief exponent of pushing member states toward a “first-to-invent”—rather than “first-to-file”—system in the style of its domestic patent regime.²⁹

With negotiations having been stalled since the December 1990 Ministerial conference, the above picture would remain basically unchanged for another nine full months until November 1991 after Uruguay round talks resumed in February of the new year. By all accounts, during the interim severe pressure continued from the United States and other countries in the global North aimed, in effect, at fashioning the TRIPS into a vehicle for elaborating substantive intellectual property rights obligations.³⁰ Two developments of note would go on to alter this status quo before the close of the year. First, on November 7, 1991, intervention from beyond the TRIPS negotiating group ensued when then Director-General of the GATT, Arthur Dunkel, released a report detailing progress on the TRIPS negotiations (hereinafter “Progress Paper”).³¹ Ostensibly meant to highlight twenty issues relating to intellectual property protection standards that were still in need of resolution, the Progress Paper diverged in important ways from the Brussels Draft.³² Among the key issue areas Dunkel highlighted was the question of whether it would be possible to agree that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced, as well as to determine the term of patent protection.³³

In turn, the Progress Paper served as an immediate preface to the second key development, which followed soon after when

29. GERVAIS, *supra* note 24, at 147 (quoting the Brussels Draft, *supra* note 26).

30. Mohamed, *supra* note 14, at 11.

31. Progress of Work in Negotiating Groups: Stock-Taking, at 8, WTO Doc. MTN.TNC/W/89/Add.1 (Nov. 7, 1991) [hereinafter Progress Paper], <https://docs.wto.org/gattdocs/q/UR/TNC/W89A1.PDF> [<https://perma.cc/78ZT-M4EQ>].

32. *Id.*

33. *Id.*

Dunkel effectively arbitrated a new draft text of the TRIPS after the discussions that had barely just resumed broke down once more by December 1991.³⁴ Against the backdrop of mounting pressure to conclude the agreement by year's end, "at the eleventh hour," then, Dunkel presented his version of the agreement on what was, in essence, a "take-it-or-leave-it" basis.³⁵ Among the new provisions within the so-called Dunkel draft was one that essentially mirrored the final text of Article 27.1, stating that:

[s]ubject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.³⁶

Yet in articulating what would go on to become the final text of Article 27.1 the Dunkel draft did not simply mark the eruption into the agreement of a new non-discrimination norm. It also threw into relief what has, ever since, remained the confusion around whether it really constitutes any such thing. This is made especially apparent by the awkwardly redundant way it invokes "patent availability" twice within the space of its two sentences while referring to "the enjoyment of patent rights" only once. Indeed, in earlier versions of the agreement, the notion of a "field of technology" was not even one that was necessarily linked to patent "availability," with one of the main alternatives—linking it instead to how "patents shall be granted"—tending away from giving the provision the appearance of elaborating an object and basis of "discriminatory" treatment.³⁷

34. See Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 378-79 (2002).

35. *Id.*

36. GERVAIS, *supra* note 24, annex 10.

37. See, for example, the so-called "Chairman's draft" or "Composite draft text" created by Lars Anell, the Chairperson of the Negotiating Group on the TRIPS, and distributed on June 12, 1990. Intended to create a "common presentation" by outlining areas of agreement and uncertainty through re-structuring existing non-consensus proposals that had been submitted in the form of "Communications" from various

Understood against the backdrop of the previous negotiating history and Dunkel's breaking the impasse that had developed between high-income countries and their developing world counterparts by imposing the new text that unofficially bore his name, the first sentence of what would become Article 27.1 is best understood as signaling how the "availability" language originated not in any preoccupation with coining a broad new non-discrimination discipline on a par with the national treatment and most favored nation principles but rather with expanding the range of what was to be counted patentable. The very subtitle that Article 27.1 would go on to be inscribed under—of "Patentable Subject Matter"—suggests the same. Moreover, in severing the "availability" from "enjoyment" language, the first of Article 27.1's two sentences throws into relief how the "field of technology" idea, itself, needed not to be shoehorned in with "place of invention" and imported/locally produced status—much less to be thought of as all of a kind with one another in their capacity as bases of prohibited "discrimination"—in the way the second sentence of the paragraph can be read to suggest they should be.

Obviously, the salience of the concern with imported versus locally produced status depends on an invention's being first turned into a product through *actual production in some place* in a way that patentability does not. Likewise, as more detailed accounts of the negotiation process confirm,³⁸ for the United States, European Community, and Japan, the focus on patent "availability" was precipitated by the desire to curtail the discretion countries had to exclude sectors like pharmaceuticals, food, and chemical products from being enclosed behind intellectual property boundaries. This contrasted sharply with previous treaty arrangements—including and especially the Paris Convention on the Protection of Industrial Property of 1883—

negotiating states—including the European Union, the United States, and several developing countries—it stated that:

1. Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.
2. Patents shall be available according to the first-to-file principle.

Brussels Draft, *supra* note 26, at 146.

38. Mohamed, *supra* note 14, at 15.

under which signatory states were broadly empowered to create such exclusions from patentability.³⁹

B. "Enjoyment of Patent Rights" and the Dunkel Draft

To leave matters here, however, only further begs the question of why the Dunkel draft nonetheless inserted the second sentence it did, restating concern with patent availability regardless of field of technology while also then joining the very same concern to the further language around enjoyment of patent rights, place of invention, and imported/locally produced status. The short answer is that underlying the insertion was what, in the years since, has nonetheless come to be understood in terms of a key flexibility the TRIPS does permit, which at the time of the negotiations countries in the global North—and especially the United States—were seeking to cut off. This had to do with compulsory licensing (allowing for use of an invention/product without authorization of the intellectual property holder).

The sudden appearance of what became Article 27.1's non-discrimination provision constituted a rear-guard maneuver to curtail rights to unlicensed use after a more sweeping attempt to do so had failed going into the Dunkel draft. The defeat of the larger global prohibition on compulsory licensing the United States was seeking is reflected in what is now Article 31 of the TRIPS, which makes it clear that "Other Use Without Authorization of the Right Holder" is, in fact, permitted under the agreement.⁴⁰ Indeed, the subtitle of Article 31 is telling insofar as it omits specific reference to compulsory licensing. This is because the United States encountered difficulty in trying to outright prohibit compulsory licensing once its antagonists in the negotiating process like India had succeeded in getting Canada, the European Community, and

39. For example, in the September 12, 1989 notes for the July 1989 meeting of the negotiating group, it records that:

Switzerland explained that no field of technology should be excluded per se from patentability; what determined whether a subject matter was patentable was its technical character. However, this did not exclude the possibility that special correctives or demarcations might be necessary in specific areas. An example was plant varieties.

Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 12-14 July 1989*, ¶ 79.4, WTO Doc. MTN.GNG/NG11/W/14 (Sep. 12, 1989).

40. TRIPS Agreement, *supra* note 12, art. 31.

Japan to withdraw support for any such prohibition by joining the issue of the legality of compulsory licensing with that of the legality of government use. As it eventually emerged, then, Article 31's "other use without authorization" provision championed a process-oriented approach focused on setting procedural conditions to be met before licenses could be granted rather than any blanket ban on their issuance.⁴¹

At the same time, the steadfastness of the United States' position meant that within the ongoing negotiation process controversy around licensing could not be fully contained by an Article 31 reflecting the direct defeat of that position. This was especially given how the issue was tied up with that of "local working" requirements. In the pre-TRIPS context patent granting countries often availed of such requirements in order to force patent holders to make use of their patents within the granting country or otherwise risk losing their monopolies. Historically, the uncontroversial position was that product importation was *not* a valid method to "work" a patent locally.⁴² Under the Paris Convention, for example, if a patent holder imported a product into whatever given country, this was no bar on that country from compulsorily licensing the product as a remedy for the right holder's failure to work; to the contrary, under the Paris Convention only "execution of the invention" within the patent granting state normally sufficed.⁴³

As the TRIPS negotiations took shape, therefore, the central debate that emerged around such requirements involved whether the definition of "local working" would be expanded to include importation.⁴⁴ This was preceded by an earlier round of

41. See CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 97 (2000); see also Mohamed, *supra* note 14, at 20–22.

42. For an account of the historical evolution of local working requirements and the later addition of importation as a means of meeting such requirements, see Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* 11–13 (Trade-Related Agenda, Development And Equity (T.R.A.D.E.) Working Paper No. 5, 1999).

43. *Id.*

44. See generally Champ & Attaran, *supra* note 34. Though helpful in outlining the timeline of the negotiating history of these issues, the finer points of the interpretation Champ and Attaran offer of these events do leave something to be desired. For example, the authors fail to acknowledge that under Article 2 of the TRIPS the compulsory licensing provisions under Article 5A(2) of the Paris Convention are independent of exceptions

disagreement that saw the United States and European Communities form an initially united front against their developing country counterparts over whether the TRIPS should permit local working requirements at all, however defined.⁴⁵ As I alluded to above, however, this unity was not destined to last given that the United States's underlying antipathy to compulsory licensing made its opposition to local working requirements much greater than that of its fellow global North countries.⁴⁶ The European Community, for example, eventually migrated to a middle ground position allowing countries to retain local working requirements so long as failure to meet them did not automatically trigger the licensing of underlying patents absent any consideration of the reasons for the failure to work.⁴⁷

It was thus only with the United States isolated in its support for a blanket prohibition on local working requirements⁴⁸ that battlelines shifted to the question of whether the TRIPS should redefine importation to suffice as a means of local working. This is evident in the draft text that preceded the Dunkel draft. The July 1990 Chairman's Draft, for example, was confined to the European Commission's middle ground position that compulsory licensing should be disallowed if the right holder could make a sufficient showing of "the existence of legal, technical or commercial reasons" for its failure to work a patent.⁴⁹ Even in the December

under Article 31 of the TRIPS Agreement. This is especially important because both provisions have their own conditions, and Champ and Attaran's view tends to obscure this.

45. *Id.* at 374.

46. *Id.* at 375.

47. *Id.*

48. In their initial draft communications (the documents from which Anell grafted together the Chairman's Draft), both the United States and the European Communities addressed the issue as part of their larger positions on compulsory licensing, and each of their respective views on local working were implied under their respective predecessor versions of what would become Article 31 in the final version of the TRIPS. The United States' preferred version from its draft communication states: "[c]ontracting parties may limit the patent owner's exclusive rights solely through compulsory licenses and only to remedy an adjudicated violation of competition laws or to address, only during its existence, a declared national emergency." *Id.* (quoting U.S. Draft Communication to the TRIPS Negotiating Group (on file with the authors)). See also *id.* at 376–77 (on the ongoing ascent of the European Communities' middle-ground position).

49. The full text of the relevant provision, which appeared in the draft's section on Compulsory Licensing (its closest analogue to what became Article 31 in the final version of the TRIPS) rather than that on Patentable Subject Matter (the would-be predecessor to the final version of TRIPS Article 27.1), reads as follows: "1.A.3.2 Compulsory licenses for non-working or insufficiency of working on the territory of the granting authority shall not

1990 Brussels draft, there was only bracketed text on the possible relevance of product importation to meeting local working requirements.⁵⁰

Through its eleventh hour ultimatum, therefore, the Dunkel draft cast a shadow of the United States' position in favor of defining local working to include importation through reiterating the "patent availability" language from the first sentence of what would become Article 27.1 in a new second sentence that reproduced that same language while further joining it to the "enjoyment of patent rights" as a second object of suspect discrimination and "whether products are imported or locally produced" as another ostensibly prohibited basis of such discrimination. By threatening to recast them as so many infringements on the "enjoyment" of the patent holder's rights Article 27.1's non-discrimination provision can thus be read as possibly delegitimizing—even if nonsensically so—the kinds of local working requirements the TRIPS simultaneously authorizes. (For example, under Article 2 of the agreement,⁵¹ there must be

be granted if the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons." GÉRAIS, *supra* note 24, at 64 (quoting July 1990 Chairman's Draft, art. 1.A.3.2).

50. This was reflected in the bracketed text of both Article 30 (the closest analogue to Article 31 in the final version of the TRIPS) and Article 34 of this draft. Article 30(a) reads as follows:

To ensure the [working] [exploitation] of the patented invention in order to satisfy the reasonable requirements of the public. [For the purposes of the Agreement the term "working" may be deemed by PARTIES normally to mean manufacture of a patented product or industrial application of a patented process *and to exclude importation*].

Id. at 155 (quoting July 1990 Chairman's Draft, art. 30(a)) (emphasis added).

Article 34 states:

Authorisation by a PARTY of such use (i.e. compulsory licensing) on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted [where importation is adequate to supply the local market or] if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons.

Id. at 162 (quoting TRIPS Agreement, art. 34).

51. Under the subtitle "Intellectual Property Conventions" the provision reads as follows:

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention.

consistency with other international intellectual property treaties, including the Paris Convention—article 5A(4) of which clearly permits failure to work as a valid ground for compulsory licensing⁵²).

IV. ADJUDICATING ARTICLE 27.1

To date, there has been only a single case adjudicated before the WTO's Dispute Settlement Body (DSB) involving, among other provisions of the TRIPS, Article 27.1's would-be anti-discrimination norm. Pitting Canada against the European Communities,⁵³ the *Canada-Patent Protection of Pharmaceutical Products* ("Canada-Pharmaceutical Patents") panel issued its final report in 2000.

While in the first sub-section below I will recount the basics of the dispute, my purpose in doing so is not to provide any comprehensive discussion of the Panel decision, even just of its every pronouncement on Article 27.1. This is not the least because neither Panel nor Appellate body decisions within the WTO's system of adjudication observe any principle of *stare decisis* requiring adherence to decisions in previous "cases." Instead, the discussion in this section will focus on the Panel's development of

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

TRIPS Agreement, *supra* note 12, art. 2.

52. This provision, in relevant part, reads as follows:

A compulsory license may not be applied for on the ground of failure to work or insufficient working . . . before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last . . . ; it shall be refused if the patentee justifies his inaction by legitimate reasons Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license

Paris Convention for the Protection of Industrial Property art. 5A(4), Mar. 20, 1883, 828 U.N.T.S. 307 (revised on July 14, 1967) [hereinafter Paris Convention (1967)]; *see also* G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 67 (1968) (quoting Paris Convention (1967)).

53. As distinct from the European Community (EC)—the new name given to the European Economic Community (EEC) after the 1993 Maastricht Treaty—the European Communities was the name used to refer, in tandem, to the European Coal and Steel Community, the European Atomic Energy Community, and the EEC.

a distinction between unlawful “discriminatory treatment” under Article 27.1—here, based mainly on field of technology given the European Communities’ objection to Canadian regulations as pertaining to pharmaceuticals—and lawful differential treatment. The section then ends by arguing that especially now, so long after the *Canada-Pharmaceutical Patents* decision and with no real further disputes in its lineage, framing the interpretive problem presented by Article 27.1 primarily in terms of formalistically drawing *a priori* and, at any rate easily manipulable, distinctions of degree is counterproductive. More than two decades later, the lawfulness of a rationally tailored deployment of the TRIPS flexibilities that developing countries fought so hard, and already successfully, to secure is better assessed against actual technology-cognizant policy proposals and policymaking in the field.

A. Overview of the *Canada-Pharmaceutical Patents* Dispute

At issue in the *Canada-Pharmaceutical Patents* dispute were various sections of Canada’s Patent Act together with Canada’s former Manufacturing and Storage of Patented Medicines Regulations, which were updated between 1992 and 1993 to bring them into line with new/pending obligations under the TRIPS, including to provide recognition for process—rather than just product—patents and the like.

Broadly speaking the regulations were focused on safety and efficacy of pharmaceutical products and elaborated a basic division between novel and generic medicines. Under these laws generics were generally subjected to less lengthy review—for a period between three to six years as opposed to eight to twelve years given the ability to rely on already existing data. However, because that review period took place only after the expiration of a novel drug’s standard twenty-year patent and generic drugs could not enter the market until the review was completed, the process of refining its patent laws precipitated by the TRIPS offered Canada an opportunity to remedy what was as much as six years of extra monopoly rights for the patent holder.

This led to the addition of two significant exceptions under Sections 55.2(1) and 55.2(2) of the Canadian Patent Act that would go on to become the point of contention with member states of the European Communities. The first allowed patents to be circumvented in the event that this was being done for the

purposes of meeting—on the standard of “being reasonably related to”—the requirements of regulatory review by releasing firms from liability for infringement.⁵⁴ The second further released firms from liability for infringement for “mak[ing], construct[ing], or us[ing] the invention . . . for the manufacture and storage of articles intended for sale after the date on which the term of the patent” came to an end; this allowed non-patent holders to effectively stockpile generic medicines for sale six months prior to the expiration of the patent.

While the Panel held under Article 28 of the TRIPS (providing for the exclusive “Rights Conferred” under a patent) and Article 30 (providing for “Exceptions to Rights Conferred,” the TRIPS so-called limited exceptions provision⁵⁵) that the regulatory review exception was permissible, it held that the stockpiling exception was not.⁵⁶ Along the way of doing so it made several further determinations of note. Among these were that the two provisions at issue should be assessed independently rather than jointly and that Article 30 should be read narrowly. More salient for the present purposes, there was also the European Communities claim that both provisions in Canadian law constituted unlawful discrimination on grounds of field of technology under Article 27.1—in the case of the stockpiling exception under Section 55.2(2) of the regulations because it was expressly directed at pharmaceuticals and in the case of the regulatory review exception

54. Patent Act, R.S.C. 1985, c. P-4, § 55(1) (Can.) (“A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damages sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.”); *see also* Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶ 2.1 (quoting § 55(1) of the Patent Act).

55. Under the heading, “Exceptions to Rights Conferred” the full text of Article 30 reads as follows:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

TRIPS Agreement, *supra* note 12, art. 30.

56. Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶¶ 7.11, 8.1. Regarding the stockpiling exception’s impermissibility, the European Communities also claimed—and the Panel concurred—that its enabling parties to begin production in the six months prior to the end of the patent term constituted a violation of Article 33 of the TRIPS (entitled “Term of Protection”), which set out the basic obligation on member states to institute patent terms of twenty years from the date of filing.

under 55.2 (1) on grounds of how the field of technology-based discrimination against pharmaceuticals was evident in the legislative history and application of the relevant provision.⁵⁷ With the stockpiling exception already held unlawful, the Panel reached the Article 27.1 challenge only in the context of the regulatory review exception, being ultimately unpersuaded that section 55.2(1) of the Canadian regulations was unlawfully discriminatory.

The further contours of the Panel's decision as relating to Article 27.1 are easiest to summarize through tracing the planks in Canada's defense of the regulatory review exception against the allegation of discrimination with respect to the "enjoyment of patent rights" on grounds of "field of technology."⁵⁸ Here Canada offered two arguments, contending, first, that Article 27.1's non-discrimination provision did not apply to exceptions under Article 30 (while accepting that it did to those for other use without authorization under Article 31).⁵⁹ Its second line of defense was that even if Article 27.1 did apply to exceptions under Article 30, the regulatory review exception was simply not discriminatory, whether on a *de jure* or *de facto* basis.⁶⁰

With the first contention—about Article 27.1 not applying to Article 30 exceptions—proving unsuccessful in the Panel's eyes, it was Canada's second line of defense that proved the ultimately determinative one in the regulatory review exception passing muster. In contrast to the stockpiling exception under section 55.2(2), section 55.2(1)'s lack of any explicit mention of the pharmaceutical sector made it easy enough for the Panel to set aside the charge of *de jure* discrimination. Regarding *de facto* discrimination, the Panel distilled the European Communities' charge into separate claims about section 55.2(1) involving a *de facto* discriminatory purpose (that would require inferring "the existence of . . . discriminatory objectives" based on "the objective characteristics of" the regulations), on the one hand, and its producing discriminatory effects, on the other. Here as well—on neither front—did the Panel feel that the European Communities made a sufficient showing controverting how on its face section

57. *Id.* ¶¶ 4.24–4.25.

58. TRIPS Agreement, *supra* note 12.

59. Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶¶ 4.16–4.18, 7.87.

60. *Id.*

55.2(1) did not single out pharmaceuticals (or any other technological domain).

B. Article 27.1 and the (Limitations of the) Panel's Decision

Since having been decided, the *Canada-Pharmaceutical Patents* decision has never been regarded as a model of clarity and nowhere more than in the context of its pronouncements about Article 27.1. In cataloguing the limitations of the decision, it is best to take up the above holdings in reverse order given that the claim of de facto discrimination required the least effort from the Panel at reasoned elaboration about either the genesis or nature of Article 27.1. Indeed, here the Panel did not have to extend its analytical labor much past drawing the distinction between de facto discriminatory objectives and discriminatory effects (before finding an insufficient showing of both).

In contrast, in rejecting Canada's claim about Article 30 exceptions being exempt from Article 27.1, the Panel devoted considerably greater effort to its non-discrimination language.⁶¹ While as noted above, it ultimately marshalled this effort to the end of rejecting Canada's attempt to stake this part of its defense on Article 30 exceptions being "permissive" in a way that supposedly distinguished them from the "mandatory" exceptions under Article 31, along the way it gave considerably more attention to the question of Article 27.1's origins. While in some ways consonant with the negotiating history rehearsed in Part II, in other more subtle ones the Panel endorsed a skewed portrait—perhaps because largely shared by the parties in the case.

In the Panel's way of depicting things, Article 27.1 thus had two "thrusts," one being to "ensure" that "patents would be available for all inventions in all fields of technology" and the other being "to eliminate compulsory licenses provisions respecting food and drug products."⁶² This idea was unpacked at greater length in the European Communities account of how Article 27.1 "became relevant," which maintained as follows:

In the past, a great number of countries . . . had provided for systems of compulsory licences where it was much less burdensome to obtain compulsory licences in certain areas of

61. *Canada-Pharmaceutical Patents* Panel Report, *supra* note 23, ¶¶ 7.88–7.105.

62. *Id.* ¶ 4.17.

technology than in others . . . While attempts had been made to define the cases in which compulsory licences could be granted in Article 31 of the TRIPS Agreement, this provision stipulated only the procedures for the grant of compulsory licences. However, Article 27.1 became relevant when it came to the choice of the situations which were made subject to compulsory licences. While Article 27.1 did not exclude any field of technology from the scope of areas to be made subject to compulsory licences, Article 27.1 required that, if they were made available for one field of technology, they had to be made available to all fields of technology under the same conditions, the underlying consideration being that it was generally politically easier for a country to adopt provisions for making compulsory licences easily available for technologies where it had little or no industry and maintaining a more stringent level for the grant of compulsory licences or not allowing such licences at all in areas of technology where its industry was more competitive. It was indeed the aim of the non-discrimination provision contained in Article 27.1 of the TRIPS Agreement to avoid this tendency and to exclude an “a la carte” approach. The reasoning developed in relation to compulsory licences applied equally to exceptions.⁶³

This line of assertion figured centrally into the Panel’s rejection of Canada’s claim that Article 27.1 applied only to Article 31’s “mandatory” exceptions and, thus, not to Article 30’s “permissive” ones. According to Canada it would be “incongruous”⁶⁴ for Article 30 exceptions to have to comport with Article 27.1 since this would mean they had to apply “across the board” if they were not to prove discriminatory as to field of technology; yet if they did so apply, such exceptions would, in turn, fail to be “limited” in the way Article 30 simultaneously required. Unfazed, the Panel simply emphasized the idea that Article 27.1’s non-discrimination language originated and found its purpose in the will to prohibit compulsory licensing. Even more stridently than as quoted above, the Panel thus maintained that:

two of the primary purposes of Article 27.1 were to eliminate two types of discrimination that had been practiced against pharmaceuticals and certain other products—either a denial of patentability for such products or, if patents were granted,

63. *Id.* ¶ 4.27.

64. *Id.* ¶ 4.36.

automatic compulsory licences permitting others to manufacture such products for a fee.⁶⁵

According to the Panel, then, Article 27.1—and not Article 31—was effectively the TRIPS's primary mechanism for addressing compulsory licensing. This was despite the fact that—as discussed in Part II—any such idea is belied by the fact that it was only with the Dunkel Draft that the issue of patentable subject matter was even brought into the vicinity of compulsory licensing—through the new language Dunkel inserted into his text—in the first place. In whatever way the two issues were thereafter co-mingled, moreover, as also discussed above in Part II, the Dunkel Draft's non-discrimination language was never tied to the issue of compulsory licensing in any overarching way but mainly as connected to the more limited question of local working requirements.

Regardless, the Panel's skewed reading of the history and purpose of Article 27.1 melded seamlessly into its way of endorsing Canada's second line of defense as well. Before leaving the question of whether Article 30 exceptions were exempt from Article 27.1's reach it thus began a retreat into a more telescopic perspective for pronouncing on discrimination in the TRIPS/trade context. Accordingly, it explained that the last main reason it was rejecting the possibility of Article 30 exceptions being exempt from the obligation of non-discrimination was because on its face "Article 27.1 prohibits discrimination as to the enjoyment of 'patent rights' without qualifying that term." With Canada obviously never contending, in the first place, that the qualification appeared on the face of Article 27.1's text, the Panel felt some evident need to elaborate this confounding point further. By way of doing so the best it offered was the seemingly question begging observation that "[a] discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves."⁶⁶

Question begging or not, the Panel's discrimination-is-discrimination posture went on to feed into its way of ultimately saving the regulatory review exception by drawing the hair-splitting distinction it effectively did between discriminatory and

65. *Id.* ¶ 7.90.

66. *Id.* ¶ 7.91.

differential treatment.⁶⁷ I say effectively making such a distinction because for its own part the Panel seemed to suggest it was doing no such thing, prefacing its handling of Canada's claim that its regulatory review exception was not discriminatory by noting how discrimination "certainly extends beyond the concept of differential treatment."⁶⁸ Yet notwithstanding this pronouncement it is hard to see how the Panel was doing anything but splitting hairs. As it went on to maintain in a key passage, it is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.⁶⁹

Indeed, ever since *Canada-Pharmaceutical Patents* was decided, those left to make sense of the decision have called attention to the "bona fide exceptions" language by way of extracting from the decision an endorsement of the idea that not all differential treatment is discriminatory under the TRIPS. This, for example, has long been the position of Carlos Correa, a leading

67. However, here it is worth remembering that regardless of whatever more the Panel had to say about the concept of discrimination, its most direct reason for concurring with Canada that the regulatory review exception was not discriminatory was because it felt the European Communities had failed to show any real evidence of either *de jure* or *de facto* discrimination.

68. *Id.* ¶ 7.94.

69. In relevant part the Panel concluded that:

It is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.

Id. ¶ 7.92.

commentator on the agreement.⁷⁰ Indeed, Correa draws on the same distinction to motivate the further proposal he has made for the lawfulness under the TRIPS of “differentiation based on . . . ‘problem areas’ as distinct from ‘fields of technology.’”⁷¹ Fred Abbott has made a similar argument, contending that in *Canada-Pharmaceutical Patents*

[t]he panel makes clear that the conduct prohibited by Article 27:1 is “discrimination” as to field of technology, and that “discrimination” is not the same as “differentiation.” The panel states that governments are permitted to adopt different rules for particular product areas, provided that the differences are adopted for bona fide purposes. The Panel did not attempt to provide a general rule regarding what differences will be considered bona fide.⁷²

With others besides Correa resting on a similar logic of distinction, perhaps the most notable attempt at offering a further layer of reasoning to corral Article 27.1’s non-discrimination norm

70. Carlos Correa’s *Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* discusses an “interesting statement” by a WTO Panel distinguishing between “discrimination” and “differentiation,” particularly regarding “bona fide exceptions to deal with problems that may exist only in certain product areas.” See CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 282 (2009); see also Mohamed, *supra* note 14, at 44 (citing CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* (2009)). While the 2009 edition was unavailable for direct consultation, the 2020 edition reaffirms this analysis with slight modifications. See CARLOS CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 64, 275–76 (2020).

71. *Id.* at 276.

72. See Fred Abbott, *Discontinuities in the Intellectual Property Regime: The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 76 (2001). Abbott makes the following observation about the case at a later point in his article:

Having made this point in the abstract, the panel . . . decided that exceptions permitted under Article 30 are in fact bounded by the restriction in Article 27:1 against discrimination among fields of technology. The reasoning of the panel was that the restriction was adopted for the purpose of precluding governments from singling out an industry, such as the pharmaceutical industry, for less favourable patent protection, and that allowing an exception would undermine the purpose for adopting the restriction. The panel was chaired by Bob Hudec, and for this reason will carry a certain precedential weight, despite the fact that the determination regarding Article 27:1 was not important to the outcome of the case, since the panel determined that the relevant Canadian legislation did not discriminate among fields of technology.

Id. at 81.

has been Milhan Ikram Mohamed's. Mohamed has offered an extended critique of the position Correa and others have staked out. More specifically, on Mohamed's view those who have seized on the *Canada-Pharmaceutical Patents* Panel's appeal to "bona fide exceptions"—raising the Panel's allusion, as he puts it, to "near biblical significance"⁷³—have fundamentally misread the decision by failing to grapple with what more the Panel, itself, had to say about differential treatment. For Mohamed the key part of the decision instead comes immediately after the Panel's earlier quoted pronouncement about discrimination "certainly extend[ing] beyond the concept of differential treatment."⁷⁴ This found the Panel opining that discrimination "is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment."⁷⁵ With this formulation—of discrimination as the "unjustified imposition of differentially disadvantageous treatment"—in hand, Mohamed goes on to offer/develop a three-pronged standard for a "justificatory concept" of differential treatment. This would require i.) a measure to be in pursuit of a legitimate policy objective, ii.) that it bear a sufficient connection to that stated objective, and iii.) that it display what Mohamed calls "even-handedness" (in essence, that due recognition of the autonomy of member states to "justifiably differentiate" be balanced by "safeguards to ensure that [they] do not abuse their rights").⁷⁶

Certainly, Mohamed's effort is not unwelcome. Its merits are to recast what is the Panel's seemingly passing reference in the more traditional form of a legal standard. Yet this can hardly be done cost-free. On the one hand, articulating any such legal standard carries with it a baseline problem of circularity as between the ostensible norm being unpacked and the test doing the purported unpacking. Whether cashing out the "unjustified imposition of differentially disadvantageous treatment" in terms of the three-pronged test Mohamed offers really adds much for the purposes of arriving at a best or even more rational way of striking a distinction between justified differential and unjustified discriminatory treatment is debatable, at best. Indeed, the same

73. Mohamed, *supra* note 14, at 47.

74. See *Canada-Pharmaceutical Patents* Panel Report, *supra* note 23, ¶ 7.94.

75. *Id.* ¶ 7.94.

76. See Mohamed, *supra* note 14, at 99, 106.

question can be iterated with respect to whether being able to distinguish “unjustified imposition of differentially disadvantageous treatment” through the three-pronged test really adds anything more than distinguishing unlawful treatment in terms of its failure to reach the level of a genuinely “bona fide” exception to the “non-discrimination” obligation.

On the other hand, there is a higher price of entry an effort like Mohamed’s demands us to pay. This is because it requires we give more credence to the Panel’s report than it necessitates, whether given its non-binding nature within the WTO’s system of jurisprudence or because the relevant part of the Panel’s decision is better regarded as a kind of dicta than a passage of near “biblical significance.” To be sure, the Panel’s mention of the “unjustified imposition of differentially disadvantageous treatment” is hardly much more developed than the fleeting reference to “bona fide exceptions to deal with problems that may exist only in certain product areas”⁷⁷ that has been more commonly the point of focus. Moreover, even if one were to regard the Panel’s report as a kind of in-effect precedent or otherwise persuasive authority, as noted earlier, the Panel’s upholding of the regulatory review distinction did not really turn on any of these wider, telescopic comments on the concept of discrimination; to the contrary, it simply concurred with Canada that no real showing had been made of either *de jure* or *de facto* discrimination.

As if to put too fine a point on this second concern, it is worth quoting the rest of the passage Mohamed places such emphasis on. For here we find the Panel seeming to at best immediately take away whatever Mohamed is suggesting we proceed by seeing it as having given. After all, it is the Panel itself that hastens to add—just after announcing its ostensibly more refined definition of discrimination as “the unjustified imposition of differentially disadvantageous treatment”—that “[t]he standards by which the justification for differential treatment is measured are a subject of infinite complexity.”⁷⁸ Elaborating them without striking distinctions without a difference, then, might just as prudently be regarded as a fool’s errand or, at least, a dead end.

77. Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶ 7.92.

78. *Id.* ¶ 7.94.

V. NON-DISCRIMINATION AND
THE DISCRIMINATING POLICY-MAKER

The juxtaposition between the imperatives of policy making in the area of intellectual property, requiring as it does the flexibility to provide targeted means by which to address specific problems, and an Article 27.1 read so as to extend non-discrimination doctrine to an entirely new set of product-identity based measures continues to present a trenchant problem. Even if the last three decades of conflict over “drugs for the developing world” had not already witnessed low- and middle-income countries securing recognition for so-called TRIPS flexibilities—whether through drawing on the object and purpose of the TRIPS itself (in Articles 7 and 8)⁷⁹ or through add-on instruments like the Doha Declaration—it would be incongruous to imagine a viable way forward can be maintained by re-litigating the *Canada-Pharmaceutical Patents* case. In the larger argument, indeed, the same holds for maintaining a viable way forward through beginning from the formalist impulse to deduce the right location, in the abstract, for drawing a line between lawful differentiation and unlawful discrimination. To the contrary, a different starting point would simply be to acknowledge the ongoing ubiquity, long after the TRIPS has held sway, of specifically tailored policy making in the patent area, which has always been foundational to the fight over affixing an agenda of upward harmonization of national intellectual property law regimes to the project of post-Cold War free trade liberalization in the first place.

79. Under the headings of “Objectives” and “Principles,” respectively, the full text of these provisions reads as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

TRIPS Agreement, *supra* note 12, art. 7. Article 8.1 goes on to state:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Id. art. 8.1.

In the present section, therefore, I canvass example situations illustrating the evidently wide-ranging social imperatives that have informed discriminating policy and legislative choice by WTO member states. For clarity's sake, the below discussion is confined to member state policy and legislative choice that is calibrated to technologically distinct substrate domains relating to patent rights.

*A. Specifically Tailored Legislative/Policy
Choice around Software Patents in Europe*

Perhaps the most noteworthy context in which even so fundamental a right as the baseline one of patentability has elicited resistance to any one size fits all approach issuing from the TRIPS has been that of computer software. Right from the outset of the TRIPS coming into effect, there was thus active internal division within Europe over recognizing the patentability of software; this tension has persisted ever since. More specifically, it has underlain the split between the approach of the European Patent Office (EPO)—as instantiated in Article 52(2)(c) of the European Patent Convention (EPC)—excluding computer programs from patentability,⁸⁰ and the position of the European Union (EU), which has pushed for the recognition of software patents as part of the larger TRIPS-related upward harmonization agenda.

Of course, it is true that over the last three decades, this intra-European friction over software patents has never really caught fire. Indeed, with the EU's new Unitary Patent System,⁸¹ by 2023

80. European Patent Convention (EPC) art. 52(2)(c), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended in 2000) [hereinafter EPC 2000], <https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ma1.html> [<https://perma.cc/TW98-NZA3>].

81. Under the Unitary Patent System parties file a common application first at the EPO, which then examines the application and grants or denies the patent under the rules of the EPC. If granted, the applicant then has the choice to opt either for a classic European Patent applicable in EPC states or a new unitary patent covering all EU states but excluding non-EU member states to the EPC. On matters of infringement and validity recipients of the unified patent agree to the exclusive jurisdiction of the EU's new Unified Patent Court, the judgments of which apply to all countries within the Unified Patent system. For recipients of classical European Patents, enforcement actions continue in national courts. The legal instantiation of the Unitary Patent system has taken place through a series of European Council Regulations as well as other instruments such as the Agreement on a Unified Patent Court. *See* Council Regulation 1257/2012, 2012 O.J. (L 361) 1; Council

friction had settled into something more like an amicable friendship. Long before the Unitary Patent Systems, moreover, tension had been practically mitigated by the EPO's recognition of patents for so-called software-related inventions if they passed the "technical effect" test—that is, if they produced requisite effects beyond those deriving from the normal interaction of hardware and software. Conversely, the strictures on software patents embedded in Article 52 of the EPC can also be seen as having made for no real split with the EU insofar as one might argue that the TRIPS excludes abstract concepts and pure mathematical ideas from patentability. This has typically been based on Article 27.2⁸² and 27.3⁸³, which outline exclusions from patentability when necessary to protect "ordre public or morality," for diagnostic, therapeutic, and surgical methods, and for certain microorganisms/biological processes for their production. Yet it would undoubtedly be misconceived to see the saga of software patents in Europe as culminating in detente because what might look to some like "discrimination" under Article 27.1 really turned out to be no more than lawful differentiation. This is for several reasons.

First, even if the EPO's stance on the patentability of software need not, in principle, be understood as violating the TRIPS, the European Union has not necessarily concurred. Despite the EPC effectively recognizing software patents for inventions capable of passing the "technical effects" test by the early 2000s, the European Union thus was not dissuaded from issuing its *Proposed Directive on the Patentability of Computer-Implemented Inventions* in 2002.⁸⁴ Nor, for that matter, was it dissuaded from the

Regulation 1260/2012, 2012 O.J. (L 361) 89; Agreement on a Unified Patent Court, 2013 O.J. (C 175) 1.

82. Article 27.2 states in full that:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

TRIPS Agreement, *supra* note 12, art. 27.2.

83. Article 27.3 allows for exclusion from patentability for various diagnostic, therapeutic, and surgical methods for treating humans or animals and for non-micro-organismic plants and animals and biological processes. *Id.* art. 27.3.

84. Dated February 20, 2002, the proposal was for a directive that "sets forth a standard for patentability for computer-implemented inventions that is consistent with

modified version of the directive passed by the European Parliament in 2003 (only for its Council of Ministers to later about face on the measure in 2005). Evidently, then, at least some EU member states *have seen* EPC members committing to an unlawful and presumably unlawfully discriminatory position under the TRIPS by singling out software patentability. Yet all the same, intra-European strife has still never approached the rancor and level of controversy that has marked competing understandings of the lawfulness of calibrating patent policy in the global pharmaceutical context. The logical corollary of this is that at least some EU member states *have not* seen EPC members to be committing any form of unlawfully discriminatory behavior and, evidently, without having had to first require those states to vindicate themselves by falling on the right side of a line establishing that EPC Article 52(2)(c) constitutes only differential treatment of the software field of technology.

Second, and related, inferring anything of note from what one *might* claim as reason for obviating the charge that EPC Article 52(2)(c) is discriminatory is simply to engage in a form of circular reasoning. As such, it is no more compelling, and indeed less compelling, than simply attributing what is to be explained—here, why EPC Article 52(2)(c) has not generally been presumed discriminatory—to whatever other normative driver like the evident inevitability of specifically tailored policy and legislative choice. Accordingly, the key questions at issue in the intra-European context could just as well have been around whether member states to the EPC are committing “field of technology” discrimination under Article 27.1 of the TRIPS or about whether software or software-related inventions constitute a field of technology. At the very least, such questions should be as salient as the parallel ones that have plagued developing countries with regard to the domain of patent-related policy making constituted

the current practice of the EPO board.” *Proposal for a Directive of the European Parliament and of the Council on the Patentability of Computer-Implemented Inventions*, COM (2002) 92 final. It proposed to require “that a computer-implemented invention make a nonobvious technical contribution to the art.” Paul J. Berman & Sinan Utku, *Trends: EC Software Patent Proposal’s Impact*, PATENT STRATEGY & MGMT. (Apr. 2002), https://ipmall.law.unh.edu/sites/default/files/hosted_resources/Hennessey_Content/ECSoftware.pdf [<https://perma.cc/X2F9-V8FV>]; *Proposal for a Directive of the European Parliament and of the Council on the Patentability of Computer-Implemented Inventions*, COM (2002) 92 final, 2002 O.J. (C 151 E) 129.

by access to medicines. That EPC members have clearly not been plagued in the same way, therefore, is just as readily understood to follow from how policy and legislative choice calibrated to the specificities of software invention/production has been regarded as legitimate/lawful as a matter of course. For example, as open-source advocates were emphasizing already before the WTO, software is inherently subject to independent “reinvention” while also having an “everything is obvious, but nothing is obvious” character.⁸⁵ This, moreover, is to say nothing of the recurrent dependence of innovation in the software context on subtle and incremental advances as well as software’s dual behavioral and textual identity.⁸⁶

Finally, there is also no distinguishing the status quo of respectable disagreement over software patentability in the intra-European context from the firestorm around non-discriminatory “patent enjoyability” in the clash between the global North and South in the domain of pharmaceuticals. For example, attempting to do so on how the former follows from exceptions to Article 27.1’s non-discrimination norm under Article 27.2 or Article 27.3 in a way that does not for the latter is untenable. Obviously, as the *Canada-Pharmaceutical Patents* DSB report demonstrated, arguing that exceptions under Articles 30 and 31 themselves fall beyond the reach of Article 27.1’s non-discrimination obligation is hardly outlandish, whatever the Panel ultimately decided on this front to the contrary through the WTO’s non-precedent-based system of adjudication. Not to mention, that to date no challenge has emerged between any EU member state party of the EPC against any non-EU member state party over the question of whether exclusions under Article 27.2 or 27.3 fail to be subject to Article 27.1’s non-discrimination obligation is telling in its own right. That is, this too can just as well be seen as following from how policy and legislative choice calibrated to the specificities of software invention/production has been regarded as legitimate/lawful as a matter of course.

85. See The League for Programming Freedom, *Against Software Patents: The League for Programming Freedom*, 14 HASTINGS COMM. & ENT. L.J. 297, 304, 309 (1991).

86. See *id.* For a more comprehensive discussion, see Pamela Samuelson, Randall Davis, Mitchell D. Kapur & J.H. Reichman, *A Manifesto Concerning The Legal Protection Of Computer Programs*, 94 COLUM. L. REV. 2308, 2316–52 (1994) (arguing against both copyright and patent as suitable legal devices for software protection).

*B. Specifically Tailored Legislative/Policy Choice
around Internet Technologies*

A similar lesson can be drawn from the context of early internet technologies and their treatment under U.S. law, as illustrated through happenings connected to business method patents. Under U.S. law, business method patents are issued by the Patent and Trademark Office under Class 705 relating to “Data processing: Financial, Business Practice, Management, or Cost/Price Determination.” In the early era of the internet’s growth, the sheer proliferation of patents sought on associated new technologies elicited concern about the intellectual property system stifling innovation. Protections for often trivial methods of doing business thus became a particular point of concern.⁸⁷

Consequently, under the American Inventors Protection Act of 1999,⁸⁸ Congress established a “First Inventor Defense,”⁸⁹ the scope of which originally extended to methods of doing or conducting business.⁹⁰ Now known as a prior commercial use defense, in its original incarnation in the 1999 act, an otherwise infringing user of a patented business method could claim a use right where, in good faith and at least one year prior to the effective filing date of the patent, they had reduced the patented business method to practice and engaged in its commercial use.⁹¹

It is not a coincidence, of course, that the legislative construction of this novel form of exception to patent rights came when it did. In other words, it was not just a general concern with the impact of business method patents on economic activity that motivated the policy response but rather one substantially tied to business methods in what was then a burgeoning, and novel, electronic commerce context that new internet technologies were suddenly making possible. Here, again, it was the precise nature of this technology—and the range of seeming trivia it could logically bring under the heading of “doing business”—that proved crucial,

87. See James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000.

88. See American Inventors’ Protection Act of 1999, Pub. L. No. 106-113, div. B, § 1000(a)(9) [Title IV], 113 Stat. 1501, 1537-41 (codified as amended at 35 U.S.C. § 297 (2018)).

89. 35 U.S.C. § 273 (2018).

90. *Id.* (since expanded and renamed as the more general prior commercial use defense).

91. See, e.g., *id.* § 273(b)(1), (3); *id.* § 273(a)(1) (defining “commercial use”).

perhaps the most notorious example being Amazon.com's "one-click" patent.⁹² Here once more, therefore, we see policy and legislative choice calibrated to the specificities of a given area of technological concern—whether defined in terms of internet technologies in general or electronic commerce more specifically—having been regarded as lawful as a matter of course.

*C. Specifically Tailored Legislative/
Policy Choice around Biotechnology*

Beyond the digital realm, tailored policy and legislative choice has been crucial in leading edge biotechnology areas as well. While it is conventional to focus on all the ways the enclosure of the genetic commons has been facilitated by patent law—usually through situating manipulated DNA sequences as novel inventions rather than the stuff of life, as in the milestone 1980 case in the United States, *Diamond v. Chakrabarty*⁹³—for the present purposes it is the other side of the coin that is most revealing. Newfound capabilities of gene sequencing and manipulation thus equally well illustrate how states on both sides of the Atlantic—as spearheaded by the United States and the United Kingdom—created measures to block patentability in a technologically domain-specific way

92. The abstract for the patent reads as follows:

A method and system for placing an order to purchase an item via the Internet. The order is placed by a purchaser at a client system and received by a server system. The server system receives purchaser information including identification of the purchaser, payment information, and shipment information from the client system. The server system then assigns a client identifier to the client system and associates the assigned client identifier with the received purchaser information. The server system sends to the client system the assigned client identifier and an HTML document identifying the item and including an order button. The client system receives and stores the assigned client identifier and receives and displays the HTML document. In response to the selection of the order button, the client system sends to the server system a request to purchase the identified item. The server system receives the request and combines the purchaser information associated with the client identifier of the client system to generate an order to purchase the item in accordance with the billing and shipment information whereby the purchaser effects the ordering of the product by selection of the order button.

Method & Sys. Placing Purchase Order via Commc'n Network, U.S. Patent No. 5,960,411 (filed Sept. 12, 1997) (issued Sept. 28, 1999).

93. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

with regard to the unaltered DNA blueprint of life.⁹⁴ Likewise, in the more specific context of plant DNA, it has been the specific nature of the domain at issue that prompted countries to either supplement or entirely move away from patent rights as the appropriate mechanism of protection in favor of various *sui generis* regimes.⁹⁵ The United States, United Kingdom, and Europe, for example, pioneered so-called plant variety rights specifically for these purposes.⁹⁶ Here as well, then, it is difficult to conceive of how measures doing so are not clearly tied up with the specific technologies at issue.

As noted earlier in the software patent context, it is imperative not to let the point at hand be confounded by claims that might be asserted about the ostensible TRIPS compliance of measures like the above. Inferring, for example, that the lawfulness of *sui generis* regimes of protection for plant varieties follows from how they formalistically align with the norm content of the TRIPS—whether, say, the substance of Article 27.3 or the interpretation of Article 27.1 holding that its non-discrimination obligations do not apply to any of the exclusions made thereunder—is simply a form of begging the question. Such circular reasoning obfuscates the real question the normative basis of whose answer demands explanation, which is about why there should not have needed to have been any such determination, or even WTO dispute, about the relationship between Article 27.1 and 27.3 in the first place.

94. See, e.g., *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013). For the United Kingdom, following the European Union Biotech Directive, see Directive 98/44/EC, art. 1(2) (excluding “discoveries” of gene sequences from patentability).

95. See, e.g., Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1541 (codified as amended at 7 U.S.C. §§ 2321–2582); Council Regulation 2100/94, 1994 O.J. (L 227) 1.

96. Patents for plant varieties are barred under Article 53(b) of the EPC. EPC art. 53(b) (“European patents shall not be granted in respect of . . . plant or animal varieties or essentially biological processes for the production of plants or animals.”). Under U.S. law, a more mixed regime exists, under which plant varieties are eligible for ordinary patents rather than simply intellectual property protection in the form of plant variety rights. Like the EPC, the United Kingdom’s Patents Act 1977 prohibits patents for plant varieties. Patents Act 1977, c. 37, § 1(3)(b) (UK) (stating that a patent shall not be granted for “any variety of animal or plant or any essentially biological process for the production of animals or plants not being a microbiological process or the product of such a process”).

*D. Technology Specific Compulsory
Licensing in the Global North*

It is well known that there has been a monumental struggle fought by advocates for broadening developing countries' access to medicines over the issue of compulsory licensing. Indeed, that struggle has unfolded over several stages: first, with developing countries aligning against being entirely prohibited from the practice and next, against their being maximally restricted in pursuing recognized rights like compulsory licensing. Therefore, it is among the greatest of ironies of the era of free trade liberalization that low- and middle-income countries have dared to issue actual compulsory licenses in only a vanishingly small number of cases. While it is difficult to construct an overall tally, studies seem to converge on what is likely less than fifty total examples of situations since 1995 of developing countries even threatening to license drug patents.⁹⁷ Surveying the period until 2012, for example, one prominent researcher constructs a method yielding thirty-four *potential* episodes in which some twenty-six different WTO member states threatened to issue a compulsory license, from which number a final database of only twenty-four verified licenses by seventeen different countries was arrived at.⁹⁸ In an even deeper irony, any such number would appear to indicate that during this same period the world's most voracious compulsory licensor has been the United States, the party that has obviously played the most dramatic role in attempting to prohibit/restrict their use in the name of free trade liberalization.⁹⁹ A 2022 study tracking the use of compulsory licensing of pharmaceuticals in high-income countries in the two decades after the 2001 Doha Declaration, for example, finds forty-five unique episodes of compulsory licensing, some twenty-four of which come from the United States.¹⁰⁰

97. See Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED., Jan. 2012, <https://doi.org/10.1371/journal.pmed.1001154> [<https://perma.cc/6DF5-Q7RL>].

98. See *id.*

99. Lindor Qunaj, Anna Kaltenboeck & Peter Bach, *Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis*, 100 MILBANK Q. 284, 284–313 (2022).

100. See *id.* On the longer history of compulsory licensing in the developed world, see Correa, *Intellectual Property Rights*, *supra* note 42, at 3.

The irony only grows thicker if we look beyond the in-effect innocence of apparent field of technology discrimination where it has come to rich country licensing of pharmaceuticals. Instead of assembling an empirical portrait of the actual number of cases of compulsory licensing over the last three decades, a more straightforward indicator can be assembled through simply looking at other technologically specific domains in which the statutory capacity for compulsory licensing has been preserved in the domestic law of high-income WTO member states. On this measure, here again we find calibrated legislative choice tends to be regarded as legitimate in a way that goes without saying if the discriminating policy maker is to stand capable of doing their job.

Here again, it is perhaps most instructive to focus on the United States. Consider the Atomic Energy Act, which permits the Nuclear Regulatory Commission (NRC) to license relevant technologies in this area if they are “fundamental” to civilian use of fissionable material.¹⁰¹ Not only does the non-military use context seem to place this type of exception outside of the scope of TRIPS Article 73 (which lays out the agreement’s exclusions for policy making in the area of “essential security interests”), but the provision itself plainly derives from determinations particular to nuclear technology. The Act is quite explicit about this last point, as demonstrated by how it allows the NRC to license relevant patents here only when “the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy.”¹⁰² It is difficult to see how such a requirement can speak to anything but a quite exclusive class of inventions the boundaries of which are marked significantly (if not wholly) by the nature of the technological domain to which they belong. Equally difficult is it to imagine anyone daring to seriously plague the United States with questions about the allegedly discriminatory character of such a provision in its law.

It is not hard to find other notable statutory provisions sanctioning licensing in the face of patentee rights that are based

101. See Atomic Energy Act of 1954, 42 U.S.C. § 2183 (2018).

102. See *id.* Under this section, the second requirement the NRC must meet in making such “affected with the public interest” declarations is that “the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.” *Id.*

expressly on the type of technology they comprehend. Consider the Clean Air Act, for instance, where pollution control technology may not be “otherwise available” to those obligated to meet the Act’s pollution control mandates based on “otherwise available technology.”¹⁰³ In this context, the Attorney General may certify a district court to order the corresponding patent holder to license their technology if its lack of availability “may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce.”¹⁰⁴ In a very different context, under the Federal Mine Safety and Health Act, tests for respiratory and pulmonary impairments in coal miners developed through research grants to public/private agencies are conditioned on any resultant patents being available to the public.¹⁰⁵ The Act thus creates in-effect compulsory licenses for black lung disease-related technologies.¹⁰⁶

The same exercise can be easily repeated with regard to European WTO member states. In British, French, and Spanish law, for example, express allowance for compulsory licensing of pharmaceuticals is even more readily provided for than in U.S. law. In its section providing for government use, the British Patents Act of 1977 creates a much broader power to sell or offer to sell licensed products if they are drugs or medicines. Under §55(1)(c), the Act states that “without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, [the government] may sell or offer to sell the drug or medicine.”¹⁰⁷ This contrasts with the basic ability set up under §55(1)(a) to sell or offer to sell licensed products only if such sale or offering to sell is “incidental or ancillary to making, using, importing or keeping.”¹⁰⁸

In providing for “ex-officio licenses” the French Code of Intellectual Property similarly makes special mention of licenses for medicinal products and the processes by which they are

103. See Clean Air Act, 42 U.S.C. § 7608 (2018).

104. See Clean Air Act § 7608.

105. Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 937 (2018).

106. See Federal Mine Safety and Health Act § 937.

107. UK Patents Act 1977, § 55(1)(c).

108. *Id.* It is worth adding that under subsection 56(4) “specified drugs or medicines” are defined as falling into two broad categories, which cover most of the entire pharmaceutical technology domain. *Id.* § 56(4).

manufactured.¹⁰⁹ Spain's 1986 Patent Law specifically legalizes compulsory cross-licenses on patents for chemical and pharmaceutical products and processes, provided, in the case of the latter, that the process patent represents a notable technical advance; it also provides for such licenses over patents pertaining to inventions that are generally related to public health.¹¹⁰

In fact, such special treatment to reserve licensing capability over medical and public health technologies is the preferred policy option outside of Europe as well. In the domain of plant biotechnology, technology-specific exclusions from patentability have been created not only through non-patent based *sui generis* regimes of protection, but also by the creation of further carve-outs within such *sui generis* regimes for compulsory licensing. Under U.S. law, for example, the special deviation from patents for plant variety rights is complemented by further domain-specific provisions where such exceptions to patent rights are themselves licensed.¹¹¹ In the section of the U.S. Code providing for the general statutory licensing power, the remedy for infringement of plant variety rights is thus limited exclusively to "the recovery of . . . reasonable and entire compensation as damages."¹¹² This, of course, effectively creates the right to license the underlying genetic knowledge by barring injunctions on non-right holder use. Under the Plant Variety Protection Act, plant variety rights are made subject to the Secretary of Agriculture's ability to declare that the protected variety be:

open to use on a basis of equitable remuneration to the owner . . . when the Secretary determines that such declaration is necessary in order to ensure an adequate supply of fiber, food, or feed in this country and that the owner is

109. Code de la propriété intellectuelle [C. prop. intell.] art. L. 613-16 (Fr.). Such public health interests are defined to include those relating to the lack of availability of a patented medicine to the public in sufficient quantities or sufficient quality or at a price that is not excessively high. *Id.*

110. See Ley de Patentes, arts. 89(3), 90 (B.O.E. 1986, núm. 169) (Spain). Art. 89(3) specifically discusses compulsory cross-licenses under patents for chemical and pharmaceutical processes and products, provided process patents represent notable technical advances. *Id.* Article 90 provides for the grant of compulsory licenses for those inventions that are related to public health. *Id.*

111. 28 U.S.C. § 1498(d) (2018).

112. *Id.*

unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair.¹¹³

A similar dynamic—allowing for discriminating policy choice to be exercised on top of discriminating policy choice—is at play in British law as well. The Patents and Plant Variety Rights Regulations of 2002 specifically allows as follows:

Where a person cannot acquire or exploit plant breeders' rights or a Community plant variety right in a new variety without infringing a prior patent, he may apply in accordance with rules to the Comptroller General of Patents for a licence under the patent and on such application shall pay the prescribed fee.¹¹⁴

In fact, the British regulations can be mentioned side by side with the even more emphatic state of affairs on the European continent in the wake of the 1998 Directive of the European Parliament on the legal protection of biotechnological inventions. As further integrated into the national legal regimes of EU member states, the so-called Biotech Directive, as it is commonly known, also provides for broad compulsory licensing capabilities in the context of plant-related patents and plant variety rights under Article 12.¹¹⁵ This includes both license applications (under Article 12.1) initiated by a holder of plant variety rights (under Article 12.1) who cannot “acquire or exploit” such rights “without infringing a prior patent” and applications (under Article 12.2) initiated by a holder of a patent who cannot “exploit” a “biotechnological invention” absent “infringing a prior plant variety right.”¹¹⁶ As in various other of the

113. Plant Variety Protection Act § 2404, 7 U.S.C. § 2404 (2018).

114. Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002, SI 2002/247, § 3 (UK). In order to make such a grant, under Section 6, the Regulations require that the controller must be satisfied that the following conditions have been met by the applicant: the applicant cannot acquire or exploit plant breeders' rights or a Community plant variety right without infringing a prior patent; the applicant has applied unsuccessfully to the proprietor of the patent concerned for a license to use the prior patent to acquire or exploit plant breeders' rights or a Community plant variety right; and the new plant variety, in which the applicant wishes to acquire or exploit the plant breeders' rights or Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent. *Id.*

115. See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13.

116. *Id.* In both cases the party whose intellectual property right is licensed gets a cross patent on the licensor's intellectual property right. *Id.*

contexts above, whatever arguments one might make—or that have been made academically, here and there—about the TRIPS-compliance of these parts of the Biotech Directive (and in the larger argument the national laws of EU member states), it is obfuscation at best to imagine that the lack of controversy over Article 12 is because of collective conviction that it has been deduced to fall on the right side of the discrimination/differentiation divide. Indeed, this is all the more the case for Article 12 than for those parts of the Biotech Directive that correspond to the EPC's exclusion of software from patentability, where the relative lack of controversy here might be attributed to Article 27.3 of the TRIPS. For even notwithstanding the three-decade absence of contest at the WTO level around the applicability of Article 27.1's non-discrimination provision to Article 27.3 exclusions, the applicability of the non-discrimination provision of Article 27.1 to Article 31 exceptions has been a different matter. Therefore, it is that much more of a mystery why the *Canada-Pharmaceutical Patents* Panel's denial of Article 27.1's applicability to Article 31 exceptions never became a cudgel against Article 12 of the EU's Biotech Directive given how robustly it has been used to castigate developing countries for demanding the TRIPS-compliance of compulsory licenses for pharmaceutical technologies.

*E. "The Overall Balance of Rights and Obligations
to be Maintained" as the Key to Non-Discrimination*

Running across the various examples of discriminating—but, evidently, not discriminatory—policy and legislative choice elucidated above is what would appear to be a latent anti-formalism that countries like the United States and in much of Europe have assumed as a matter of course for the purposes of assessing their own legal regimes. The hallmark of such latent anti-formalism is to eschew any working idea that the TRIPS-compliance of these countries' own policy and legislative choices should follow from deducing whether they fall under some inevitably underdetermined category of "discrimination" or "differentiation."

Indeed, to come full circle back to *Canada-Pharmaceutical Patents*, a careful reading of the Panel's report reveals the United States to have endorsed just such a position with regard to Canada's regulatory review exception, the fate of which would

have likely borne on the United States' own so-called Bolar exception.¹¹⁷ The name of this exception derives from a 1984 case called *Roche Inc. v. Bolar Pharmaceutical Company*, in which the Court of Appeals for the Federal Circuit rejected a defendant-generic drug maker's claim to the legality of its use of an on-patent chemical before the expiration of the Plaintiff-pharmaceutical firm's patent for the purposes of gauging the bio-equivalency of its own generic version of the plaintiff's drug.¹¹⁸ The case gives its name to an exception to patent rights because shortly after the decision, it was effectively reversed through Congressional passage of the 1984 Hatch-Waxman Act¹¹⁹ ("The Drug Price Competition and Patent Act"), which legitimized the kind of experimental use exception Bolar was arguing for in the case.

The United States' otherwise difficult-to-parse submission to the DSB panel in *Canada-Pharmaceutical Patents* on the Article 27.1 aspect of the dispute becomes easier to make sense of against this backdrop. After using the submission first to emphatically reject Canada's defense of its regulations based on the non-applicability of Article 27.1 to Article 30 exceptions, the United States began its comments on Article 27.1 by highlighting how there was no previously established definition of the TRIPS's notion of "enjoyment" of patent rights—whether in the TRIPS, itself, or "any other international intellectual property convention."¹²⁰ From here, highlighting the dictionary definition of "enjoyment,"¹²¹ it then went on to stress that "it was . . . not the case that every exception to patent rights had to apply to all fields of technology." To elaborate the point, the United States drew on a

117. See *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984); 35 U.S.C. § 271(e)(1) (codifying the Bolar exception).

118. See *Roche*, 733 F.2d at 858. The case involved a conflict between Roche, a prominent pharmaceutical firm, and a generic drug maker over the latter's generic version of the former's brand name sleep aid Dalmane, the key chemical ingredient of which, Flurazepam, was patent protected. *Id.* Bolar began using the patented compound during the patent term to conduct tests and obtain regulatory approval for a generic version of the drug prior to expiration of Roche's patent. *Id.*

119. The Act's official name is the Drug Price Competition and Patent Term Restoration Act. Pub. L. No. 98-417, 98 Stat. 1585. The Act affects various parts of the U.S. Code, including the Bolar exception in 35 U.S.C. § 271(e)(1).

120. Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶ 5.

121. *Id.* (quoting THE NEW SHORTER OXFORD ENGLISH DICTIONARY 823 (4th ed. 1993) (defining "enjoyment" as "have the use or benefit of something pleasant or advantageous")).

GATT decision from 1989, *United States—Section 337 of the Tariff Act of 1930* (hereinafter the “Section 337” dispute¹²²), which it argued “provided guidance in approaching the discrimination analysis under Article 27.1.”¹²³ The United States set out this position despite the fact that the Section 337 dispute involved the European Union suing the United States under the 1947 GATT’s Article III (on national treatment).¹²⁴ As per the “panel’s analysis” in the Section 337 dispute, the United States’ submission in *Canada-Pharmaceutical Patents* continued, “formally identical treatment of products could constitute discrimination, and in such a situation a WTO Member might be required to apply formally different treatment to ensure that there was no discrimination.”¹²⁵ In some circumstances, therefore, differential treatment could actually restore parity in the enjoyment of patent rights rather than resulting in discrimination.¹²⁶ Ultimately, therefore, the United States advised the DSB as follows:

[i]n the present dispute, the Panel should assess whether the aspects of the Canadian regime that applied differentially to pharmaceuticals effectively and consistently accorded less favourable treatment in the enjoyment of rights to pharmaceutical inventions, as compared to inventions in other fields of technology. *In undertaking this analysis, the Panel should take into account the significant impact of the regulatory process on the enjoyment of patent rights in the pharmaceutical market, and the need to ensure that the regulatory process itself did not cause discrimination in the effective enjoyment of patent rights for pharmaceuticals.*¹²⁷

Appearances notwithstanding, the United States was not here simply endorsing the kind of distinction between discrimination and differentiation that the Panel would ultimately proffer, as discussed in Part III above. To the contrary, consistent with defending its own Bolar exception, what the United States appears here to have really been calling for was to start from the normative force of the vital socio-political ends and specificities informing

122. *Id.*; GATT Panel Report, *United States—Section 337 of the Tariff Act of 1930*, GATT Doc. L/6439 (Nov. 7, 1989).

123. *Canada-Pharmaceutical Patents* Panel Report, *supra* note 23, ¶ 5.36.

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

policy making in context-dependent product/technology areas. Insofar as the regulatory process was particularly salient—or at least, subject to its own salient particularities—in the pharmaceutical context and, thus, inseparable from the socio-political ends that made it desirable for pharmaceutical technologies to be made *properly* available in the first place, the position of the United States becomes easier to discern. In essence, it was here arguing that it would be appropriate to offload some of the responsibility for ostensible discrimination that might otherwise appear to inhere in the content of any given legal norm/policy choice to these exogenous factors of context and collective purpose instead.

It was in this respect, therefore, that in its submission to the Panel the United States could be found advising that were unequal treatment to be necessary to meet particularized regulatory demands, then it would be just as well to read an ostensibly discriminatory legal rule—whether Canada’s regulatory review exception or, one would guess, its own Bolar provision—as providing instead for merely differential, and hence lawful, treatment.¹²⁸ Indeed, this is reflected even more clearly in the United States’ subsequent comment to the Panel in its submission. Here the submission argues that a similar anti-formalism “could raise more serious issues under Article 27.1” regarding Canada’s stockpiling exception.¹²⁹ For in the latter case, the United States suggested

there was no connection between the special pharmaceutical regulatory process and “stockpiling.” Every firm that sought to begin manufacturing a product to compete with an innovative product that was going off patent faced the same dilemma—the difficulty of selling competing products the instant that the patent expired because of the need to manufacture the products, which was not possible until after expiration of the patent term.¹³⁰

128. Canada-Pharmaceutical Patents Panel Report, *supra* note 23, ¶ 5.36.

129. *Id.*

130. *Id.*

Given the United States' seeming concern with its own Bolar law¹³¹ and what more we know about its general hostility in the TRIPS negotiation context to increasing latitude for exceptions to upward harmonization of patent rights would require that one be forgiven for wondering if it was engaging in motivated reasoning here. After all, it would not be hard to assert that there *was* a connection between a "special regulatory process" and the stockpiling exception given how that exception worked hand-in-glove with the regulatory review one. Indeed, this was precisely what Canada did argue to the Panel, including through recounting how the complementarity was hard-wired into the passage of the two provisions into Canadian law, which involved looking to how under its neighbor to the south's Bolar law "an FDA guideline required a generic manufacturer, as a precondition to marketing authorization, to make at least three full production runs on a full commercial scale."¹³²

The United States' arbitrary stopping point for its own approach to retrospectively finding the legitimacy in tailored legislative and policy choice aside, it is clear that the logic of that approach is neither exclusive to its own discernment nor unique. To re-characterize the approach in terms of anti-formalism is thus, in a salutary way, to sharpen its difference compared to an approach that would instead purport—invariably, in a fictional manner—to rest on divining the essence of a distinction between unlawful discrimination and lawful differentiation under Article 27.1. Indeed, it even stands to enliven and breathe new analytical life into such line drawing approaches—for example, by allowing the idea of "the enjoyment of patent rights" to include the public or a licensee's enjoyment. That is, by having the United States' preferred dictionary definition of enjoyment include the public or a licensee's ability to "have the use or benefit of" those rights.

In its own submission to the *Canada-Pharmaceutical Patents* dispute, Australia (thinking, no doubt, of its own exceptions that it wanted to preserve) argued precisely along these lines, capturing the spirit of the proposal in a possibly more palatable—or, at least, more familiar—manner than as a commitment to anti-formalism.

131. Notably, in the course of instantiating the regulatory review exception into law, Canada not uncoincidentally referred to it by the name—among others—of its own "Bolar exemption." See *id.* ¶ 4.21.

132. *Id.*

By way of closing—and explicating the title of the present subsection of Part IV—it is worth quoting Australia’s position in full:

Enjoyment of patent rights without discrimination as to field of technology under Article 27.1 of the Agreement did not require that identical rules should apply to patents in all technological fields. Patent administration could require differential treatment according to technological subject-matter. *The key to non-discrimination was for the overall balance of rights and obligations to be maintained.* Where legislatures or courts sought to sustain this balance by taking account of technology-specific factors (such as specific regulatory regimes for pharmaceuticals), this was legitimately characterized as seeking to ameliorate discrimination rather than as creating it . . . In considering the balance of rights and obligations, one should not assume that the diverse interests engaged by the patent system were fundamentally divergent or in conflict. The acknowledged mutual advantage and common public benefits accruing from the very existence of adequate private patent rights should be kept in focus. *Private patent rights in the pharmaceutical field did not merely benefit patentees, but also served the interests of the public, by promoting the development and preparation for marketing of new pharmaceuticals; of governments, by advancing public health objectives; and indeed of generic competitors, by providing them with a source of technological information and research data, new products and new commercial opportunities* (emphasis added).¹³³

VI. CONCLUSION

As the world moves into its fourth decade of conflict over patents and public health—and, in ways, further convergence between the ordinary inhabitants of the global North and South with respect to their positioning in these conflicts¹³⁴—it is a striking feature of the landscape of international economic law that an interpretive fog remains around key provisions within treaties like the TRIPS. By reviewing one such area of occlusion inhering in the language of Article 27.1 of the TRIPS, this article has sought to

133. *Id.* ¶¶ 5.3–5.4.

134. See, e.g., Faisal Chaudhry, *Intellectual Property Rights and the Global Crisis of Non-Communicable Disease*, 18 N.C. J.L. & TECH. 175, 256 (2017).

summarize the contours and sources of the interpretive problem at play. At the same time, it has also counterposed the most common proposed solution to addressing this interpretive problem—by falling back on an a priori kind of distinction between lawful differential treatment and unlawful discriminatory treatment—with actual instances of technology-specific legal and policy choice by countries in the global North during the TRIPS era. In so doing, the article has sought to document the latent anti-formalism that has informed such legal and policy choice. At the same time, it has also juxtaposed this anti-formalism with the stance of many of those same countries on patents in relation to their developing world counterparts in the domain of pharmaceutical technologies. In the larger argument, the paper has also offered a broader critique of formalism as a mode of solving interpretive problems when grappling with the legal regimes of free trade liberalization and social provisioning that emerge from instruments like the TRIPS.