

The Power of Ideas: The Declaration of Patent Protection and New Approaches to International Intellectual Property Lawmaking

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INTRODUCTION

The International Intellectual Property (IIP) system has become increasingly complex. Once a patchwork of bilateral treaties relating solely to intellectual property, it has transformed into an intricate system comprising bilateral and multilateral treaties, international institutions, multinational enterprises, nongovernmental organizations, and other nonstate actors, affecting areas as diverse as public health, the environment, human rights, and biodiversity, among others.¹ Navigating this complex system is difficult. Making changes within this system is even more so.

Chief among the various components that comprise the IIP system is the World Trade Organization's (WTO) 1994 Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS), the most significant development in modern intellectual property law. In 2014, in the context of the twentieth anniversary of TRIPS, the Max Planck Institute of Innovation and Competition drafted the Declaration on Patent Protection: Regulatory Sovereignty under TRIPS (Declaration). The Declaration purports to merely clarify the regulatory options that states retain under TRIPS.² It does not. Rather, the Declaration goes beyond merely clarifying policy space and appears intended to modify existing legal rules under TRIPS and/or to limit the adverse effects of WTO decisions interpreting various TRIPS provisions. Paradoxically, the Declaration simultaneously undermines TRIPS and extends TRIPS's influence.

To be clear, this is not a criticism of the Declaration's substantive objectives. The majority of the Declaration indeed identifies legitimate policy space, and this Article agrees with the Declaration's ultimate goal of providing states with greater discretion to implement domestic intellectual property laws consistently with states' technological and economic development.³ Moreover, changed circumstances since

1. As recently as the early 1990s, the treaties and international organizations concerned with intellectual property occupied a highly specialized and technocratic corner of international law, with few connections to other issue areas. That relative isolation ended in 1994, when the United States and the European Communities, pressured by their respective intellectual property industries, shifted negotiations over intellectual property from the World Intellectual Property Organization (WIPO) to the World Trade Organization (WTO) and linked the result of those negotiations (the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement) to the new WTO dispute settlement system. See Laurence Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 20–22 (2004).

2. Matthias Lamping et al., *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS*, 45 INT'L REV. INTELL. PROP. & COMPETITION L. 679, 680 ¶ 2 (2014).

3. Elsewhere I have argued that we should seek ways in which TRIPS can “provide more freedom to developing countries to explicitly consider public welfare and other national and

the adoption of TRIPS may justify changes to existing law. But, in notable areas, the Declaration pronounces as law interpretations that are difficult to reconcile with current law. This Article highlights those areas.

The Declaration is a significant pronouncement of the state of contemporary IIP law, but it is just as significant for what it teaches us about contemporary IIP lawmaking. Hence, in addition to evaluating some of the Declaration's specific provisions, this Article focuses on the process of IIP lawmaking by which relevant actors might pursue desired outcomes. Traditional modes of lawmaking involve strategies and changes within a particular structure or organization (i.e., horizontal lawmaking). Over time, however, shifts in governance have also occurred through different modes of lawmaking, such as "regime shifting," whereby states and nonstate actors attempt to change law by relocating rulemaking processes to other venues to effect more favorable outcomes, and "competitive regime creation," where actors create new regimes that compete with existing ones.⁴ The drafters of the Declaration might, too, change existing law, but from outside the state-centric world of international organizations. That alternative approach might be characterized as a "bottom-up" approach (i.e., vertical lawmaking).

Looking to these various alternative modes of IIP lawmaking (including regime shifting and competitive regime creation) and also to grassroots movements, this Article identifies key criteria that should exist for an effective bottom-up process. These criteria include, at a minimum, (1) strategic planning by a group of experts with the legitimacy to create alternative policies, (2) building transnational solidarity around the alternative policies, (3) establishing both formal and informal channels of communication with states' policymakers, and (4) using the influence of the transnational network to foster an international dialogue that urges states' policymakers to consider the consequences and benefits of alternative policies. Applying these criteria, the Article evaluates the Declaration's effectiveness in using the power of ideas to agitate and exert pressure on existing doctrine, for example, the arguably restrictive nondiscrimination provision in TRIPS. As stated at the outset, effecting change is difficult. But it begins somewhere, and the Declaration may just be that beginning.

Seen from this perspective, the Declaration and alternative modes of international lawmaking invite us to rethink the various dimensions of power. Rather than the *market power* of the IP world, or the *material power* of well-organized and well-financed trade associations that can lobby to secure their interests in

international policy interests, such as public health, human rights, environmental rights, and biodiversity." Donald P. Harris, *TRIPS and Treaties of Adhesion Part II: Back to the Past or a Small Step Forward?*, 2007 MICH. ST. L. REV. 185, 189 (2007); see also Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 743 (2006) ("[T]he objectives and principles of the treaty assist in balancing the private rights of inventors with the rights of an invention's users. In any debate over TRIPS, therefore, WTO Panels and the AB must recognize and preserve these objectives and principles.").

4. Julia C. Morse & Robert E. Keohane, *Contested Multilateralism*, 9 REV. OF INT'L ORG. 385, 392 (2014) [hereinafter *Contested Multilateralism*].

legislation, or the *political power* of the United States in international negotiations, or even the *institutional power* of the WTO vis-à-vis other international organizations, the Declaration reminds us of another, sometimes hidden, dimension of power: the power of ideas.

The Article proceeds as follows: Part II briefly describes the international intellectual property system and how it has been transformed. Part III introduces the Declaration, examines the stated goal of the Declaration, and evaluates a number of key provisions. This Part also questions the underlying basis of the Declaration that WTO Member states are free to deny protection to inventions by differentiating among inventions, despite both the specific language of TRIPS and WTO decisions interpreting relevant TRIPS provisions. Part IV then challenges the Declaration by reviewing these key WTO decisions, and by also recounting the TRIPS negotiation history. While there are strong arguments on both sides of the interpretation issue, the WTO decisions and the negotiation history present a compelling case against the interpretation advanced in the Declaration.

Part V explores the changing dynamics of international lawmaking. In particular, this Part demonstrates that lawmaking is no longer dominated by one mode. Rather, as the international intellectual property system has changed, the dynamics of lawmaking have changed. This Part suggests that even if the Declaration's interpretation of existing law is flawed, it can nevertheless serve as a springboard for change through one or any number of the new modes of lawmaking. Finally, Part VI advocates for the drafters of the Declaration to consider these alternative modes, and attempts to identify ways to ultimately strengthen the goals of the Declaration. In other words, recent developments make clear that there are numerous ways to effectuate change in the international intellectual property system. While much of the Article is somewhat pessimistic about the method advanced in the Declaration, the Article is optimistic that other methods might prove more fruitful and that the Declaration can be instrumental in accomplishing its ultimate goal. This Part, while not advocating for any particular mode, does, however, offer a few suggestions on how these goals might be achieved.

I. THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM

Developed in 1994 under the General Agreement on Tariffs and Trade (GATT) Uruguay Round trade negotiations, TRIPS "is unquestionably the most important development in international intellectual property law" since the international intellectual property treaties of the 1880s (i.e., the 1883 Paris Convention for the Protection of Industrial Property and the 1886 Berne Convention for the Protection of Literary and Artistic Works).⁵ TRIPS significantly strengthens intellectual property rights worldwide.

5. Charles R. McManis, *Intellectual Property and International Mergers and Acquisitions*, 66 U. CIN. L. REV. 1283, 1286 (1998).

TRIPS was an attempt to reconcile varying levels of intellectual property protection and enforcement in different states. The varying levels are due to each country's widely different goals, values, histories, cultures, political climates, and economic and technological stages of development. To reconcile these varying interests, TRIPS mandates that all countries provide intellectual property protection at specified levels significantly beyond those previously established in any international intellectual property treaty.⁶ For some countries, this required very little change in their laws. For others, however, TRIPS required significant changes.

Prior to 1994, intellectual property matters fell under the purview of the World Intellectual Property Organization (WIPO). Because the United States and the European Union (EU) considered the United Nations (UN) and its organizations hostile—or, at the very least, indifferent—to developed countries and overly sympathetic to developing countries, the United States began efforts to move intellectual property from WIPO to the WTO. The WTO's trade regime traditionally favored developed countries with large, attractive export markets. In addition to being a more favorable forum, the WTO included the relatively strong and effective enforcement mechanism, which was lacking in WIPO. That mechanism was among the prizes sought by the developed countries in TRIPS. The move from WIPO to the WTO was monumental, allowing developed countries to flaunt their trade advantage and superior bargaining position within the context of intellectual property rights, inevitably producing an intellectual property treaty slanted in their favor.

Although they are now being eclipsed by TRIPS, the Berne Convention and the Paris Convention also form part of the international intellectual property system, and, they have had a resurgence in recent years. In addition, a proliferation of bilateral and plurilateral agreements as well as other newly created intellectual property regimes make up the now very fragmented system.

II. THE MAX PLANCK INSTITUTE DECLARATION OF PATENT PROTECTION

To lessen the burden that implementing heightened standards of intellectual property protection might pose for developing and lesser-developed countries, TRIPS provided for transition periods for these countries so that their obligations were deferred.⁷ Developing country obligations were deferred for five years, while lesser-developed countries' obligations were deferred for ten years.⁸ These periods were later extended.⁹ When the transition periods expired, countries were confronted with the realities of the TRIPS Agreement and the constraints the

6. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 41, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 319 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

7. *Id.* at art. 65.

8. *Id.* at art. 66.

9. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, WTO Doc. IP/C/40 (Nov. 30, 2005).

Agreement placed on state discretion to address public policy objectives and development concerns. States and nongovernmental organizations (NGOs) shifted negotiations from one venue to another within the international intellectual property system in attempts to create policy space either within the particular institution or to create norms in that institution that could have spillover influence in other institutions, such as the WTO. In so doing, the actors (e.g., developed and developing countries) created conflicting principles and rules that compete with existing rules, hoping to supplant these rules or, at minimum, register dissent with the long-term goal of altering rules. The Max Planck Institute for Innovation and Competition launched the Declaration, which appears designed to drive change in international patent law.

The Declaration was drafted in collaboration with forty international patent scholars from twenty-five countries. The Declaration expressly aims to “clarify some of the regulatory options states still retain under international law, in particular the TRIPS Agreement,” which is now over twenty years old.¹⁰ As the Declaration correctly observes, either underprotection or overprotection of patents “causes a distortion of competition in that it prevents an efficient allocation of market revenues according to the competitive performance of market actors.”¹¹ Because there is ambiguity where obligations end and flexibilities begin, the Declaration attempts to clarify the two. The Declaration begins by highlighting the flexibilities that states have when interpreting and implementing TRIPS provisions in their respective national legislation.¹²

The Declaration also makes specific recommendations. For example, it recommends that, as a matter of policymaking, states’ protection of certain inventions depends on the technological field concerned.¹³ In other words, states can differentiate. The Declaration also asserts that states can shape patent policy by defining terms and concepts such as “invention” or “technical in nature,” and by defining what constitutes a lack of novelty and an inventive step.¹⁴

A. The Purpose and Goals of the Declaration

The Preface to the Declaration states: “In order to ensure an efficient functionality of the patent system as an innovation policy tool, patent rights ought to be defined, justified and continually reconsidered by reference to their socio-economic benefits and costs.”¹⁵ The Declaration’s stated purpose is “to clarify the policy space that the ‘Agreement on Trade-Related Aspects of Intellectual Property Rights’ (TRIPS Agreement) leaves to national legislators and judicial authorities

10. Lamping et al., *supra* note 2, ¶ 5.

11. *Id.* ¶ 6.

12. *Id.* ¶¶ 2, 5.

13. *Id.* ¶ 7.

14. *Id.* ¶¶ 3.1–2.

15. *Id.* ¶ 1.

with regard to the implementation and administration of their patent systems.”¹⁶ This is particularly important, according to the Declaration, so that intellectual property law can respond to changed circumstances: “Sovereign states should retain the discretion to adopt a patent system that best suits their technological capabilities as well as their social, cultural and economic needs and priorities, with the proviso that the exercise of such discretion must remain within the boundaries of international law.”¹⁷ In short, the Declaration is a statement that TRIPS (like other intellectual property treaties) is not a one-size-fits-all instrument and that countries should take advantage of the inherent flexibilities in TRIPS (and other treaties) to fashion laws that address countries’ particular needs and concerns.

B. *Specific Provisions*

The Declaration thus sets out to clarify boundaries of international intellectual property law, while also making clear the discretion that states retain. It does so in twelve specific provisions:

- (1) General Principles
- (2) Differentiation
- (3) Patentability, Disclosure
- (4) Scope of Protection
- (5) Exhaustion
- (6) Exceptions to the Scope of Protection
- (7) Compulsory License
- (8) Government Use
- (9) Undisclosed Information
- (10) Enforcement
- (11) Transit
- (12) Criminal Measures¹⁸

Many of these provisions accurately describe contemporary international IP law, as embodied in TRIPS provisions and elsewhere.¹⁹ Still other provisions reasonably interpret provisions that have as yet to be interpreted by WTO jurists.²⁰ Other provisions are more problematic. These include (1) Differentiation, (2) Scope

16. *Id.*

17. *Id.*

18. *Id.* ¶¶ 1, 6, 9, 16, 18, 20, 27, 34, 35, 37, 40, 41.

19. The provisions on (1) Patentability, Disclosure; (2) Government Use; (3) Undisclosed Information; (4) Enforcement; (5) Transit; and (6) Criminal Measures appear consistent with current doctrine. *Id.* ¶¶ 9, 34, 35, 37, 40, 41.

20. The Compulsory License provision is consistent insofar as it relates to general requirements of issuing compulsory licensing. *Id.* ¶ 27. Its position with regard to local working requirements, however, is not without controversy. 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, 366–67 (2002).

of Protection, (3) Exceptions to the Scope of Protection, and (4) Compulsory License.²¹ The challenging thread running through each of these provisions is that, in fashioning domestic IP systems, states remain free to discriminate with regard to the field of technology. This cannot be easily reconciled with TRIPS's non-discrimination principle, Article 27.1, which prohibits countries from discriminating with respect to inventions.²² The Declaration supports this seemingly contradictory position by: (1) relying on the distinction between “differentiation” and “discrimination”; (2) applying the interpretive principle of *in dubio mitius*, which provides for a restrictive interpretation of treaty obligations in deference to state sovereignty; and (3) arguing that important states' interests trump TRIPS's non-discrimination principle.²³ These justifications are not without merit.²⁴ They might even support overriding TRIPS's non-discrimination principle, if we were writing on a blank slate. We are not. As explored below, the TRIPS negotiating history, TRIPS's underlying goals, and WTO decisions interpreting TRIPS's provisions strongly suggest that countries cannot discriminate against particular technologies. In this light, rather than “clarifying” TRIPS provisions, the Declaration can be read

21. As mentioned above, the Compulsory License provision is at least open to debate regarding its view on local working requirements. As with other provisions, it also relies on differentiation, which is the subject of much of this Article. However, in light of the Doha Declaration, the differentiation argument stands on firmer ground.

Arguably, the Exhaustion provision is also problematic. Exhaustion regimes are classified as international, national, or regional. Rights owners prefer a national exhaustion regime, under which they can segment markets and price differentiate, i.e., determine different prices for entry into each market. Developing countries are generally regarded as being disadvantaged by such a system because they “lack a sufficient consumer base to attract market entry at the lowest possible prices.” Sean M. Flynn et. al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 130 (2012). Although the provision in the Declaration correctly states that TRIPS Article 6 allows states to choose the type of exhaustion regime they wish to apply (i.e., international or national exhaustion), it further states that TRIPS Article 27 does not prevent states from discriminating among industries or fields of technology. As this particular argument is made throughout the Declaration, there is no need to separately respond to it with regard to the exhaustion provision.

22. I am not unsympathetic to the Declaration's ambitions. I simply believe that the Declaration is a revisionist and potentially biased interpretation of TRIPS. See Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, *supra* note 3, at 742 (“Discussions in the TRIPS Council have focused only on whether members have implemented their TRIPS obligations relating to the minimum standards of protection. Rather than being an agreement that balances developing countries' concerns about technology transfer and promoting the public interest against developed countries' concern for protecting intellectual property rights, it has instead been converted into a means of enforcing private rights—irrespective of the impact that protecting these rights has on sectors of vital importance to developing countries.”).

23. Such interests include “environmental protection, biological diversity, health care (including managing the risks of pandemics), nutrition, food security, technological and scientific progress, education and security.” See Lamping et al., *supra* note 2, ¶ 3.

24. See, e.g., Graeme B. Dinwoodie, *The Development and Incorporation of International Norms in the Formation of Copyright Law*, 62 OHIO ST. L. J. 733, 751 n.73 (2001); Annette Kur, *Of Oceans, Islands, and Inland Water—How Much Room for Exceptions and Limitations Under the Three-Step Test?*, 8 Rich. J. Global L. & Bus. 287 (2009).

as an effort to reinterpret or amend TRIPS provisions.²⁵ While reinterpretation might be appropriate, we should at least acknowledge it as such. The next section explores the premises upon which the Declaration is grounded and then questions whether these are well founded.

III. ANALYSIS OF THE DECLARATION'S PROVISIONS' PERCEIVED INCONSISTENCIES

A. Sovereignty

At the heart of the Declaration is the principle of sovereignty and a state's power to retain for itself its decision-making authority regarding matters within the state's domestic jurisdiction.²⁶ I have no quarrel with this. No other state nor the WTO has the right to intervene in matters over which a given state has not voluntarily ceded authority.²⁷

The reason for jealously guarding sovereign power is obvious. Treaties by their very nature are general. And international institutions such as the WTO must account for the needs of over 160 Member states with divergent policies and interests. Therefore, states rather than treaties are in the best position to address domestic concerns. Moreover, treaties are biased in favor of the "winners" of international negotiations. These inherent biases, coupled with the inability of treaties such as TRIPS to specifically address individual countries' concerns, demand that countries retain discretion over all matters not expressly delegated to the particular organization.

Of course, states that enter into treaties explicitly use their sovereignty to cede power over certain matters, thus allowing for international governance over those matters.²⁸ This is uncontroversial. Such matters are generally ones that affect other

25. This is consistent with "the overwhelming trend in multilateral institutions toward protection of TRIPS flexibilities for developing countries to promote access to affordable medications." See Flynn et al., *supra* note 21, at 120.

26. More particularly, the Declaration deals with vertical sovereignty, i.e., the amount of deference granted to states vis-à-vis international or supranational tribunals or organizations. Decision making can occur on vertical and horizontal levels. "The vertical allocation involves the level of social organization that decides regulatory policy, from the local to the global." Gregory Shaffer, *Power, Governance, and the WTO: A Comparative Institutional Approach*, in POWER IN GLOBAL GOVERNANCE 1, 140 (Michael Barnett & Raymond Duvall eds., 2005). In particular, what amount of deference should be granted to national regulation vis-a-vis supranational rules? "The horizontal allocation of authority involves choices between [global] market processes, political and administrative processes, [international] judicial processes, and other governance mechanisms." *Id.* Here, we deal exclusively with vertical decision making (i.e., the United States vs. the WTO).

27. See, e.g., Henry Schermers, *Different Aspects of Sovereignty*, in STATE, SOVEREIGNTY, AND INTERNATIONAL GOVERNANCE 185, 185 (Gerard Kreijen et al. eds., 2002).

28. See, e.g., Raj Bhala, *The Power of the Past: Towards de Jure Stare Decisis in WTO Adjudication (Part Three of a Trilogy)*, 33 GEO. WASH. INT'L L. REV. 873, 975 (2001) [hereinafter Bhala, *Stare Decisis Part III*] ("If we are serious about constructing a global economic community governed by the rule of law, then we ought not to grasp tenaciously the proposition that countries can enter into a set of

states and become matters to be solved within the international community.²⁹ Entering into TRIPS considerably constrained countries' discretion with regard to intellectual property; the question the Declaration attempts to answer is just how much discretion those states retain.³⁰

In the original treaty negotiations, developing country governments successfully adopted a number of TRIPS provisions whose texts preserve states' discretion. Article 1.1, for example, provides limited discretion concerning the implementation of TRIPS provisions:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. *Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*³¹

TRIPS Articles 7 and 8 preserve more general state discretion to consider interests other than intellectual property. Article 7 states:

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.³²

Article 8 includes TRIPS principles, which comprise (1) the ability of countries to adopt measures necessary to protect public health and promote the public interest in sectors of vital importance to their socioeconomic and technological development, and (2) the prevention of the abuse of intellectual property rights or

international legal obligations as extensive as those in the GATT-WTO system, but simultaneously retain complete freedom under international law to do as they please.”).

29. Donald P. Harris, *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States*, 25 NW. J. INT'L L. & BUS. 99, 111 n.49 (2004) [hereinafter Harris, *TRIPS' Rebound*] (“Such matters may include human rights, genocide, apartheid, systematic killing of people, ethnic cleansing, torture, nuclear energy and weapons, labor, and the environment.”).

30. Abdicating discretion is the price countries paid to become part of the trade regime. *Id.* at 115 (“Countries became WTO members, and accepted TRIPS, not as much for what TRIPS offered but because they perceived that they would be worse off without the WTO”); see also Shaffer, *supra* note 26, at 8 (“The risk of exclusion can induce developing countries to agree to comply with international rules that may contravene their interests such as the TRIPS Agreement...”); see also Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed By the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 73, 115 (1998) (“As a consequence of the Uruguay Rounds, State sovereignty over IPRs no longer appears especially significant in terms of ensuring that intellectual property protections meet domestic public interests”); Bhala, *Stare Decisis Part III*, *supra* note 28, at 975 (“I confess an instinctive desire to respond to the sovereignty concern with a flip ‘so be it, what did you expect when you signed up to the WTO Agreement?’”) (emphasis omitted).

31. TRIPS Agreement, *supra* note 6, at art. 1.1.

32. *Id.* at art. 7.

practices that adversely affect the international transfer of technology.³³ TRIPS's objectives and principles assist in balancing the private rights of inventors with the rights of users. The provision, however, is not unqualified. Countries' discretion under these Articles is constrained by the proviso that "such measures are consistent with the provisions of this Agreement."³⁴

No WTO panel has fully addressed Articles 7 and 8. But the Appellate Body in *Canada—Term of Patent Protection* held out hope that panels might yet give greater meaning to these Articles.³⁵ That panel stated: "[Our ruling does not] in any way prejudice the applicability of Article 7 or Article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote the policy objectives of the WTO members that are set out in those Articles. Those Articles still await appropriate interpretation."³⁶ They may ultimately provide the discretion the Declaration seeks.³⁷

B. Differentiation, Scope, and Exceptions

The Declaration's more problematic provisions are those regarding differentiation, scope, and exceptions. According to the Declaration's drafters, because of the uniqueness of various technologies, states can provide different levels of protection based on the technology at issue.³⁸ If this argument is true, this provides states the ability to implement public policy goals and to distinguish protection based on the inherent differences in the technology. The Declaration contends that measures to accommodate these differences cannot be viewed as violating TRIPS's nondiscrimination principle, TRIPS Article 27(1). Here, the Declaration states: "While that provision prohibits discrimination as to the field of technology, it does not prevent states from treating different situations differently."³⁹ Therefore, the Declaration recommends that states exclude certain subject matter from patentability and/or limit patent rights based on the field of

33. Article 8 (Principles) provides:

1. 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.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

TRIPS Agreement, *supra* note 6, at art. 8.

34. *Id.*

35. Appellate Body Report, *Canada—Term of Patent Protection*, ¶ 1, WTO Doc. WT/DS170/AB/R (Sept. 18, 2000).

36. *Id.* ¶ 101.

37. See Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, *supra* note 3, at 743 ("WTO Panels and the AB can read Articles 7 and 8 as overarching provisions that should qualify, rather than be circumscribed by, other TRIPS provisions.")

38. See Lamping et al., *supra* note 2, ¶ 7.

39. *Id.*

technology.⁴⁰ This distinction between “differentiation,” on the one hand, and “discrimination” on the other, forms the basis upon which the Declaration’s conclusion rests, and underlies each of the controversial provisions. To understand the significance of this distinction, it is necessary to parse through statements made by the WTO panel in *Canada—Patent Protection of Pharmaceutical Products (Canada-Pharmaceuticals)*, where Canada made these very arguments.⁴¹

1. *Canada—Patent Protection of Pharmaceutical Products*

In 1998, Canada amended its patent act by enacting two targeted pieces of legislation. The first allowed entities other than the patent owner to use patented inventions to comply with regulatory review requirements, e.g., to ensure the safety and efficacy of pharmaceuticals before marketing them (the regulatory review exception).⁴² The purpose of this exception was to permit potential competitors to obtain government approval before a patent expired, even though the competing product could not be sold until after the patent expired.⁴³ The second exception allowed generic manufacturers to make and stockpile the patented invention, e.g., pharmaceutical products, before the patent expired (the stockpiling exception).⁴⁴ This allowed competitors to manufacture and then stockpile patented goods during a certain period (e.g., six months before patent expiration). As with the first exception, the competing stockpiled goods could not be sold prior to the patent expiring.

The European Communities (EC) filed a WTO complaint alleging that both regulations violated TRIPS.⁴⁵ The EC argued that the regulations violated TRIPS

40. “When designing exceptions and compulsory licenses, state thus remain free to discriminate with regard to the field of technology, provided that such action is reasonable in the light of other public policy goals.” *See id.* ¶ 3.

41. The Declaration concedes that this interpretation is at odds with *Canada—Term of Patent Protection*, but claims that this decision was wrongly decided. Lamping et al., *supra* note 2, at 686. The three-step test has been criticized by others as well. *See* Flynn, *supra* note 21, at 139 n.108; *see also* Jonathan Griffiths et al., *Declaration: A Balanced Interpretation of the “Three-Step Test” in Copyright Law*, 39 INT’L REV. INTEL. PROP. & COMPETITION L. 707 (2008).

42. Section 55.2(1) of the Canadian Patent Act provided:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 2.1, WTO Doc. WT/DS114/R (adopted Apr. 7, 2000) [hereinafter *Canada-Pharmaceuticals*].

43. *Id.* ¶ 7.2.

44. Section 55.2(2) of the Patent Act provides:

It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct, or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage for articles intended for sale after the date on which the term of the patent expires.

Id. ¶ 2.1.

45. *Id.* ¶ 3.1.

Article 28.1 by violating EC members' basic patent rights (i.e., making and using the patented invention),⁴⁶ and also that both regulations violated TRIPS Article 27.1 by discriminating as to the field of technology. This is the argument relevant here. Article 27.1 provides:

[P]atents shall be available for any inventions, whether products or processes, in all fields of technology . . . 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.⁴⁷

The EC argued that the regulatory review and stockpiling exceptions discriminated as to the field of technology, in particular as to pharmaceuticals.

Canada defended on two grounds: First, it relied on TRIPS Article 30's exceptions to patent rights and argued that Article 30 permitted states to enact limited exceptions to Members' patent rights and that Canada's particular exceptions satisfied Article 30.⁴⁸ Second, Canada argued that the Article 30 exceptions were not limited by Article 27's nondiscrimination principle.⁴⁹ In other words, even if the stockpiling and regulatory review exceptions discriminated against pharmaceuticals (the regulations did not expressly do so), the exceptions could be upheld as valid exceptions.⁵⁰ Canada argued that Articles 7 and 8 mandated such a construction because it would otherwise become difficult for countries to target particular social problems.⁵¹ As mentioned above, Articles 7 and 8 permit Members to balance Members' rights and obligations⁵² and allow Members to adopt

46. Article 28.1 provides:

A patent shall confer on its owner the following exclusive rights:
where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of:
making, using, offering for sale, selling, or importing for these purposes that product;
where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the acts of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

TRIPS Agreement, *supra* note 6, at art. 28.1.

47. *Id.* at art. 27.1.

48. See *Canada-Pharmaceuticals*, *supra* note 42, ¶ 4.10.

49. See *id.* ¶ 7.87.

50. *Id.* ¶ 7.88 (“[G]overnments may discriminate when making the ‘limited’ exceptions allowed under Article 30, but they may not discriminate as to patent rights as modified by such exceptions.”). With regard to *de jure* discrimination, the panel concluded that the EC had not presented sufficient evidence to rebut Canada's claim that the regulation was not limited to pharmaceuticals. The panel also, however, allowed for *de facto* discrimination. *Id.* ¶ 7.94 (“Discrimination may arise from explicitly different treatment, sometimes called ‘*de jure* discrimination,’ but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called ‘*de facto* discrimination.’”). The panel found that the EC failed to prove that the adverse effects of the regulatory review exception were limited to pharmaceuticals or “that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of *de facto* discrimination.” *Id.* ¶ 7.105.

51. *Id.* ¶ 7.89.

52. Article 7 (Objectives) states:

measures to promote the public interest, provided such measures are consistent with the other TRIPS provisions.⁵³ The panel rejected both of Canada's arguments.⁵⁴

The panel first interpreted TRIPS's limitation and exceptions provision. Article 30 provides: "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."⁵⁵ The panel ruled that Article 30 imposed a tripartite test (the so-called "three-step test").⁵⁶ An exception must (1) be "limited"; (2) "not unreasonably conflict with the normal exploitation of the patent"; and (3) "not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."⁵⁷ Notably, the panel concluded that the elements were cumulative, since each of these elements must be met for an exception to pass Article 30 muster.⁵⁸ As for two of the conditions ("unreasonably prejudice" and "unreasonably conflict"), the panel evaluated the exception exclusively in light of the economic impact the exception had on the right holders.⁵⁹ As to the first condition ("limited"), the panel focused on the extent the right holders' legal right was curtailed.⁶⁰ After defining and applying the three-step test, the panel upheld the regulatory review exception but found that the stockpiling exception violated Article 30.⁶¹

In rejecting Canada's second argument, that states could discriminate when making exceptions to patent rights, the panel stated (and Canada acknowledged) that the primary purpose of Article 27 was to eliminate discrimination against pharmaceuticals. More specifically, Article 27 sought to (1) eliminate the earlier state practice of either denying protection altogether, and (2) prohibit states from automatically granting compulsory licenses on patented pharmaceuticals.⁶² The panel noted that there was no way to milk Canada's construction from the language

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 6, at art. 7.

53. *Id.* at art. 8.

54. *See Canada-Pharmaceuticals, supra* note 42.

55. The three-step test arises from the Berne Convention, Article 9.2. There are some differences between Article 9.2 and TRIPS Article 30, most notably that Berne applies to copyright and only to the reproduction right. *See* Berne Convention for the Protection of Literary and Artistic Works art. 9.2, Sept. 9, 1886, 828 U.N.T.S. 221 [hereinafter Berne Convention].

56. *Canada-Pharmaceuticals, supra* note 42, ¶ 7.20.

57. *Id.*

58. *Id.*

59. *Id.* ¶ 7.31.

60. *Id.*

61. *Id.* ¶¶ 7.36, 7.50.

62. *Id.* ¶ 7.90.

of Article 27 or Article 30.⁶³ The panel pointed out that Article 27 prohibits discrimination as to the enjoyment of patent rights, without qualifying that term.⁶⁴ Moreover, Article 30 explicitly states that exceptions are “to the exclusive rights conferred by a patent.”⁶⁵ Nothing in either provision indicated that exceptions were intended to be exempt from the non-discrimination principle.⁶⁶ The panel concluded: “A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as discrimination in the basic rights themselves.”⁶⁷

The panel also rejected Canada’s policy arguments. With regard to being able to target particular social problems by discriminating as to fields of technology, the panel suggested that the prohibition against discrimination was specifically intended to guard against states relying on such concerns:

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-discriminating 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.⁶⁸

This acknowledgment seriously undermined Canada’s (and other Members’) ability to consider legitimate interests in fashioning patent exceptions. Significantly, however, the panel qualified this statement: “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 The panel’s conclusion that the three-step test must be applied cumulatively, rather than as separate and independent requirements, as well as the panel’s definition of the specific elements, heavily favor rights owners.⁷⁰ As other scholars have noted, this

63. *Id.* ¶ 7.91 (“The text of the TRIPS Agreement offers no support for such an interpretation.”).

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* The panel found that even though Canada’s regulatory review exception did not explicitly apply to pharmaceutical products (de jure discrimination), the discriminatory impact (de facto discrimination) could justify a finding that the exception violated Article 27.

68. *Id.* ¶ 7.92.

69. *Id.* (emphasis added).

70. See P. BERT HUGENHOLTZ & RUTH L. OKEDIJI, CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT: FINAL REPORT (2008), <http://www.ivir.nl/publicaties/download/937> [<https://perma.cc/V77A-NKF9>] (tracing the history of the three-step test, Hugenholtz and Okediji make a convincing argument that the WTO panel in Section 110 changed the very nature of the test by focusing more on the rightsholders’ interest, rather than users’ interest); *id.* at 18 (arguing that the WTO incorrectly interpreted the three-step test); *id.* at 17

result was not preordained.⁷¹ The panel could have, for example, adopted a “holistic” approach that offered Members more flexibility by envisioning the three “steps” merely as factors that a tribunal could weigh (similar to the fair use factors in Section 107 of the U.S. Copyright Act).⁷² The Declaration’s attempt to reinterpret the three-step test is discussed below. Here, we take a closer look at the Declaration’s differentiation argument.

That argument depends on a fundamental but simple premise: differentiation is different from discrimination. It is tempting to say this is mere semantics. But it is not. The distinction paves the way for countries to provide different forms of protection (or no protection) for pharmaceutical products, i.e., as necessary to promote technological development and socioeconomic developments, without restrictions. The Declaration’s Drafters are surely right that differentiation and discrimination are not the same.⁷³ Moreover, the *Canada-Pharmaceutical* panel’s acknowledgment that the nondiscrimination principle does not limit states’ ability to target certain products for bona fide reasons supports this view.⁷⁴ It is not surprising, then, that the panel decision has engendered strong responses. One set of commentators views the decision restrictively, requiring absolute technological neutrality and prohibiting all forms of differential treatment as discriminatory.⁷⁵

(“During its transformation from a norm of international copyright to a norm of international trade law, the focus of the test has shifted from the interests of *the author* to those of the *right holder*. This paradigm shift is not without consequences; it brings to the foreground the commercial interests of intermediaries (‘right holders’), while downplaying the interests of the authors.”) (emphasis in original).

71. *Id.*

72. *See id.* at 22 (conceding that it “takes more liberties with the wording of the provision” although advocating for such an approach, and comparing such an approach with the fair use factors in section 107 of the U.S. Copyright Act and arguing this would “do more justice”).

73. *See also* Graeme Dinwoodie & Rochelle C. Dreyfuss, *Diversifying without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. TECH. L. REV. 445 (2007) (providing three examples where the authors claim states should be able to diversify without discriminating in violation of TRIPS Article 27). Two of these I do not contest.

74. *See Canada-Pharmaceuticals*, *supra* note 42, ¶ 7.94 (“The ordinary meaning of the word ‘discriminate’ . . . certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the *unjustified* imposition of differentially disadvantageous treatment.”).

75. *See* Jonathan Michael Berger, *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 CONN. J. INT’L L. 157, 199 (2002) (noting that in response to the inquiry “whether it is permissible to design provisions such as a compulsory licensing scheme solely in relation to pharmaceutical products,” the pharmaceutical industry argues that Article 27.1 “prohibits member states from adopting compulsory licensing regimes that specifically target the pharmaceutical industry without being applicable to other sectors”); Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317, 346 n.198 (2006); Robert Chalmers, *Evergreen or Deciduous? Australian Trends in the “Evergreening” of Patents*, 30 MELB. U.L. REV. 29, 47 (2006) (“Arguably these [anti-evergreening] provisions [in Australia’s Therapeutic Goods Act], in mounting additional hurdles for patentees seeking to enforce their rights over pharmaceutical inventions, do discriminate in relation to the enjoyment of patent rights.”); Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?*, 44 IDEA 1, 48 (2003) (noting that 35 U.S.C. § 271(e)(1) is an experimental use exception for regulatory submissions in the United States and applies solely to the “development and submission of information under a Federal law which regulates

Another set of commentators views the decision as less restrictive, allowing for different rules for different technological inventions so long as the rules are based on legitimate reasons. The majority of commentators appear to adopt this less restrictive view that differentiation only amounts to discrimination when there is no justifiable reason for the dissimilar treatment.⁷⁶

In the abstract, the conventional (i.e., less restrictive) differentiation argument is compelling; however, when placed in context and framed in light of TRIPS negotiating history, the argument looks less so. Yet, there might be an unexplored middle ground. Although it may prove less satisfying than either of the two extremes, such a middle ground appears justified based on the negotiating history, and is also consistent with the panel's decision. This middle ground posits that *most* differentiation (i.e., justifiable discrimination) is permitted under TRIPS. But differentiation with regard to pharmaceutical products may not be. This requires closer inspection.⁷⁷

2. General Principles of Treaty Interpretation

Treaty interpretation begins with the Vienna Convention on the Law of Treaties (VCLT). VCLT Article 31 requires that in interpreting TRIPS, terms must be given their ordinary meaning,⁷⁸ and TRIPS must be interpreted in context and in

the manufacture, use, or sale of *drugs or veterinary biological products*," and may therefore violate Article 27.1's mandate that patent rights be enjoyable without discrimination as to field of technology (emphasis added); Bryan Mercurio, *The Impact of the Australia–United States Free Trade Agreement on the Provision of Health Services in Australia*, 26 WHITTIER L. REV. 1051, 1094 (2005) (“[T]he International Federation of Pharmaceutical Manufacturers (IFPMA) felt that [the Australian government’s amendments to the United States Free Trade Agreement Implementation Bill restricting drug manufacturer infringement claims] violated the TRIPS Agreement by discriminating against pharmaceutical patent holders and dissuading holders from seeking to protect and enforce their rights.”) (footnote omitted); LiLan Ren, Comment, *A Comparison of 28 U.S.C. § 1498(a) and Foreign Statutes and an Analysis of § 1498(a)’s Compliance with TRIPS*, 41 HOUS. L. REV. 1659, 1696 (2005) (arguing House Bills 1708 and 3235 “as currently written could face opposition because they only regulate pharmaceutical and safety-related patents” and should be changed to cover all fields of technology to “avoid any issue of discrimination” under TRIPS Article 27.1).

76. See Berger, *supra* note 75, at 200; see also Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT’L ECON. L. 77, 85 (2005) [hereinafter Abbott, *New Era*] (“[Article 27.1] does not, however, mean that a patent with respect to an Internet search engine must be treated the same as a patent on a steam turbine . . . Inventions are not neutral with respect to field of technology. The invention of a new variety of disease-resistant rice has fundamentally different implications than the development of a new microprocessor or machine tool.”); Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 7 [hereinafter Correa, *Public Health*] (“[D]ifferential treatment does not necessarily mean discriminatory treatment, because different technologies might require different treatment.”).

77. The nondiscrimination principle may require just that, regardless of differences in technology, as this “may well constitute a deliberate limitation” by the TRIPS drafters. *Canada-Pharmaceuticals*, *supra* note 42, ¶ 7.92.

78. See Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331. The text of TRIPS Article 27 is ambiguous. See also *Canada-Pharmaceuticals*, *supra* note 42, ¶ 7.94 (finding that “discrimination” was broader than differentiating).

light of its object and purpose. In *Canada-Pharmaceuticals*, the panel found that “discrimination” is “a normative term, pejorative in connotation, referring to the unjustified imposition of differentially disadvantageous treatment.”⁷⁹ It also found that the term “extends beyond the concept of differential treatment.”⁸⁰ Beyond that, the panel refused to provide a precise definition of the term, claiming that “[d]iscrimination is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision that the concept contains.”⁸¹ I will not attempt here to more precisely define “discrimination” other than to suggest that the panel’s avoidance implies that the term is ambiguous. If so, recourse to TRIPS’s negotiations and the circumstances of TRIPS’s conclusion is appropriate to resolve such ambiguity.⁸² In so doing, it is hard to conclude that differentiation, even as separate from discrimination, would allow states to enact laws specifically targeting pharmaceuticals, regardless of public interests. Stated differently, while the differentiation argument has force when applied to new technologies or even then-existing technologies that were not the target of tremendous and intense international attention, the argument presents a more challenging question when applied to pharmaceuticals—which were the focus of intense lobbying.⁸³

As recounted elsewhere,⁸⁴ TRIPS was heavily influenced by the pharmaceutical industry with a firm mandate to protect pharmaceutical products internationally. Prior to TRIPS, many states—particularly developing states—barred patents on medicines and agricultural goods as inimical to societal concerns

79. *Canada-Pharmaceuticals*, *supra* note 42, at ¶ 7.94.

80. *Id.*

81. *Id.*

82. See Vienna Convention on the Law of Treaties art. 31.1, May 23, 1969, 1155 U.N.T.S. 331 (“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”); *Id.* at art. 32 (“Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31 . . .”).

83. Arguably, the Doha Declaration might cut against this reading. The Doha Declaration allowed countries to discriminate/differentiate as against pharmaceuticals. Article 31b waives the domestic production requirement as to *pharmaceutical product* being exported to an “eligible importing member.” World Trade Organization, Amendment of the TRIPS Agreement, Dec. 8, 2005, WTO Doc. WT/L/641.

84. Watal notes that because the pharmaceutical sector disproportionately relies on patents to appropriate to itself returns on research & development and profits for future innovation, “[i]t is therefore no surprise that the pharmaceuticals industry was the main non-state actor influencing the *demandeurs*’ position on the patents section of the TRIPS Agreement.” Jayashree Watal, *Patents: An Indian Perspective*, in THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 295, 298 (Jayashree Watal & Antony Taubman, eds., 2015); *id.* (“As the negotiations proceeded and as the United States Trade Representative notched up more and more bilateral successes in persuading the US’ trading partners to agree to ‘effective and adequate’ standards on IPRs, especially in the pharmaceuticals sector, the greater or more expansive became the demands of its industry.”).

and public benefit.⁸⁵ Other states provided limited protection for such inventions, usually by providing a shortened protection period.⁸⁶ States further distinguished between product patents and process patents.⁸⁷ This distinction was most visible with respect to pharmaceutical and chemical patents.⁸⁸ Through this distinction, states were able to issue patents on pharmaceutical and chemical *processes*, but deny protection for pharmaceutical and chemical *products*.⁸⁹ Local manufacturers could thus produce patented pharmaceutical products as long as they did not use the same patented process.⁹⁰ States certainly had legitimate reasons for distinguishing pharmaceutical patents (and agrochemicals and foodstuffs). Yet, these areas and the lack of protection were some of the most contentious and controversial issues during the TRIPS negotiations.⁹¹ The United States, unquestionably the driving force behind TRIPS, at the behest of the pharmaceutical industry, sent a strong message that any access to U.S. markets was inextricably linked to increased patent protection for pharmaceutical products.⁹² It would seem odd then, to say the least, that these TRIPS provisions should nevertheless be interpreted to allow for differentiation as to pharmaceutical products when the differentiation can be meaningfully justified.⁹³

85. See, e.g., Harris, *supra* note 29, and sources cited therein.

86. See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 523 (1996).

87. Harris, *supra* note 29, at 133.

88. Adelman and Baldia, *supra* note 86, at 520.

89. India, for example, did not provide protection for products made by processes. See *id.* at 524–25.

90. Harris, *supra* note 29, at 133.

91. Abbott, Cottier, and Gurry note that patents were the most contentious subjects of the Uruguay Round and solutions in the field of exclusions of patentability were of a “profoundly controversial nature.” Thomas Cottier, *Negotiation of TRIPS Agreement Norms: The Prospects for Intellectual Property in GATT*, in *THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM* 686, 694–95 (1999). To balance Article 27’s broad grant, Article 27 provides limited exceptions. Specifically, it provides that members may exclude inventions from patent protection when necessary to protect “*ordre public or morality*” and may exclude “diagnostic, therapeutic and surgical methods for the treatment of humans and animals.” TRIPS Agreement, *supra* note 6, at art. 27, ¶¶ 2–3. Members also may exclude plants and animals other than micro-organisms as long as members provide for *sui generis* protection. *Id.*

92. Antony Taubman, *Thematic Review: Negotiating “Trade-Related Aspects” of Intellectual Property Rights*, in *THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS* 15, 30 (Jayashree Watal & Antony Taubman eds., 2015).

93. “The US negotiating team accepted proposals on what are now known as ‘flexibilities’ that were in line with its own domestic laws, including use of patents by or on behalf of government upon payment of full compensation or compulsory licenses to address anticompetitive behaviour.” *Id.* at 35. Unless the United States allowed for differentiation with regard to patent rights, it is hard to believe it would allow that in TRIPS.

It should be noted, however, that TRIPS Article 70, paragraphs 8 and 9, left countries that did not yet have product patents for pharmaceuticals—with not even a day of a transition period for the most sensitive sector in the TRIPS negotiations, since patent applications for pharmaceuticals and agricultural chemicals had to be permitted to be filed from 1 January 1995 onwards. Watal, *supra* note 84, at 299.

Moreover, if this interpretation is adopted, the Declaration calls for ignoring or overruling *Canada-Pharmaceuticals*.

IV. OVERRULING OR IGNORING WTO DECISIONS

The *Canada-Pharmaceuticals* decision is not without controversy; indeed, it has invited a good deal of criticism.⁹⁴ But ignoring the decision or disregarding it has serious consequences and the obstacles to overcome are significant.

A. Arguments Against Ignoring WTO Decisions

The strongest argument against ignoring previous WTO decisions is that these decisions serve as existing, binding authority. Disregarding these decisions will create instability within the IIL system. Despite oft-repeated (and technically accurate) pronouncements that WTO decisions are nonbinding and the international law system is not a *stare decisis* system, in practice many observe that the system is just that.⁹⁵ Raj Bhala is the strongest proponent of this view. Bhala's early and important work on *stare decisis* in WTO adjudication shows the doctrine in operation. In a trilogy of articles,⁹⁶ Bhala persuasively argues that WTO adjudicators and, equally important, WTO Members regard prior WTO decisions as binding precedent.⁹⁷ In *Part I* of this trilogy, Bhala argues that "the idea that *stare decisis* does not operate in international trade law is a myth borne of impure origins and relying on a dubious distinction between 'binding' and 'non-binding' precedent."⁹⁸ In *Part II*, Bhala demonstrates that *stare decisis* "resonates strongly throughout the WTO Appellate Body reports."⁹⁹ He declares that these reports "are a testament to the hypocrisy in our discourse on international trade law."¹⁰⁰ Time and again, Bhala shows that panels and the WTO Appellate Body (AB) cite and rely

94. See, e.g., P. Bernt Hugenholtz & Ruth L. Okediji, *supra* note 70 (contending that contrary to some widely held beliefs, the available space is still quite remarkable, provided that the three-step test is interpreted correctly—meaning in particular that the overly cautious approach observed by the WTO panel in *US – Copyright 190* should not be followed).

95. To be clear, I do not argue that the WTO system should be a *stare decisis* system. There are compelling reasons it should not be. Rather, the argument here is simply that regardless of the virtues or shortcomings of a *stare decisis* system, as a practical matter states behave as if the WTO system operates under that principle. We should thus respond to challenges with WTO Agreements in this light.

96. Raj Bhala, *The Myth About Stare Decisis and International Trade Law (Part One of a Trilogy)*, 14 AM. U. INT'L L. REV. 845 (1999) [hereinafter Bhala, *Stare Decisis Part I*]; Raj Bhala, *The Precedent Setters: De Facto Stare Decisis in WTO Adjudication (Part Two of a Trilogy)*, 9 J. TRANSNAT'L L. & POL'Y 1 (1999); Bhala, *Stare Decisis Part III*, *supra* note 28.

97. Bhala, *Stare Decisis Part III*, *supra* note 28, at 978 ("Like it or not, precedent, or *stare decisis*, in the Anglo-American sense of these terms, is alive and well in the practice of the Appellate Body.").

98. *Id.* at 876.

99. *Id.*

100. *Id.*

upon prior holdings to determine the outcome in cases.¹⁰¹ Bhala forcefully makes the case:

While there are a variety of methodological approaches to the problem [of WTO adjudication], we can see this doctrine [of *stare decisis*] in operation by tracing lines of precedent on critical and recurring procedural and substantive issues. In both categories of issues, the lines are obvious to anyone who takes the time to look. Indeed, after looking, one gets a strong impression of the gap between the old-fashioned conventional wisdom about *stare decisis* in the international legal arena, and the reality of what is going on in WTO adjudication.¹⁰²

Bhala concedes that the doctrine is not one in law, but one in fact. This “de facto” body of law is a “body of international common law of trade emerging as a result of adjudication by the WTO’s Appellate Body.”¹⁰³ As Bhala states: “We need only watch how the adjudicator comes to its conclusions to see *stare decisis* in operation.”¹⁰⁴

WTO Panels’ reliance on prior WTO decisions “create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute.”¹⁰⁵ In *Part III*, Bhala thus calls for the international community to formally embrace a *de jure* doctrine of *stare decisis*.¹⁰⁶

101. *Id.* at 877. He also notes that “[a]t other times, it seems that a prior holding channels or directs the thinking of a WTO panel or the Appellate Body in a certain direction, but does not actually force a conclusion. Indeed, it may give rise to a counter-stream, *i.e.*, to efforts in a different direction.” He refers to this as “the flexible side of the doctrine.” *Id.* (“A prior holding becomes something to be dealt (even struggled) with and modified.”). Even unadopted panel opinions can provide “useful guidance” for subsequent panels. Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, 13, WTO Doc. WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted Oct. 4, 1996) [hereinafter *Japan—Alcohol*].

102. Bhala, *Stare Decisis Part III*, *supra* note 28, at 977.

103. Bhala, *Stare Decisis Part I*, *supra* note 96, at 850. This body of law is similar to the body of law used by the International Court of Justice, presciently noted in the *Japan—Alcohol* Appellate Body decision in Footnote 101:

It is worth noting that the Statute of the International Court of Justice has an explicit provision, Article 59, to the same effect [as the WTO in that past decisions are not binding]. This has not inhibited the development by that Court (and its predecessor) of a body of case law in which considerable reliance on the value of previous decisions is readily discernible.

Japan—Alcohol, *supra* note 101, at 13 n.30. See also Adrian T. L. Chua, *Precedent and Principles of WTO Panel Jurisprudence*, 16 BERKELEY J. INT’L L. 171, 183 (1998).

104. Bhala, *Stare Decisis Part I*, *supra* note 96, at 937.

105. *Id.* (citing *Japan—Alcohol*, *supra* note 101, at 14–15) (citations omitted). Not being able to rely on prior cases causes uncertainty in WTO disputes. See, e.g., Joseph A. Conti, *The Good Case: Decisions to Litigate at the World Trade Organization*, 42 LAW & SOC’Y REV. 145, 160 (2008) (“The emergent and developing character of WTO jurisprudence combined with the lack of formal authority to establish precedent creates considerable uncertainty related to determining what arguments must be made to construct a good legal case.”).

106. Bhala, *Stare Decisis Part III*, *supra* note 28, at 977 (“There are simply too many strong rationales in favor of a *de jure* doctrine of *stare decisis* to be ignored. It is time, indeed long past time, for WTO Members to embrace openly a time-honored and truly grand doctrine, and thereby take another step towards ideal global economic governance. If they really are against lawless freedom, then they will do so.”).

Sungjoon Cho and Meredith Lewis corroborate Bhala's understanding. Cho states:

No matter how one labels WTO jurisprudence, the label itself has never actually bestowed compliance pull upon those decisions. Regardless of the label, Members *perceive* these precedents as well-established "jurisprudence" which they voluntarily observe: they cite, quote and refer to the AB's precedents to substantiate and reinforce their own legal positions in the dispute. While not all Members abide by the WTO jurisprudence all the time, such breaches do not necessarily nullify the legal authority of the jurisprudence.¹⁰⁷

Moreover, Lewis observes that "panels and the Appellate Body routinely reference and apply previous reports. Thus there is no de jure system of precedent, but de facto, previous decisions are generally followed."¹⁰⁸ Bhala and Gantz make the same point: "Appellate Body members . . . realize they do not practice in a world of one-shot appeals from initial arbitration decisions. Surely it bespeaks their perception of the legal world in which they operate, one typified by existing, evolving, and emerging precedents."¹⁰⁹

Lewis welcomes this de facto stare decisis. As she observes, "[p]anels that diverge from previous decisions are arguably not acting in accordance with the objective of the dispute settlement system to provide security and predictability of the multilateral trading system."¹¹⁰

The AB also acknowledges the existence of the de facto system. Perhaps the most explicit examples are the recent AB cases involving the issue of zeroing.¹¹¹ In

107. Sungjoon Cho, *Global Constitutional Lawmaking*, 31 U. PA. J. INT'L L. 621, 653 (2010).

108. Meredith Kolsky Lewis, *Dissent as Dialectic: Horizontal and Vertical Disagreement in WTO Dispute Settlement*, 48 STAN. J. INT'L L. 1, 23 (2012) (citations omitted).

109. Raj Bhala & David A. Gantz, *WTO Case Review 2001*, 19 ARIZ. J. INT'L & COMP. L. 457, 499 (2002) (citations omitted). States closely adhere to WTO panel decisions.

110. Lewis, *supra* note 108, at 32. In describing the Appellate Body's ruling in *Korea Beef*, where the AB reversed the panel because the panel had "gotten it wrong," Bhala and Gantz exclaim: Why would the Appellate Body care to spend nearly three pages (paragraphs 133-138) on the correct legal interpretation of "treatment no less favourable" if it were nothing more than akin to an arbitral body? To read these pages is to see common law judges, at the international level, in action. Indeed, why else would the Appellate Body take such pains in citing the body of case law that backed each sentence of the legal standard it had set in *Japan-Alcoholic Beverages* and was applying in *Korea Beef*?

Bhala & Gantz, *supra* note 109, at 499. See also Appellate Body Report, *United States—Final Anti-Dumping Measures on Stainless Steel from Mexico*, ¶ 160, WTO Doc. WT/DS344/AB/R (Apr. 30, 2008) [hereinafter Appellate Body Report, *U.S.—Zeroing (Mexico)*] ("Ensuring 'security and predictability' in the dispute settlement system, as contemplated in Article 3.2 of the DSU, implies that, absent cogent reasons, an adjudicatory body will resolve the same legal question in the same way in a subsequent case.") (emphasis added) (footnote omitted).

111. "Zeroing" is a methodology employed by the United States Department of Commerce in which it "exclude[s] transactions that have a negative dumping margin." Edward T. Hayes, *International Law*, 55 LA. B.J. 274, 275 (2008). The dumping margin is calculated by subtracting export price from the domestic price; thus, a negative dumping margin is one in which the export price is higher than the domestic price. Sungjoon Cho, *The WTO Appellate Body Strikes Down the U.S. Zeroing Methodology Used in Antidumping Investigations*, AM. SOC'Y INT'L L. (May 4, 2006), <http://www.asil.org/insights/>

an eight-year span (2001–2009), the AB issued a series of six cases that repeatedly struck down the zeroing policies of WTO Members as violating the WTO Antidumping Agreement.¹¹² With each decision, the AB appeared determined to send a message to WTO Members that zeroing, which was being used as a protectionist measure, was inconsistent with the WTO anti-dumping regime, which itself was designed to counteract a foreign producer’s pricing behavior.¹¹³

These decisions were controversial. Many observers believed not only that the zeroing methodologies were valid, but also that the WTO AB’s anti-zeroing decisions were contrary to prior GATT decisions. This might explain why the next panel to decide a zeroing complaint ignored the AB’s repeated messages. “In a ‘shocking move,’ the panel in *U.S.—Zeroing (Mexico)* explicitly defied the AB’s” newly established anti-zeroing position, instead relying on the earlier, pro-zeroing decisions.¹¹⁴ The panel justified its departure by emphasizing that panels “are not, strictly speaking, bound by previous Appellate Body or panel decisions that have addressed the same issue.”¹¹⁵

As expected, this did not sit well with the AB. The AB reversed the panel’s findings and, in so doing, “expressed its deep concern over the panel’s rebellious behavior.”¹¹⁶ In a concurring opinion, one of the AB Members warned future panels not to further disobey the AB’s anti-zeroing jurisprudence by relying on rulings of the previous panels.¹¹⁷ The opinion is worth quoting:

Adopted panel and Appellate Body reports are often cited by parties in support of legal arguments in dispute settlement proceedings, and are relied upon by panels and the Appellate Body in subsequent disputes. In addition, when enacting or modifying laws and national regulations pertaining to international trade matters, WTO Members take into account the legal interpretation of the covered agreements developed in adopted panel and Appellate Body reports.

volume/10/issue/10/wto-appellate-body-strikes-down-us-zeroing-methodology-used-antidumping [https://perma.cc/X8NJ-RMJF] (discussing that by using the zeroing methodology, the general dumping margin of a product is inflated “because the zeroing methodology precludes any offsetting effect of negative individual dumping margins”).

112. See Cho *supra* note 107, at 629–41.

113. *Id.* at 638 (“The AB’s anti-zeroing jurisprudence reached its climax in [Appellate Body Report, *United States—Measures Relating to Zeroing and Sunset Reviews*, WT/DS322/AB/R (Sep. 01, 2007)]. The decision, which was dubbed the ‘death knell of zeroing,’ has thus far been the most sweeping and unyielding zeroing decisions in the WTO.”) (citation omitted).

114. Cho, *supra* note 107, at 639.

115. Panel Report, *United States—Final Anti-Dumping Measures on Stainless Steel from Mexico*, ¶ 7.102, WTO Doc. WT/DS344/R, (Dec. 20, 2007) [hereinafter Panel Report, *U.S.—Zeroing (Mexico)*].

116. Appellate Body Report, *U.S.—Zeroing (Mexico)*, *supra* note 110, ¶ 162.

117. Appellate Body Report, *United States—Continued Existence and Application of Zeroing Methodology*, ¶ 312, WT/DSR350/AB/R (Feb. 4, 2009).

At a point in every debate, there comes a time when it is more important for the system of dispute resolution to have a definitive outcome, than further to pick over the entrails of battles past.¹¹⁸

Equally pragmatic, most informed observers would be concerned that noncompliance with prior decisions, and, particularly, deliberate and conscious noncompliance, would represent a threat to the system. The individual and collective interest in an effective dispute system would (and should) outweigh the interest any particular state has in any particular interpretation reached in any particular dispute.¹¹⁹ By and large, states, including nonparty states, comply with WTO interpretations.¹²⁰

In addition to the arguments above, disregarding WTO precedent not only may fail to achieve its desired goal, but may also have the perverse effect of strengthening that precedent. The AB zeroing cases illustrate this point. After each of the cases, Member states attempted to craft more creative zeroing policies, subtly (and sometimes not so subtly) defying the AB's central anti-zeroing message.¹²¹ The AB rejected each attempt.¹²² More importantly, Members' actions resulted in the AB taking more and more restrictive positions until it made clear that zeroing was intolerable.¹²³ As Sungjoon Cho states: "[T]he judicial rulemaking on zeroing was the AB's purposeful mission of institutionalizing a 'proper test' which would shrink the domestic government's administrative discretion and thus render a pro-zeroing interpretation 'impermissible' under Article 17.6(ii) in this particular anti-dumping issue."¹²⁴ The relevant fear here is that a WTO panel, and of more concern the AB, might find that a developing state's attempt to manipulate patent requirements under a subterfuge of a textual ambiguity in Article 27 requires intervention. Rather than highlighting discretion, such a plan may ossify the nondiscrimination principle and the current interpretation of the three-step test.

This ossification may already have occurred. WTO adjudicators have addressed the proper interpretation of TRIPS exceptions and limitations three separate times, and each time the panel respected and abided by the prior interpretation. First was the panel interpretation of patent exceptions in *Canada-Pharmaceuticals* itself.¹²⁵ Months later, a second panel ruled on permissible

118. Cho, *supra* note 107, at 655 (citing Appellate Body Report, *U.S.—Zeroing (Mexico)*, *supra* note 110, ¶ 160).

119. See, e.g., Appellate Body Report, *United States—Continued Existence and Application of Zeroing Methodology*, *supra* note 117, ¶ 312.

120. See David Epstein et al., *Implementing the Agreement: Partisan Politics and WTO Dispute Settlement*, in *TRADE DISPUTES AND THE DISPUTE SETTLEMENT UNDERSTANDING OF THE WTO: AN INTERDISCIPLINARY ASSESSMENT* 121, 124 (James C. Hartigan ed., 2009).

121. See Cho, *supra* note 107, at 633–40.

122. *Id.*

123. *Id.* at 640.

124. *Id.* at 647.

125. See *Canada-Pharmaceuticals*, *supra* note 42.

exceptions for copyrights in *United States – Section 110(5) of the US Copyright Act*.¹²⁶ Third, a panel five years later ruled on permissible exceptions to trademarks in *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*.¹²⁷ The TRIPS provisions allowing for exceptions to copyrights (Article 13) and trademarks (Article 17) are nearly identical in text and structure to the provision governing patents (Article 30).¹²⁸ These latter two cases followed the *Canada-Pharmaceuticals* holding.¹²⁹ In each case, the WTO found that the exceptions involved cumulative elements. *U.S. – Section 110* and *Canada-Pharmaceuticals* were decided close in time, which might account for the similarity of the decisions. But *European Communities – Protection of Trademarks* was decided five years later, which gave the WTO time to fully consider and to rethink its position. Nonetheless, it interpreted the trademark exceptions in the same manner as the previous panels.¹³⁰ It appears the WTO has spoken on the issue, with *European Communities – Protection of Trademarks* perhaps sounding the death knell for the more holistic interpretation advanced by some commentators regarding TRIPS's exceptions.

126. Panel Report, *United States—Section 110(5) of the US Copyright Act*, WTO Doc. WT/DS160/R (adopted June 15, 2000).

127. Panel Report, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WTO Doc. WT/DS174/R (adopted Mar. 15, 2005).

128. TRIPS Agreement, *supra* note 6, at art. 13 (“Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.”); *id.* at art. 17 (“Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.”).

129. See *Canada-Pharmaceuticals*, *supra* note 42.

130. If one were so inclined, one might be able to distinguish the *EC-Protection of Trademarks* opinion from the earlier WTO opinions as a more lenient and permissive opinion concerning Member discretion. The panel did note that Article 17 covering trademark exceptions differed from Articles 13 and 30 covering copyright exceptions and patent exceptions, respectively. The panel stated:

The structure of Article 17 differs from that of the other exceptions provisions to which the parties refer [Articles 13 and 30] . . . [U]nlike these other provisions, Article 17 contains no reference to “conflict with a [or the] normal exploitation,” no reference to “unreasonable prejudice” to the “legitimate interests” of the right holder or owner, and it not only refers to the legitimate interests of third parties but treats them on par with those of the right holder.

EC-Protection of Trademarks, ¶ 7.649. The panel thus explained that “whilst it is instructive to refer to the interpretation by two previous panels of certain shared elements found in Articles 13 and 30, it is important to interpret Article 17 according to its own terms.” *Id.*

On the other hand, as relevant here, the *EC-Protection of Trademarks*' panel interpreted Article 17 as requiring a tripartite test, and also defined common terms in precisely the same manner as did the previous panels. See *id.* ¶ 7.650 (“The panel agrees with the view of the Panel in *Canada-Pharmaceutical Patents*, which interpreted the identical term in Article 30”), ¶ 7.663 (“We agree with the following view of the Panel in *Canada-Pharmaceutical Patents*, which interpreted the term ‘legitimate interests’ of a patent owner and third parties in the context of Article 30”) Thus, while there is certainly a difference in how the *EC-Protection of Trademarks*' panel defined trademark exceptions, that difference is, arguably, attributable to the difference in language among the various exception provisions, rather than an attempt to interpret the provision more favorably than prior panels.

Finally, TRIPS was developed through a political process of negotiation among states. Rewriting the rules, or ignoring consistent decisions and instead interpreting provisions that are inconsistent with this negotiation process, interferes with those expressions of state sovereignty. Doing so might unfairly undo agreements achieved during the negotiation process.¹³¹ Some would argue that this would amount to nothing more than judicial activism by the AB or WTO panels.¹³²

The negotiation history tends to confirm this risk. The provisions concerning pharmaceuticals, and the related exceptions and limitations, were some of the more controversial TRIPS provisions. Again, prior to TRIPS, many states—particularly developing states—(1) barred patents on medicines and agricultural goods for the public's benefit, (2) provided a shortened protection period, and (3) distinguished between product patents and process patents.¹³³ By requiring Member countries to provide patent protection in “all fields of technology,” Article 27's subject matter provision prevents states from excluding pharmaceuticals.¹³⁴ These pharmaceutical exclusions were “profoundly controversial,”¹³⁵ but the United States firmly considered them “nonnegotiable.”¹³⁶ Moreover, the newly expanded definition of patentable subject matter did away with the product/process distinction (“patents shall be available for any inventions, whether products or processes, in all fields of technology.”)¹³⁷

131. See, e.g., Jose E. Alvarez, *How Not to Link: Institutional Conundrums of an Expanded Trade Regime*, 7 WIDENER L. SYMP. J. 1, 19 (2001); Jagdish Bhagwati, *Afterword: The Question of Linkage*, 96 AM. J. INT'L L. 126 (2002); Debra Steger, *Afterword: The “Trade and . . .” Conundrum—A Commentary*, 96 AM. J. INT'L L. 135 (2002); see also Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447 (2011).

132. Such activism “is incompatible with democratic accountability and WTO legitimacy, which are threatened because: (1) AB judges are not elected; (2) AB decisions are not readily reversible by democratically accountable means; and (3) member states are deprived of their right to participate in policy decisions.” Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, *supra* note 3, at 717; see Joel P. Trachtman, *The Domain of WTO Dispute Resolution*, 40 HARV. INT'L L.J. 333, 342 (1999); see also Patrick Kelly, *Judicial Activism at the World Trade Organization: Developing Principles of Self-Restraint*, 22 NW. J. INT'L L. & BUS. 353, 365 (2002). The fear here appears to be that while WTO dispute resolution involves ensuring that members comply with WTO rules, it also involves quasi-legislation, which should be limited to matters that WTO members have already considered and negotiated. *Id.* at 339 (“Of course, dispute resolution plays two roles. First . . . dispute resolution is necessary to the application of legislation. In this regard, dispute resolution is not important for its own sake but as the place where legislation becomes binding and effective. Legislation without adjudication at least raises greater concerns regarding the application and effectiveness of the legislation Second, dispute resolution . . . inevitably interprets and expands upon legislation. In a common law system, indeed, dispute resolution amounts unabashedly to a type of legislation.”).

133. Harris, *TRIPS' Rebound*, *supra* note 29, at 138–39.

134. TRIPS Agreement, *supra* note 6, at art. 27.

135. Thomas Cottier, *Negotiation of TRIPS Agreement Norms: The Prospects for Intellectual Property in GATT*, in THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM, *supra* note 91, at 694–95 (noting that patents were the most contentious subjects of the Uruguay Round and solutions in the field of exclusions of patentability were of a “profoundly controversial nature”).

136. *Id.*

137. TRIPS Agreement, *supra* note 6, at art. 27. To balance this broad grant, Article 27 provides limited exceptions. Specifically, it provides that members may exclude inventions from patent

Against this backdrop of hard-fought gains, rewriting or reinterpreting TRIPS's exceptions to allow countries policy space to differentiate amongst pharmaceutical patents could be institutionally improper and at odds with the rule of law approach adopted by the WTO, or it might amount to judicial activism; at the very least, it could prove challenging.¹³⁸

B. Arguments in Favor of Ignoring WTO Decisions

The arguments for adhering to WTO decisions are strong, but they are not insurmountable. First, all of the exceptions cases (*Canada-Pharmaceuticals, U.S. – Section 110*, and *European Communities – Protection of Trademarks*) are panel decisions, as opposed to AB rulings. There is, arguably, a potential distinction between disregarding a panel report and an AB report.¹³⁹ From a systemic perspective, the more worrisome practice is the failure to adhere to decisions vertically;¹⁴⁰ it is hard to justify ignoring an AB ruling.¹⁴¹ When a ruling is made by “just” a panel there is at least a colorable claim that the AB might interpret an Article differently and, as such, the claim might not be foreclosed until the AB opines. After all, the reversal rate of panels is relatively high. The Ministerial Conference and the TRIPS Council have final and exclusive authority as to what TRIPS provisions mean, and they have the authority to interpret Articles 27 and 30 in the manner suggested by the Declaration.

Second, Bhala and others' strong arguments regarding a de facto stare decisis WTO system notwithstanding, Members have not taken up Bhala's call to establish a formal de jure system, so the system remains in principle one of non-binding precedent. As the WTO states: “As in other areas of international law, there is no rule of stare decisis in WTO dispute settlement according to which previous rulings bind panels and the Appellate Body in subsequent cases.”¹⁴² Accordingly, panel

protection when necessary to protect “*ordre public* or morality” and may exclude “diagnostic, therapeutic and surgical methods for the treatment of humans and animals.” *Id.* Members also may exclude “plants and animals other than micro-organisms” as long as members provide for sui generis protection. *Id.*; see also Harris, *TRIPS' Rebound*, *supra* note 29, at 132–33.

138. See *Canada-Pharmaceuticals*, *supra* note 42, at 154 (“[T]he three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to renegotiation of the basis balance of the Agreement.”).

139. See Lewis, *supra* note 108, at 10–11.

140. *Id.*

141. See, e.g., Cho, *supra* note 107, at 654 (“A WTO panel, as a lower tribunal, is not entitled to question the validity of a constitutional decision rendered by the AB—a constitutional tribunal.”); *id.* at 655 (citing Panel Report, *United States—Final Anti-Dumping Measures on Stainless Steel from Mexico*, ¶ 161 WTO Doc. WT/DS344/R (adopted Dec. 20, 2007)) (“[A] panel's defiance is against the hierarchical division of labor in DSU under which only the AB can ‘uphold, modify or reverse’ panels' legal interpretations.”).

142. *Legal Status of Adopted/Unadopted Reports in Other Disputes*, WTO, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s2p1_e.htm [https://perma.cc/76W3-V4XQ] (last visited Feb. 17, 2016).

dispute settlement reports and AB reports, if adopted, bind only the parties to the dispute and do not bind other WTO Members.¹⁴³

The idea of disregarding prior reports is not novel.¹⁴⁴ Panels and the AB have ignored prior WTO decisions.¹⁴⁵ In the AB zeroing decisions described above, the AB arguably disregarded prior GATT precedent in finding that the zeroing regulations were impermissible.¹⁴⁶ Admittedly, this was not done lightly. Cho calls this type of practice “constitutional lawmaking.”¹⁴⁷ According to Cho, this was necessary because the AB “recognized the structural damage that zeroing, if left unchecked, could inflict on the global trading system through the propagation of antidumping measures.”¹⁴⁸ “Constitutional lawmaking” is appropriate in narrow circumstances, depending on the nature of the subject matter and the “topicality” of the issue. Zeroing and antidumping measures fit the bill because zeroing was widely used as a protectionist measure, replacing traditional trade barriers such as tariffs. Cho is careful to point out, however, that “constitutional lawmaking” is not always appropriate.¹⁴⁹ He is reluctant to recommend it beyond the zeroing instance.

However, there are strong warrants for constitutional lawmaking in the context of IIP. As with zeroing, TRIPS limitation and exception provisions are critical to the underlying objectives and principles expressly identified in TRIPS. Moreover, the limitations provisions significantly affects states’ ability to address serious public health and policy concerns. The restrictive nature of the TRIPS limitations and exceptions interpretation and the futility of the “one-size-fits-all” approach might substantiate a future panel/AB decision recognizing the holistic approach for limitations.

A final argument for disregarding a WTO panel decision relies on changed circumstances after the adoption of TRIPS. Under narrow circumstances, changed circumstances may relieve parties of their treaty obligations.¹⁵⁰ The term *rebus sic stantibus* is a treaty law doctrine that addresses a fundamental change occurring with regard to those circumstances existing at the time of the conclusion of a treaty and not foreseen by the parties. Article 62(1) of the Vienna Convention on the Law of Treaties limits application of this principle:

143. See *Japan—Alcohol*, *supra* note 101, at 13.

144. Cho, *supra* note 107, at 624, 652–53.

145. *Id.*

146. See Cho, *supra* note 107 at 624 (“This Article construes the AB’s anti-zeroing position not as a simple jurisprudential change but as a more serious judicial revolution, which is tantamount to ‘constitutional lawmaking’ in its determined endeavor to contain WTO members’ manipulative use of zeroing methodologies under the subterfuge of the textual ambiguity of the relevant WTO norms.”).

147. *Id.*

148. *Id.*

149. “[T]his Article captures and theorizes *one* notable constitutional dynamic as it emerges in the WTO.” *Id.* at 626 (emphasis in original).

150. Vienna Convention on the Law of Treaties, art. 62, 1155 U.N.T.S. 331 (1969) (entered into force Jan. 27, 1980).

A fundamental change of circumstances may not be invoked as a ground for terminating or withdrawing from a treaty unless: (a) the existence of those circumstances constituted an essential basis of the consent of the parties to be bound by the treaty; and (b) the effect of the change is radically to transform the extent of obligations still to be performed under the treaty.¹⁵¹

The argument here is that in the over twenty years since TRIPS was adopted, circumstances have changed so dramatically that Members should be excused from their obligations. Global revolutions in communication and information exchange were not fully anticipated or appreciated in 1994. The Internet is a notable example. Since then, intellectual property has transformed from a property right encouraging future endeavors into a vehicle that affects and reaches into previously unforeseen areas as diverse and fundamental as public health; the environment; biotechnology; and digital communication, reproduction, and distribution. Unfortunately, as compelling as they may be, these new dimensions of international intellectual property may provide an inadequate reason to relieve a state from its obligations. Not once in the history of international law has a state successfully invoked changed circumstances to avoid prior commitments.

In the end, while there is some room available for differentiation, consistent with the WTO decisions, the arguments favoring decisional consistency, supported by the TRIPS negotiating history, overwhelm contrary arguments of unfettered discretion to differentiate. Therefore, we should look to other institutional mechanisms for change.

V. DYNAMIC MODES OF IIP LAWMAKING

My conclusion against unfettered differentiation is troublesome, particularly from a public policy perspective. While there are strong rule of law benefits from institutional stability and credibility from international treaties and WTO decisions that are binding, viewed from the public policy optic, states should certainly have wide discretion to fashion intellectual property regimes to respond to their current conditions and local needs. Moreover, states should have the power to change the existing regime to account for changed circumstances. The inability to treat inventions that affect various sectors within a state differently can frustrate this power. Yet, this conclusion seems inescapable as a matter of treaty interpretation. Regardless, this conclusion does not ineluctably lead to the entrenchment or privileging of economic and private rights over other interests. The remainder of this Article thus examines ways in which the Declaration might lessen the rigidity of TRIPS provisions in other ways. The following sections propose that the Declaration can still act as a catalyst for change by using the fragmentation of the international intellectual property system, as well as by appreciating the power of ideas.

151. Vienna Convention on the Law of Treaties art. 62(1), *opened for signature* May 23, 1969, 1155 U.N.T.S. 331.

A. The Power of Ideas

Intellectual property scholars are quite familiar with the power of ideas. Indeed, patent law is premised on the protection of new and useful ideas. Here, however, ideas are used in a different context. Ideas here are not protectable subject matter; rather, they are a foundation for civil disobedience. They are the bedrock of social movements. And here, ideas are the basis upon which a different view of TRIPS can emerge, one that takes into account the differing levels of economic, social, and technological development of its Members. More particularly, the Declaration introduces ideas and norms that countries can adopt to design IP systems that promote welfare and allow for the diverging needs of Member states. To borrow from Professor Kapczynski, the Declaration can “reframe” the debate about IP protection such that the international community no longer views IP from a mere economic perspective in which IP rights are good and more IP is better, but rather one in which IP is framed in light of human rights, public health, and one of any number of inputs into a system fostering economic and technological development.¹⁵² At bottom, the system is and should be seen as allowing for the growth of all states, and not solely benefiting the “haves” but also the “have nots.”

To be sure, this reframing is already well under way. Mechanisms both within and outside the WTO contribute to the ongoing development of IIP and have allowed groups to successfully translate their ideas and interpretations into concrete outcomes. This has been fueled by changes in the international lawmaking process. Examining these changes in lawmaking may be helpful in identifying concrete methods or possible avenues the drafters of the Declaration might pursue.

B. Changes in Lawmaking Activity

The conclusion of the Uruguay Round negotiations and the adoption of TRIPS comprised a monumental moment in international intellectual property. A dramatic departure from the prior international intellectual property framework, TRIPS was the most comprehensive and far-reaching international intellectual property treaty concluded at that time (and since). Rather than address a single intellectual property area, TRIPS covered a wide range of forms of intellectual property, including copyrights, trademarks, patents, undisclosed information, semiconductors, and geographical indications, among others. In addition, by bringing intellectual property within the institutional framework of the multilateral trading regime, TRIPS subjected intellectual property for the first time to the most-favored-nation principle and also to detailed provisions concerning the administration and enforcement of intellectual property rights, backed with an effective enforcement mechanism not previously seen in international intellectual policy.

152. Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L. J. 804 (2008).

Even as TRIPS transformed the IIP scene, however, it was only the beginning. As Anthony Taubman, the Director of the Intellectual Property Division of the WTO exclaims: “The period since the Agreement entered into force has undoubtedly been the most active, the most intensively debated and the most geographically and economically diverse phase of intellectual property law-making and policy-making processes ever experienced.”¹⁵³

Put simply, the international intellectual property regime has become increasingly complex. This complexity is characterized by competing institutions; bilateral, plurilateral, and multilateral treaties; and numerous actors, including traditional and new domestic and transnational actors. Maneuvering through this fragmented system can be complicated, yet also strategic. When states and nonstate actors become dissatisfied with institutional policies, there are an increasing number of avenues they can pursue. As the international intellectual property system has changed, so too have these avenues. Institutions, states, nonstate actors, and other nongovernment organizations use these new and different strategies to promote policies designed to both challenge and alter the status quo. These strategies include:

- (1) The “traditional” method of changing existing norms from within the particular organization (e.g., changing WTO norms within the WTO)
- (2) Relocating to a more favorable forum (i.e., “regime shifting”)
- (3) Establishing norms outside of the existing structure with the purpose of incorporating those norms into that structure (e.g., creating copyright norms outside of either WIPO or the WTO and then having either institution adopt those norms)
- (4) Creating norms in a competing institution with the goal of having those norms incorporated into the target institution (“competitive regime creation”)
- (5) Creating norms for issues not previously existing in any particular structure and incorporating these norms into an existing structure (e.g., by grouping banking, telecommunications, finance, etc. as “services” and then characterizing these as “trade related” so as to incorporate them into GATT/WTO).

The objectives underlying these modes of lawmaking have been to change the policies, rules, or procedures of various organizations and to do so customarily through strong pressure from industry, states, NGOs, and others. Moreover, different organizations and players have affected both vertical and horizontal governance structures by organizing at all levels of government (i.e., local, national, and international). Examining the hows and whys of these shifts in strategy can inform suitable options with respect to IIP patent exceptions.

153. Taubman, *supra* note 92, at 16 (“[T]he period since the Agreement was concluded has unquestionably been the most dynamic and challenging time ever for the IP system in general.”).

1. *Creating and Incorporating New Issues*

The more recent changes to international lawmaking for IIP can be seen as early as the 1980s in the context of services that were governed by issue-specific domestic regulatory schemes.¹⁵⁴ The interaction of different groups led to a different governance structure, i.e., an international trade regime and the rules embodied in GATT. This process illustrates a mode of lawmaking wherein an issue without an existing structure (services) is created and then incorporated into an existing structure (GATT/WTO).

Until the 1986 GATT Uruguay Round negotiations, services were treated as discrete activities, and no comprehensive regulatory system existed to govern them.¹⁵⁵ Services were within the exclusive province of national regulation. Consequently, a comprehensive regime was also absent at the international level. The institutions and organizations responsible for regulating services did so on an industry-by-industry basis, and these institutions and their constituencies were staunchly resistant to open domestic competition, to say nothing of global competition.¹⁵⁶ In the 1980s, a new idea emerged, one that revolutionized trade and services by linking the two. The first step in this process was to establish that services as diverse as telecommunications, banking and finance, transportation, shipping, management consulting, advertising, construction, education, entertainment, massages, and haircuts shared a common interest: trade. The novel idea advanced was not only that services shared a common interest in trade, but also that comprehensive global liberalization of trade would benefit each of the service industries.¹⁵⁷

William Drake and Kalypto Nicolaïdis detail this transformation at great length. According to them, this shift to a trade discourse “was a revolution in social ontology: it redefined how governments thought about the nature of services.”¹⁵⁸ It required “a fundamental change in mind-set” to persuade industry participants and governments that the benefits of liberalized trade would outweigh concomitant costs.¹⁵⁹

The process began by establishing an epistemic two-tiered community of experts. The first tier included personnel from institutions such as governments, international agencies, and private firms. These individuals were important because

154. See, e.g., William J. Drake & Kalypto Nicolaïdis, *Ideas, Interests, and Institutionalization: “Trade in Services” and the Uruguay Round*, 46 INT’L ORG. 37 (1992).

155. *Id.* at 44 (“[M]ost governments simply lumped services into a broad ‘tertiary’ sector comprising everything that was not agriculture and manufacturing.”).

156. *Id.*

157. Of course liberalization would affect different industries in different ways, but so long as each industry was convinced that trade would lead to benefits, a grouping of a “services community” could be accomplished.

158. Drake and Nicolaïdis, *supra* note 154, at 38.

159. *Id.* (“It took a fundamental change of mind-set to believe that the long-term benefits of trade liberalization could outweigh the substantial adjustment costs and risks involved.”).

they worked for organizations that had direct interests in alternative policy solutions.¹⁶⁰ The second tier included individuals with a more intellectual focus, such as academics, lawyers, industry specialists, and journalists. This second tier could legitimize the first tier's view because its members appeared relatively unbiased and were organizationally independent. To external policymakers, their views were "scientifically objective" and "susceptible to truth tests."¹⁶¹ They were also more likely to seek solutions and pursue outcomes that benefited the global community as a whole, rather than individual entities or industries.¹⁶²

In tracing the history of services' inclusion in GATT, Drake and Nicolaïdis identify three distinct stages: (1) formation of the epistemic community; (2) consolidation of issues that could then be presented to the global community via placement on the Uruguay Round negotiation agenda; and (3) the Uruguay Round negotiations, where the issues were further discussed, refined and eventually adopted.¹⁶³ I will refer to these as the national stage, the international stage, and the implementation stage.

At the national stage, a community of experts was established. The focus of this stage was "consciousness raising."¹⁶⁴ The formed community framed issues and decided who got a seat at the table. They fostered dialogue with international counterparts, thus growing the epistemic community in both size and diversity but also maintaining to a large extent the community's common beliefs, conceptual framework, and agenda.¹⁶⁵ The community was then eventually able to exert influence on policymakers.

The international stage involved the epistemic community's dissemination and refinement of its ideas with a feedback loop from an increasing number of participants.¹⁶⁶ Issues were consolidated, and eventually the first-tier community introduced "trade in services" as a new discussion topic within GATT.¹⁶⁷ The introduction of this new concept resulted in a strong demand for basic information about the nature and extent of services.¹⁶⁸ It also required governments to obtain particularized knowledge and strategic input on how liberalization would affect their countries.¹⁶⁹ In response, the community provided studies and reports containing more detailed assessments on critical issues, offering further input, and solidifying positions.¹⁷⁰

160. *Id.* at 39.

161. *Id.*

162. *Id.*

163. *Id.* at 38.

164. *Id.* at 41–42.

165. *Cf.* Kapczynski, *supra* note 152, at 883–84.

166. Drake & Nicolaïdis, *supra* note 154, at 62.

167. *Id.* at 53.

168. *Id.*

169. *Id.* at 54.

170. *Id.* at 55–56.

Understandably, at the implementation stage the process considerably slowed, as developing countries were (1) wary of the comparative disadvantage of including services, (2) skeptical of the industrialized countries' motives, and (3) concerned that including services would detract from issues of greater importance to them.¹⁷¹ Through communication from first-tier and second-tier members, a coherent and convincing body of thought developed, which made those who opposed including services in trade negotiations appear to stand "on a shaky intellectual ground."¹⁷²

The implementation stage is characterized by governments negotiating final commitments.¹⁷³ Here, in contrast with the previous stages, the epistemic community's influence declined, and traditional power and bargaining dynamics surfaced.¹⁷⁴ Nevertheless, the community's work set the stage for these negotiations, and governments adopted one policy from the range of options presented by the community.¹⁷⁵

From this short summary of the process, some events are noteworthy. First, because the idea of services relating to trade was novel, top policymakers lacked both organized information regarding the nature and volume of services transactions as well as experts to turn to. The epistemic community filled this void.¹⁷⁶ The second striking aspect of the process was the epistemic community's access to top policymakers, both through formal and informal channels. While this access was primarily accomplished through the first-tier community, the steady and continuous feedback among and between the first- and second-tier communities resulted in the second-tier community's ideas reaching these top policymakers.¹⁷⁷ The level of influence depended heavily on access to these top policymakers.¹⁷⁸

2. "Contested Multilateralism"

Other forms of lawmaking have emerged with respect to other international regimes. "Contested multilateralism" is a term coined by Julia Morse and Robert Keohane to describe situations where states, multilateral organizations, and nonstate actors use multilateral institutions to challenge the rules or norms of existing or newly created multilateral institutions.¹⁷⁹ When the multilateral

171. *Id.* at 57–58.

172. *Id.* at 64–65.

173. *Id.* at 65.

174. *Id.* at 66.

175. *Id.* at 41. Policy options were not always or even frequently adopted in whole; rather, governments often modified proposals. Still, the community's influence was evident.

176. *Id.*

177. *Id.* at 40–41.

178. *Id.* at 41.

179. *Contested Multilateralism*, *supra* note 4, at 385 ("'Contested multilateralism' describes the situation that results from the pursuit of strategies by states, multilateral organizations, and non-state actors to use multilateral institutions, existing or newly created, to challenge the rules, practices, or missions of existing multilateral institutions. It occurs when coalitions dissatisfied with existing

institutions used to generate counternorms are existing institutions, the process is referred to as “regime shifting.”¹⁸⁰ When the institutions are newly created, the term used is “competitive regime creation.”¹⁸¹ Coalitions pursue the contested multilateralism strategy when they are dissatisfied with existing institutions; they then threaten to either exit or create alternative institutions to pursue different policies.¹⁸² Three criteria define a situation involving contested multilateralism:

- (1) A multilateral institution exists within a defined issue area and with a mission and a set of established rules and institutionalized practices.
- (2) Dissatisfied with the status quo institution, a coalition of actors—whether members of the existing institution or not—shifts the focus of its activity to a challenging institution with different rules and practices. This challenging institution can be either pre-existing or new.
- (3) The rules and institutionalized practices of the challenging institution conflict with or significantly modify the rules and institutionalized practices of the status quo institution.¹⁸³

Examples abound of both regime shifting and competitive regime creation in the international lawmaking system.

a. Regime Shifting

As described above, regime shifting involves state and nonstate actors relocating rulemaking processes to international venues that favor their concerns and interests.¹⁸⁴ Laurence Helfer argues that countries “regime-shift” to use norms developed in other regimes to help define or inform norms created in the WTO.¹⁸⁵ In other words, countries, NGOs, consumer advocate groups, etc., seek to generate counter-WTO norms in other fora (perhaps to fill gaps, for example), and then seek to have WTO panels rely on these norms.¹⁸⁶ Rather than seeking a single favorable decision, the goal of regime shifting “is an iterative, longer-term strategy that seeks to create outcomes that have feedback effects in other venues.”¹⁸⁷

Moving intellectual property from WIPO to the WTO in the early 1990s constituted a regime shift. This shift ended the relative isolation of intellectual

institutions combine threats of exit, voice, and the creation of alternative institutions to pursue policies and practices different from those of existing institutions.”).

180. *Id.* at 392.

181. *Id.* at 398.

182. *Id.* at 390.

183. *Id.* at 388.

184. Laurence R. Helfer, *Regime Shifting in the International Intellectual Property System*, 7(1) PERSP. ON POL. 39 (2009) (“Regime shifting works by broadening the policy spaces within which relevant decisions are made and rules are adopted, thereby expanding the constellation of interests and issues that actors must consider when defining rules, norms, and decision-making procedures.”).

185. *Id.* at 41.

186. *Id.*

187. *Id.* at 39.

property, which had previously occupied a specialized part of international law, unconnected or very loosely connected to other issue areas in international law.¹⁸⁸ Unlike the inclusion of services in international trade law, intellectual property did not involve a newly created issue area, as it existed long before the adoption of TRIPS. In fact, of all the subjects included in the Uruguay Round negotiations, intellectual property was the longest established internationally, having been the subject of treaty obligations under the Berne Convention for the Protection of Literary and Artistic Works (1886) and the Paris Convention for the Protection of Industrial Property (1883).¹⁸⁹

Originally under the aegis of WIPO, which administered both the Berne and Paris Conventions, intellectual property issues shifted to the WTO because developed countries became increasingly frustrated with WIPO's failure to protect their IP-related interests.¹⁹⁰ This led to faltering negotiations and eventually to these countries seeking a more favorable forum in the WTO, where their trading power gave them a competitive advantage and leverage.¹⁹¹

The difficulty of changing TRIPS and its adverse effects, which only materialized following the adoption of TRIPS, contributed to another regime shift.¹⁹² Before the ink was dry on the TRIPS Agreement, efforts were underway to negotiate IP issues in WIPO rather than the WTO.¹⁹³ As TRIPS was adopted in 1994, deficiencies in its scope immediately surfaced: TRIPS did not address issues raised by the digital environment. Rather than return to the negotiating table after the tumultuous eight-year ordeal, developed states moved negotiations to WIPO, which drafted and now administers the WIPO Internet Treaties.¹⁹⁴

188. *Id.*

189. *See* Berne Convention (governing copyrights); Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *revised at Stockholm* July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 305 [hereinafter Paris Convention] (protecting patents and trademarks). WIPO administered both the Paris and Berne Conventions.

190. *See* Helfer, *supra* note 1, at 20–21.

191. *See id.* Prior to TRIPS, developing states attempted to weaken intellectual property rights within WIPO, while developed states sought to further protection, particularly as to pharmaceutical products. (“The proverbial straw that broke the camel’s back was the demand of developing countries that compulsory licenses be exclusive, meaning thereby that the patent owner be excluded from exploiting the invention in markets where a compulsory license has been issued. (footnote omitted) As is well known, this was one of the factors that led to the shifting of forum from WIPO to GATT and to the now-famous prefix ‘trade-related aspects of’ before ‘intellectual property rights.’”). *Patents: An Indian Perspective*, *supra* note 84, at 297–98 (footnote omitted).

192. *Cf.* Rochelle C. Dreyfuss, *The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms for Intellectual Property and Intellectual Property Lawmaking* 19 (N.Y.U. Pub. Law & Legal Theory Res. Paper Series, Working Paper No. 09-53, 2009), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1442785 [<https://perma.cc/3LN4-LH4A>] (“Because there are both formal and informal ties between WIPO and the WTO, developments in WIPO can create both freestanding intellectual property norms and also exert considerable influence on the interpretation of the TRIPS Agreement.”).

193. *Id.* at 4.

194. *See* Ruth L. Okediji, *The Regulation of Creativity Under the WIPO Internet Treaties*, 77 *FORDHAM L. REV.* 2379, 2379 (2009). The WIPO Internet Treaties consist of the WIPO Copyright

Developing countries also regime shift. Recent events in WIPO demonstrate that organizations devote increasing attention to issues peculiar to developing countries and to identifying policy space in which developing countries can operate.¹⁹⁵ As such, developing countries in the last decade have sought to develop comprehensive protection for, among other things, genetic resources, folklore, and traditional knowledge; but they have done so in WIPO, rather than the WTO.¹⁹⁶ The shift back to WIPO has enabled developing countries to make significant progress on these contentious issues.¹⁹⁷

In both of these cases, either because of an impasse in one organization, or the perception that issues are weighted too heavily toward one side or the other, actors have relocated IIP issues to fora in which their interests are better served. They have used regime shifting either as an intermediate strategy to later have rules created and incorporated in TRIPS, or to have rules created in WIPO that would have the effect of constraining or broadening states' discretion elsewhere.¹⁹⁸ As

Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT). *Id.* These treaties were meant to update and supplement existing IP treaties, such as TRIPS, by responding to developments in technology, hence the moniker "Internet Treaties." *Id.* at 2379–80. The WCT, for example, addresses issues such as the treatment of temporary copies in computers' random access memories, liability for Internet Service Providers for the infringing conduct of their subscribers, and the prohibition against the circumvention of technological protection measures used by copyright holders to prevent access and copying of their works.

195. See Helfer, *supra* note 1, at 26, 27.

196. See *id.* at 70, 71.

197. Catherine Saez & William New, *WIPO Assembly Extends Talks on Traditional Knowledge, Design; Sets Policy for New Offices*, INTELL. PROP. WATCH (Oct. 15, 2015), <https://www.ip-watch.org/2015/10/15/wipo-assembly-extends-talks-on-traditional-knowledge-design-sets-policy-for-new-offices/> [<https://perma.cc/AXT3-PN99>].

198. Of course, the efforts to secure greater protection of intellectual property need not occur within an organization at all. The United States and the European Union have concluded bilateral and plurilateral treaties to obtain protections greater than those obtained in TRIPS or elsewhere. The United States has negotiated bilateral agreements with Australia, Bahrain, Chile, Colombia, Central America—Dominican Republic, Jordan, Malaysia, Morocco, Oman, Peru, Singapore, South Korea, Thailand, and the Southern Africa Customs Union, among others. See U.S. TRADE REP., Free Trade Agreements, <https://ustr.gov/trade-agreements/free-trade-agreements> [<https://perma.cc/B7JR-6ZP4>] (last visited Sept. 10, 2016); U.S. TRADE REP., Trade & Investment Framework Agreements, <https://ustr.gov/trade-agreements/trade-investment-framework-agreements> [<https://perma.cc/4ADH-UHCT>] (last visited Sept. 10, 2016). These so-called TRIPS-plus treaties have been the subject of increasing criticism. "From the United States' and European Union's perspectives, bilateral agreements containing TRIPS-plus provisions remedy the perceived deficiencies in TRIPS, resolve TRIPS' ambiguities in their favor, and limit TRIPS' built-in flexibilities." Harris, *Adhesion Part II*, *supra* note 3, at 207. Frederick Abbott refers to this as the "TRIPS II Agenda." Frederick M. Abbott, *TRIPS II, Asia and the Mercantile Pharmaceutical War: Implications for Innovation and Access* 1 (Stanford Ctr. for Int'l Dev., Working Paper No. 308), <http://scid.stanford.edu/publications/trips-ii-asia-and-mercantile-pharmaceutical-war-implications-innovation-and-access> [<https://perma.cc/859H-XPJH>]. The TRIPS I agenda was characterized by industries in developed countries wanting to prevent industries in developing countries from substituting counterfeit goods in local markets, while the TRIPS II Agenda has been concerned with competition from generic producers and "emerging originator enterprises." *Id.* at 2 (footnote omitted); see also Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 80 (2004) (describing

should be evident, and as further explained below, the particular forum chosen strongly influences the negotiating strategy adopted by the various actors.

b. Competitive Regime Creation

Another form of contested multilateralism is competitive regime creation. Similar to regime shifting, competitive regime creation explains how and why actors pursue policies and practices different from those of existing institutions, this time by creating alternative institutions.¹⁹⁹

Clearly, competitive regime creation exacerbates the fragmentation of the international intellectual property regime. And as with regime shifting, it is contingent upon credible threats of outside options, whether such options include existing institutions or the ability to create a competing institution.²⁰⁰ Power imbalances influence state options under this approach.²⁰¹ While powerful states have formal and informal means to create alternative mechanisms, weaker states have fewer options, and may only be able to mount “symbolic challenge[s].”²⁰²

The Global Alliance for Vaccines and Immunization (GAVI) is an example of competitive regime creation. In the early 1980s, public health officials concerned

the European Union efforts to secure TRIPS-plus bilateral agreements); Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 *FORDHAM L. REV.* 505, 509 (2005) (describing how developed countries renege on their obligations to transfer technology while demanding that developing countries comply with their TRIPS obligations); Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 *U. OTTAWA L. & TECH. J.* 125, 128–29 (2004) (describing how U.S. bilateralism is the dominant policy of the United States post-TRIPS and is designed to roll back both substantive and strategic gains of the TRIPS Agreement for developing countries). See generally Sean M. Flynn et al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 *AM. U. INT’L L. REV.* 105, 109 (2012) (“[T]he offer of increased market access by the United States in exchange for the other country accepting ‘TRIPS-plus’ commitments on domestic intellectual property regulation (i.e., minimum standards in excess of those required by the TRIPS Agreement.)”); Pedro Roffe et al., *Intellectual Property Rights in Free Trade Agreements: Moving Beyond TRIPS Minimum Standards*, in 1 *RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 266, 273* (Carlos M. Correa ed., 2010) (discussing the proliferation of “TRIPS-plus” intellectual property standards in free trade agreements, particularly between developing countries and the United States); Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 *J. INTELL. PROP. L.* 447 (2011).

199. See *Contested Multilateralism*, *supra* note 4, at 392.

200. See *id.* at 390 (“The key is that the challenging coalition must have an alternative to the existing institution that would serve its interests, and the coalition must be able to credibly threaten to use this alternative organization or practice. State power is a major determinant of whether coalitions have outside options.”).

201. See *id.* (“A group of dissatisfied actors that includes states with significant resources and institutional leverage will have an easier time identifying credible outside options than a coalition of weaker actors.”).

202. See *id.* at 389 (“A dissatisfied coalition composed of primarily weak states, for example, may only be able to mount a symbolic challenge, critiquing an existing institutional practice but being unable to force immediate change. Over time, however, such a challenge may change actor preferences, ideas, and values in a way that delegitimizes an institution, forcing concomitant changes or institutional exit.”). Recent developments may challenge this conclusion.

with producing vaccines for developing world diseases harnessed advances in biotechnology.²⁰³ The World Health Organization (WHO) was the natural choice to coordinate efforts, as it was the central multilateral institution for global health issues. However, health advocates soon became dissatisfied with WHO's efforts, and so a coalition of nonstate actors, including civil society organizations, public health advocates, and the vaccine industry, created GAVI outside the structure of the WHO;²⁰⁴ they accomplished this despite WHO resistance.²⁰⁵ GAVI successfully worked with outside support, including the Gates Foundation and the World Bank.²⁰⁶ WHO's resistance helped generate this competitive regime creation and through contested multilateralism, GAVI "challenged WHO's dominance of vaccine development and delivery."²⁰⁷

Morse and Keohane note that attempts at contested multilateralism are "remarkably common" and occur across issue areas, including intellectual property, renewable energy, health, and security.²⁰⁸ Moreover, contested multilateralism targets not only the institutional rules but also the missions or practices of established organizations.²⁰⁹ In sum, contested multilateralism has been used to create, reinforce, or expand regime complexes and, in the context of patent exemptions, it can be used to help analyze how such moves affect the international system.²¹⁰

c. Grassroots Movements

Traditional grassroots and social movements also have much to teach us about effectuating change in institutions, practices, and rules. Not surprisingly, many similarities exist between these efforts and the efforts described above. One area where grassroots movements have enjoyed considerable success is in the human rights arena.

Nongovernmental organizations (NGOs) and international organizations (IOs) continually find obstacles in the international community. Particularly with regard to the human rights and labor movement, the NGOs and IOs must advocate policy changes that affect the "big players" in the international community, such as transnational corporations and powerful developed states. For this reason, grassroots movements seek out powerful enforcement mechanisms within

203. *See id.* at 403.

204. *See id.* at 404.

205. *See id.*

206. *See id.*

207. *Id.* at 404 ("GAVI emerged . . . because of organization resistance by the WHP and incomplete information that prevented the WHO from accurately gauging the seriousness of the challenge.").

208. *Id.* at 407.

209. *Id.*

210. *See id.*

organizations such as the UN, the International Court of Justice (ICJ), and the International Labor Organization (ILO).²¹¹

Dean Hubbard illustrates how grassroots efforts in the workers' rights movement successfully moved the needle on international protection for laborers' rights, while also detailing the particular obstacles for the movement.²¹² NGOs and IOs encountered considerable resistance in traditional enforcement mechanisms such as the UN, the ICJ, and ILO.²¹³ The structure of the UN reinforces the status quo between developing and developed states because the five permanent members of the UN Security Council and its ten rotating members effectively control the decision-making process.²¹⁴ In theory, the ICJ could serve as a forum, but its judgments are only enforceable by the UN Security Council, which presents the same obstacles.²¹⁵ The ILO is ostensibly the natural forum to pursue changes for workers' rights; however, the tripartite structure of this organization requires an unlikely consensus among government representatives, employers, and workers before it can act.²¹⁶ Thus, the power structures within these international bodies only reinforce the status quo.

The seemingly insurmountable obstacles in the international arena led workers' rights advocates to turn to regional forums.²¹⁷ But as Hubbard explains, these regional efforts must be linked to transnational networks in order to build the power structure necessary for transforming the systemic political and economic environment.²¹⁸ Hubbard advocates diverse, decentralized movements as the means by which the status quo in the international order can be overcome.

Hubbard identifies four steps in the process that can lead to successful grassroots movements.²¹⁹ First, the domestic government blocks action and thus creates social pressure for change.²²⁰ Second, grassroots efforts in the form of active leadership and coordinated collective action foster community.²²¹ Third, the local activists seek out international allies.²²² Lastly, Transnational Action Networks

211. See Dean Hubbard, *Reimagining Workers' Human Rights: Transformative Organizing for a Socially Aware Global Economy*, 5 HASTINGS RACE & POVERTY L.J. 1, 8–15 (2008) [hereinafter Hubbard, *Reimagining Workers' Human Rights*].

212. The workers' rights movement advocated change within the human rights regime. See *id.* at 3 (describing the changes in workers' rights as economic human rights law).

213. *Id.* at 8–10.

214. *Id.* at 12 (“The U.N.’s espousal of the ideals of economic human rights generates an appearance of legitimacy, but when it comes down to the reality of power, the world’s economic powerhouses arguably use the U.N. and its agencies in a stark exercise of authority over the world’s developing nations.”).

215. *Id.* at 9.

216. *Id.* at 9–10.

217. See *id.* at 13.

218. *Id.* at 25.

219. See *id.* at 25–26.

220. See *id.* at 25.

221. See *id.* at 26.

222. See *id.* at 25.

(TANs) bring pressure to bear on states or corporations from angles other than those traditionally pursued, such as the UN, ICJ, and ILO.²²³

However, grassroots movements need active leadership of workers at grassroots levels.²²⁴ This entails coordinated collective action among the heads of social movements and subsidiary local groups.²²⁵ Central to this approach, the leaders of the grassroots movement need to teach “ordinary people” at the local level or “bottom” of the movement to make their own demands, rather than relying on someone to speak for them.²²⁶

Once the “bottom” of the grassroots movement at the local level has solidified, Hubbard suggests that the movement create a network to establish a climate and culture where the action or movement can thrive.²²⁷ This can be in the form of small local groups such as workplaces, schools, and communities that are linked to other similar groups in different locations.²²⁸ Here, NGOs and IOs participating in the grassroots movement collaborate with groups outside the NGO sphere, including the academic community, the media, and social networking groups.²²⁹ Through these communities, and particularly through TANs, changes to status quo emerge.

d. The Marrakesh Treaty for the Blind

Two other events in the IIP system merit discussion. What these events reveal is that change to the international intellectual property landscape can occur in traditional IP settings, for example within the WTO and WIPO. Two key developments in international intellectual property law provide examples of this phenomenon, and might provide additional insights on how to change the policy and normative landscape of the IIL system. These developments include the 2001 Doha Declaration and the 2013 Marrakesh Treaty for the Blind.²³⁰ Both are revolutionary in different ways. Both were accomplished in different venues. Both are noteworthy not only because of the process by which each was achieved, but also because of the result that each obtained.

223. *See id.* at 25–26.

224. *Id.* at 24.

225. *See id.* (“Experience has repeatedly proven that grass roots community and workplace organizations that facilitate ordinary people’s coordinated struggles to gain control over their political, economic, and cultural lives are the most effective vehicles for systemic change.”).

226. *Id.* at 24–25.

227. *Id.* at 25.

228. *Id.*

229. George E. Edwards, *Assessing the Effectiveness of Human Rights Non-Governmental Organizations (NGOs) from the Birth of the United Nations to the 21st Century: Ten Attributes of Highly Successful Human Rights NGOs*, 18 MICH. ST. J. INT’L L. 165, 207 (2010).

230. World Trade Organization, Ministerial Declaration of 14 November 2001 on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002); Marrakesh Treaty to Facilitate Access to Public Works by Visually Impaired Persons and Persons with Print Disabilities, June 27, 2013, http://www.wipo.int/edocs/mdocs/diplconf/en/vip_dc/vip_dc_8.pdf [<https://perma.cc/DUG4-DCPQ>] [hereinafter Marrakesh Treaty].

Ninety percent of the over 314 million visually impaired persons in the world live in developing states.²³¹ Moreover, of the over two million books published per year per country, less than 7 percent are published in formats accessible to the visually impaired.²³² Copyright law, particularly its reach into digital and electronic media, is blamed for this “book famine.”²³³ Although a number of countries’ copyright laws have specific provisions allowing for exceptions for visually impaired persons (usually Braille or large print), the vast majority does not.²³⁴

The 2013 Marrakesh Treaty for the Blind (Marrakesh Treaty) goes a long way towards remedying this. The Marrakesh Treaty was accomplished through a coordinated effort of NGOs and developing countries. Though efforts to create copyright exceptions for the blind began as early as the 1980s, the movement gained traction in international conversations when, in 2003, Professor Sam Ricketson prepared for WIPO an examination of copyrights exceptions for the visually impaired.²³⁵

The movement took off in 2008 when The World Blind Union and Knowledge Ecology International convened an expert group to consider a possible treaty for blind, visually impaired, and other reading disabled persons. The World Blind Union, in particular, spearheaded efforts to raise public consciousness about the international human rights aspect of access to information and the book famine. The following year, developing countries presented to WIPO the World Blind Union’s proposed Treaty for the Blind, which after much negotiation and modification ultimately formed the basis for the Marrakesh Treaty.²³⁶

The Marrakesh Treaty is unique in many ways.²³⁷ Most importantly, the Marrakesh Treaty is the first in IIP that expressly recognizes minimum standards for *limitations and exceptions* to copyright.²³⁸ Prior to the Marrakesh Treaty, all other

231. Action Plan, World Health Org., *Vision 2020 Global Initiative for the Elimination of Avoidable Blindness: Action Plan 2006-20011*, 1, 3 (2007).

232. Press Release, World Blind Union, WIPO Negotiations Treaty for Blind People (June 17, 2013), <http://www.worldblindunion.org/English/news/Pages/JUNE-17-Press-Release-for-WIPO-Book-Treaty.aspx> [https://perma.cc/FZ5W-HSQL].

233. *Id.*

234. World Intell. Prop. Org., *Study on Copyright Limitations and Exceptions for the Visually Impaired*, 1, 70 (Feb. 20, 2007), http://www.wipo.int/edocs/mdocs/copyright/en/sccr_15/sccr_15_7.pdf [https://perma.cc/H87G-HSD2].

235. Danielle Conway, *The Miracle at Marrakesh: Doing Justice for the Blind and Visually Impaired While Changing the Culture of Norm Setting at WIPO*, in *DIVERSITY IN INTELLECTUAL PROPERTY: IDENTITIES, INTERESTS, AND INTERSECTIONS* (Irene Calboli & Srividhya Ragavan eds., 2015).

236. Proposals were submitted by Brazil, Ecuador, and Paraguay, and the African Group. Later, the United States and European Union also submitted proposals.

237. Unlike previous international standards, the four substantive obligations imposed by the treaty are unique in that they expressly recognize international minimum standards for limitations and exceptions.

238. Lesley Ellen Harris, *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled*, COPYRIGHTLAWS.COM (Aug. 1, 2015), <http://www.copyrightlaws.com/international/marrakesh-treaty-to-facilitate-access-to-published->

WIPO initiatives sought to protect, promote, or enforce IP rights. The Marrakesh Treaty did the opposite: “[I]t aims to formalise a global normative framework that scales back IP rights by introducing exceptions and limitations to copyrights in order to make copyrighted works accessible to visually impaired persons, persons with other disabilities, libraries, archives, research and education.”²³⁹

The Marrakesh Treaty has four substantive requirements. Countries must (1) adopt limitations and exceptions in their national copyright laws that provide the right to reproduce, distribute, and make available works in accessible formats for beneficiary persons; (2) provide for export of an accessible format copy; (3) permit import of an accessible format copy; and (4) ensure that legal remedies against circumvention of effective technological protection measures (TPMs) do not prevent beneficiary persons from enjoying the limitations and exceptions provided for in the Marrakesh Treaty.²⁴⁰ The Marrakesh Treaty provides a striking example of the shift in international attitudes toward intellectual property, viewing enhanced protection with skepticism and challenging the dominant IP rationale.²⁴¹

e. The Doha Declaration

The Doha Declaration provides another striking example of shifting IIP attitudes. It was widely believed that because of the stalemate between developed countries that wanted to further strengthen TRIPS protections and developing countries that sought to limit TRIPS, TRIPS was ultimately impervious to change. The Doha Declaration is perhaps the most well-known post-TRIPS event that cast doubt on TRIPS’s inflexibility and whether it can be reshaped or reformed.

works-for-persons-who-are-blind-visually-impaired-or-otherwise-print-disabled/ [https://perma.cc/Q7NH-MST8].

239. Nandini Kotthapally, *From World Intellectual Property Organization (WIPO) to World Innovation Promotion Organization (WIPO)? Whither WIPO?*, 3 WORLD INTELL. PROP. ORG., no. 1, 2011, at 59.

240. Marrakesh Treaty, *supra* note 230, art. 4(1), 6, 7.

241. Although some wanted the treaty to cover audiovisual works, the treaty as concluded covers only works consisting of “text, notation and/or related illustrations”—essentially, print works—that are published or otherwise made publicly available in any media. *Id.* at art. 2(a). The treaty defines its beneficiaries as persons who are blind; who have visual impairments or perceptual or reading disabilities that render them unable to read printed works to the same degree as those who do not have such impairments or disabilities; or who are otherwise unable, due to physical disabilities, to hold or manipulate books or focus or move their eyes to the extent that would be normally acceptable for reading. *Id.* at art. 3.

The treaty has two main operative provisions: The first requires parties to adopt limitations and exceptions to copyright, as further defined in the treaty, to facilitate access by treaty beneficiaries to formats of works that are accessible to them. *Id.* at art. 4. The second requires parties to allow cross-border exchange of accessible-format copies, so that an accessible-format copy made in one state could be sent to and used in another state. *Id.* at art. 5. Importantly, “accessible format” is understood to include, not only formats that are specialized for visually impaired use, such as Braille, and audio generated by synthetic voice technology, but also commercially available audiobooks. The treaty has not yet entered into force; it will enter into force three months after twenty eligible parties have deposited their instruments of ratification or accession. *Id.* at art. 18.

The TRIPS Council is the body responsible for administering TRIPS and for clarifying and interpreting TRIPS provisions.²⁴² The Council passed the lone amendment to TRIPS, the Doha Declaration on the TRIPS Agreement and Public Health (2001),²⁴³ the accompanying Decision on the Implementation of Paragraph 6 of the Doha Declaration (2003),²⁴⁴ and the Protocol Amending the TRIPS Agreement (2005), all of which concerned the permissibility of and conditions under which countries could issue compulsory licenses.²⁴⁵

As it relates to pharmaceutical products, compulsory licensing was also an area of intense negotiations leading up to TRIPS. Developed countries generally sought stronger protection of patented technologies, including pharmaceuticals.²⁴⁶ Developing countries coveted easier access to patented technology, primarily through compulsory licenses.

The compromise resulting from the negotiations was TRIPS Article 31.²⁴⁷ That section, titled “Other Use Without Authorization of the Right Holder,” gives countries broad discretion on, inter alia, government use of compulsory licensing.²⁴⁸ However, the grounds are not unlimited; TRIPS contains numerous conditions that must be met before a government can authorize licenses. Three of the main conditions are that, as a general rule, (1) an effort should be made to negotiate a voluntary license on reasonable commercial terms, (2) the government must provide for “adequate remuneration” to the right holder, and (3) the licensed use must be “predominantly for the supply of the domestic market.”²⁴⁹

While negotiations surrounding the TRIPS compulsory licensing provision were contentious, compulsory licensing in action took center stage in 2001, when South Africa attempted to reduce drug costs and address its AIDS pandemic by enacting the South African Medicines and Related Substances Control Amendment Act of 1997 (the Act).²⁵⁰ The Act allowed local manufacturers to make AIDS drugs (compulsory licensing) or import them from neighboring countries that produced them less expensively than the patent owners (parallel importation).²⁵¹ The Act

242. The Council is also responsible for monitoring compliance with states’ TRIPS obligations by reviewing states’ national implementation legislation.

243. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 ILM 746 (2001) [hereinafter Doha Declaration].

244. *Id.*

245. Jayashree Watal, *From Punta Del Este to Doha and Beyond: Lessons from the TRIPS Negotiating Processes*, 3 WIPO J. 24, 26 (2011) [hereinafter WIPO JOURNAL]. To read which NGOs were helpful to the amendment process, see James Love, *What the 2001 Doha Declaration Changed*, KNOWLEDGE ECON. INT’L (Sept. 16, 2011), <http://keionline.org/node/1267> [<https://perma.cc/2XJX-5BFQ>].

246. Harris, *TRIPS’ Rebound*, *supra* note 29.

247. TRIPS Agreement, *supra* note 6, at art. 31.

248. *Id.*

249. *Id.*

250. Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.).

251. *Id.* at §§ 15C(b), 22A(11)(a).

sought to ensure the supply of drugs at affordable prices, thus allowing those in need to obtain the drugs much less expensively than they would be able to otherwise.²⁵²

In response to the Act, the patent owners of the HIV/AIDS drugs—primarily European and U.S. pharmaceutical companies—objected, arguing that the Act violated international patent laws, including TRIPS.²⁵³ According to these parties, the Act violated TRIPS because it allowed the South African Minister of Health to act unilaterally without first proving that a drug manufacturer abused its patent, and it allowed local manufacturers to make the drugs without first seeking the patent owner’s permission—both of which are required under TRIPS.²⁵⁴

Although the pharmaceutical companies eventually dismissed the suit, the suit highlighted the likelihood that patents and monopoly pricing would keep essential medicines out of the reach of millions of HIV/AIDS patients. This “growing crisis” led WTO Members to meet in Doha, Qatar, to engage in extensive negotiations to address the issue.

In April 2001, in Norway, the WTO Secretariat coordinated with the WHO Secretariat and developed a Workshop on Differential Pricing and Financing of Essential Medicines.²⁵⁵ At about the same time, in a TRIPS Council meeting, the African Group requested a special discussion on IP and access to medicines.²⁵⁶ This took place in June 2001. Developing country demands and pressure from civil society groups that were insistent on improved access to essential medicines caused the WTO Ministerial Conference to adopt the Doha Declaration on the TRIPS Agreement and Public Health in November 2001.²⁵⁷

The Doha Declaration confirmed that patents would not prohibit countries from using compulsory licenses to address public health needs.²⁵⁸ It also granted countries wide discretion and great flexibility in issuing compulsory licenses, including the grounds upon which such licenses could be issued and the amount of remuneration given to the patentee.²⁵⁹ The Doha Declaration also identified a glaring weakness of TRIPS’ compulsory licensing provision: the inability of countries lacking sufficient manufacturing capacity to take advantage of compulsory

252. *Id.*

253. Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 384 (2011).

254. *Id.* at 384–85.

255. See WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines*, WTO Doc No IP/C/M/31 (Restricted) (July 10, 2001), http://www.iatp.org/files/Special_Discussion_on_Intellectual_Property_an.htm [<https://perma.cc/C2WE-NKD9>].

256. *See id.*

257. Duncan Matthews, *WTO Decision On Implementation Of Paragraph 6 Of The Doha Declaration On The Trips Agreement And Public Health: A Solution To The Access To Essential Medicines Problem?*, 7 J. INT’L ECON. L. 73, 81–82 (2004).

258. Harris, *supra* note 253, at 386.

259. *Id.*

licenses to locally manufacture generic medicines. This was remedied a few years later with the August 30, 2003 Decision, which led to an Amendment of Article 31: Article 31bis.²⁶⁰

On December 6, 2005, the WTO Members adopted the Amendment to Article 31.²⁶¹ The Amendment enabled countries without the capacity to manufacture generic substitutes for patented pharmaceuticals under domestic compulsory licenses to import those substitutes from countries that had the manufacturing capability, without risk of interference from patent holders.²⁶² Article 31bis was intended to address the “public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.”²⁶³

The Doha process achieved what many before then had thought impossible: amending the TRIPS Agreement. As I have stated elsewhere, both the process and the result were significant:

As to the process, the WTO members reached a consensus; it was only through their coordinated efforts that they were able eventually to produce the Declaration and then the Amendment. This is nothing short of a miracle, given the challenges involved in getting the WTO Members to agree to what that amendment would entail. Compulsory licensing became politically salient only shortly after TRIPS took effect and at a time when it seemed unlikely that the parties would consider renegotiating an agreement that took over eight years to conclude (the Uruguay Round lasted from 1986-1994). Yet, the WTO members responded and reached a consensus on a contentious issue.

Moreover, the fact that they were able to use the system in the manner they did demonstrates that the system is flexible enough to permit a political process to generate a result that was better than the status quo. The significance of amending a WTO Agreement cannot be overstated. To date, only one WTO Agreement has ever been amended—TRIPS Article 31. In view of the hard fought gains made during the Uruguay Round, and the contentious nature of much of the negotiations, such an achievement demonstrates that TRIPS is responsive to change and that WTO members can indeed “recalibrate the rules.”²⁶⁴

260. *Id.*

261. *Id.*

262. *Id.*

263. *Id.* (quoting World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 ¶ 1 (2002)).

264. *Id.* at 396–97. Unfortunately, amending TRIPS again is improbable. For almost fifteen years, developing countries have attempted to amend TRIPS to clarify the relationship between TRIPS and the Convention on Biological Diversity (CBD), hoping to incorporate a patent disclosure requirement, which would substantiate prior informed consent and benefit-sharing with the country of origin of any biological material and associated traditional knowledge. See Ahmed Abdel Latif, *Change and Continuity in the International Intellectual Property System: A Turbulent Decade in Perspective*, 3 WIPO J., 36, 42 (2011) (“Their latest proposal, in this regard, was submitted to the TRIPs Council in April

In short, the Doha Declaration was revolutionary, as it led to the only amendment of the TRIPS Agreement. The Amendment was the result of widespread participation by NGOs and their coordinated efforts with developing countries. Unlike the examples above, the Doha Declaration was realized within the existing structure of the WTO. As with the Marrakesh Treaty, the Doha Declaration is part of the latest shift in IP thinking, challenging the IP maximalist dogma and reinterpreting TRIPS as more flexible and reflective of the appropriate balance between right holders' interests and the public interest.

Against this background, a number of lessons might be learned. First, there is a change in tide. Developing countries have mobilized and put a halt, if only temporarily, to the ever-increasing rights granted to intellectual property holders. This illustrates Kapczynski's framing theory in action.²⁶⁵ In stark contrast to the conventional IP maximalist philosophy underpinning TRIPS's initial movement, a new notion has arisen that frames intellectual property not as a right, but as a means for improving social and economic development for all countries, particularly developing countries.

Second, there are two important consequences that flow from this shift. It is unlikely that new norms enhancing IP protection will arise outside the current efforts by the United States/EU in bilateral and plurilateral treaties—and even these have come under increasing attacks. Furthermore, as clearly established by the Doha Declaration, the Marrakesh Treaty for the Blind, and other recent developments, developing countries' interests can sometimes take precedence over the interests of individual right holders. While tension between these interests remains and will continue, the global outcry against intellectual property rights that limit countries' discretion in vital areas of public interest has given civil rights organizations, NGOs, developing countries, etc. a platform for change in the IIP system. However, if history is any guide, this opportunity may not last. The cyclical nature of the IIP system and, particularly, the battle between stronger protection for intellectual property rights and the public interest in benefiting from the use of intellectual property suggests that now is the time to press forward. The examples of lawmaking above can provide guidance on how to do so.

VI. THE DECLARATION: A NEW MODE OF IIP LAWMAKING?

The Declaration does not fit neatly within any of the above modes of lawmaking. It is outside the dominant state-centric institutions, and involves an issue that is already part of the international discourse, unlike the services narrative. But this is of no consequence. The previous section was intended to highlight two points. The first is the changing nature of IIP lawmaking. The point here was neither to suggest that these are exhaustive modes of lawmaking, nor to highlight

2011. However, that proposal continues to face strong opposition and has little chance of being concretized in any near future, more so in the context of the current stalemate in the Doha Round of Trade Negotiations.”).

265. Kapczynski, *supra* note 152, at 884–85.

any particular mode of lawmaking. Rather, it was meant to capture the changing nature of lawmaking and to point out that international actors have these paths available to them. In that sense, the preceding section breaks no new ground, but it is a reminder not to focus myopically on one mode when others are available.

The second point is that despite seemingly overwhelming odds, change can indeed happen, and it can happen with regard to controversial and contentious issues. The Doha Declaration and accompanying Protocol significantly changed the rules regarding states' ability to manufacture and export pharmaceutical drugs—an extremely contentious issue. The Amendment changed existing rules, which is no easy task. The Marrakesh Treaty did not change existing law, but just as importantly, it created new mandates for countries to expand—as a right—their copyright limitations and exceptions, again providing countries greater discretion in implementing intellectual property laws by expressly taking into account other interests. States' discretion in general, and specifically with regard to pharmaceutical products, as well as the ability to expand limitations and exceptions to intellectual property rights, are relevant with regard to the Max Planck Institute Declaration on Patent Protection.

How, then, might we use the Declaration? I do not pretend here that there is a silver bullet, nor do I advocate for a particular approach in order to achieve the desired ends. What I do share is the ultimate goal of the Declaration. I do not, however, believe the solution lies with the unorthodox interpretation advanced in the Declaration. Renouncing the negotiating history and overcoming *de facto* stare decisis are obstacles not easily overcome.

The Declaration presents an opportunity. The Declaration can leverage the lessons of these various modes of lawmaking to realize its desired objective. Moreover, doing so by these alternative modes allows the Declaration to purchase legitimacy and certainty.

While there is no silver bullet, the prior successful models provide some ideas. First, the forum matters. While this is undoubtedly true in most global governance, in intellectual property, the decision-making forum impact is more pronounced.²⁶⁶ Thomas Cottier and Marina Foltea observe that for states wishing to better balance owners' interests and public interests, multilateral institutions fare better than other institutions (e.g., bilateral and plurilateral arrangements).²⁶⁷ Multilateral regimes are superior because of “their ability to reflect and achieve a finer balance among the interests at stake.”²⁶⁸ If this is true, WIPO seems to be the forum with the greatest promise.

266. Thomas Cottier & Marina Foltea, *Global Governance in Intellectual Property Protection: Does the Decision-making Forum Matter?*, 3 WIPO J. 139, 143 (2012).

267. *Id.* (“[M]ultilateral institutions offer a more appropriate balance of rights and obligations than bilateral and plurilateral instruments.”). The authors note that “the interests to be weighed depend on the issues and the forms of IP concerned in a specific case and may appear in diverse forms.” *Id.*

268. *Id.*

Immediately after the WTO was created, WIPO lost relevance. Since then, however, WIPO has been successful at reestablishing itself as a major venue for negotiating intellectual property issues. This is important because the WTO has become a more difficult forum in which to negotiate, as evidenced by the stalled Development Round.²⁶⁹ Moreover, the WIPO process is markedly different and more favorable than the WTO. In particular, WIPO, unlike the WTO, permits private parties to participate.²⁷⁰ These private parties play a significant role at WIPO negotiations.²⁷¹ The Secretariat has accredited various NGOs, which are now permitted to attend most preparatory meetings as well as the formal negotiating sessions.²⁷² They observe and participate, “making ‘interventions’ to explain to governments their perspectives on the issues.”²⁷³ In contrast, the WTO is decidedly less open, not only excluding private parties but also limiting the distribution of WTO documents that are submitted or drafted by governments.²⁷⁴ The WIPO level of transparency and openness provides greater room for parties to balance interests to the mutual advantage of different interest groups.²⁷⁵ As Cottier and Foltea state: “This type of decision-making is more likely to garner the support of national lawmakers on the merits of the negotiated proposal and undoubtedly enhances the legitimacy of the multilateral norm-setting process.”²⁷⁶

A number of other factors also favor WIPO. It is the venue of the most recent success story, the Marrakesh Treaty, which also involved limitations and exceptions to intellectual property rights. Further, it is also the forum that administers the treaty to which TRIPS’s limitation and exceptions provisions and the three-step test owe their origin: the Berne Convention. TRIPS’s limitations and exceptions provisions were all modeled on Berne Article 9.2, which provides: “It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”²⁷⁷ While there are some differences, it would not seem

269. *Contested Multilateralism*, *supra* note 4, at 394. See generally MAY & SUSAN SELL, INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY (2006).

270. Cottier & Foltea, *supra* note 266, at 160.

271. *Id.*

272. Nancy Kremers, *Speaking with a Forked Tongue in the Global Debate on Traditional Knowledge and Genetic Resources: Are U.S. Intellectual Property Law and Policy Really Aimed at Meaningful Protection for Native American Cultures?*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1, 55 (2004).

273. Doris Estelle Long, “Democratizing” Globalization: Practicing the Policies of Cultural Inclusion, 10 CARDOZO J. INT’L & COMP. L. 217, 257–58 (2002).

274. See General Council Decision, Guidelines for Arrangements on Relations with Non-Governmental Organizations, ¶ VI, WT/L/162 (July 23, 1996), http://www.wto.org/english/forums_e/ngo_e/guide_e.htm [<https://perma.cc/W3V4-WWJ5>] (“As a result of extensive discussions, there is currently a broadly held view that it would not be possible for NGOs to be directly involved in the work of the WTO or its meetings.”).

275. Cottier & Foltea, *supra* note 266, at 143.

276. *Id.* at 150.

277. Berne Convention, *supra* note 55, at art. 9, ¶ 2.

inappropriate for WIPO to issue an authoritative interpretation of corresponding TRIPS provisions, particularly as WIPO and the WTO have engaged more recently in collaborative efforts.

Second, beyond the forum, process matters. Jayashree Watal, the Indian negotiator during the TRIPS negotiations and a counselor at the WTO Intellectual Property Division, provides valuable insight regarding the different outcomes for developing countries in TRIPS as contrasted with Doha by contrasting the process involved in each.²⁷⁸ In particular, she identifies three main considerations that led to the successful Doha outcome, which were absent for developing countries in the decidedly less than successful TRIPS outcome.²⁷⁹ First, she states that a genuine coalition presenting a coherent, united front is more likely to succeed than not.²⁸⁰ Second, she advises, “negotiating proposals need to be specific and credible.”²⁸¹ Finally, she notes that an important factor contributing to the credibility of negotiating positions is public support.²⁸²

In greater detail, she explains how during TRIPS the developed countries had a coordinated plan, directed by the United States and European Communities, and came forward with a detailed draft for TRIPS negotiations.²⁸³ In contrast, developing countries did not prepare a counterdraft and instead relied on the GATT Secretariat to prepare one draft for all developing countries, but that draft contained vague and general language and did not fully or accurately represent the various differences among the developing countries.²⁸⁴ Further, “interested parties in developed countries spread the perception that developing countries were pirates and counterfeiters—and by and large, the moral high ground was held by the accusers.”²⁸⁵ This put developing countries on the defensive with regard to intellectual property, a position from which they did not recover. These, she claims,

278. See generally Jayashree Watal, *From Punta Del Este to Doha and Beyond: Lessons from the TRIPs Negotiating Processes*, 3 WIPO J. 24, 24–35 (2011).

279. *Id.* at 34.

280. *Id.*

281. *Id.*

282. *Id.* (“Gained from the interested public outside, especially civil society groups in developed countries.”).

283. *Id.* at 27. (“However, in large part, the TRIPs language reflects the texts put forward in the first half of 1990 by developed countries due to the relatively united positions adopted by them from the early stages of the negotiations, as against the largely divided South, who could only enunciate very general positions in Approach B. It did not help that there was no support from interested persons in the general public, which were instead hostile, at least in developed countries, to the cause espoused by developing countries.”).

284. *Id.* at 26. (“On standards, the B group [developing country] proposals were limited to general language about leaving substantive rules up to national legislation, including on the term of protection of various IPRs. This may well have been a mistake as more specific proposals, say a patent term of 15 years, may have been easier to defend or amend in a timely way, in order to negotiate a middle ground on standards as there was no way to achieve consensus on such broad language, especially when pitted against quite specific proposals made by developed countries.”).

285. *Id.* at 25.

were important factors outside the TRIPS negotiations that influenced the final outcome.²⁸⁶

Doha was different. There, developing countries presented a unified front. Due to active campaigning by civil society groups with regard to access to essential medicines, the public took “keen interest” in this issue throughout the buildup to Doha.²⁸⁷ During negotiations, key delegations made statements to the press, who were waiting outside council meetings, “demonstrating how the statements were made as much for public consumption as for other Members.”²⁸⁸ Moreover, in addition to the African Group, which proposed to the WTO Council a meeting on the subject, a substantial group of developing states submitted a joint proposal at the Council meeting requesting a special declaration on the TRIPS Agreement and access to medicines.²⁸⁹ This joint proposal ultimately formed the basis of the Doha Declaration.²⁹⁰ “Thus,” as Watal exclaims, “developing countries spoke in one voice and set the agenda by focusing on clarification of TRIPs flexibilities.”²⁹¹ She compares the response of the developed countries: “However, when it came to making a counter submission to the developing countries’ text or to the later more legalistic text to help negotiate a declaration, the United States, joined by Australia, Canada, Japan and Switzerland, only came up with general preambular language even as late as one month before the Doha ministerial meeting.”²⁹² It is no surprise, then, that the outcomes of TRIPS and Doha differed significantly.

Watal’s insight about public perception coincides with Kapczynski’s about framing. Kapczynski argues that “acts of interpretation” play a vital role in “instigating, promoting, and legitimating collective action.”²⁹³ She argues that “[t]hese acts of interpretation or framing are both socially mediated and contingent.”²⁹⁴ As she explains, “ideas can be a resource for those engaged in mobilization, but one that is not fully in their control. Frames thus can lay the scaffolding for a countermovement even as they pave the way for a movement’s success.”²⁹⁵ Like Watal, Kapczynski credits public support, garnered by effective framing, as being crucial to the success of the access to medicines campaign.²⁹⁶

Building on these insights, the drafters can then lean on the teachings above regarding the new dynamics of intellectual property lawmaking and grassroots movements. The contribution of these efforts begins with the process of forming a community of experts, with the goal of presenting a unified position on TRIPS’s

286. *Id.*

287. *Id.* at 28.

288. *Id.*

289. *Id.*

290. *Id.*

291. *Id.*

292. *Id.*

293. Kapczynski, *supra* note 152, at 804.

294. *Id.*

295. *Id.*

296. *Id.*

flexibilities that reaches decision makers responsible for forming IP policy. The Declaration has an excellent start, having been drafted by experts from across the globe. The key here is not only to clarify positions, but also to raise public consciousness. Of course, access to top policymakers will be crucial.

As should be obvious, these efforts need not be limited to intellectual property folks, as public interest often overlays with other regimes. This provides an opportunity to join with other groups, civil rights organizations, and those interested in the greater use of goods to increase social welfare. The reach of intellectual property into many other diverse areas should make joining with other groups a relatively easy task. Also, again, WIPO's framework supports this. Here, too, reports, articles, and the Declaration can be widely disseminated, as was done in the labor movement's successes. Moreover, as was done there, transnational action networks must be developed to provide alternative and additional channels for communication. In the realm of human rights, NGOs have enacted this step by playing major roles in conferences in areas other than human rights, such as nutrition, development, and peace.²⁹⁷ I submit that these steps might be a starting point.

CONCLUSION

Above I detailed efforts by nonstate actors, such as the Max Planck Institute and the drafters of the Declaration for Patent Protection, to agitate to generate pressure on existing doctrine, with an eye towards undermining that doctrine in the long term. Perhaps there is nothing extraordinary going on here and the ideas contained in the Declaration represent part of an ongoing give-and-take over trade rules that constitutes a healthy trade politics. But I am not optimistic about the content of the Declaration, even while sharing the Declaration's ultimate goal. I believe the doctrine holding the Declaration together is not strong enough to renounce the TRIPS's negotiating history or to ignore contrary WTO decisions.

But my pessimism does not lead me to abandon the Declaration. Instead, it leads me to look for other ways to achieve the goal by examining other modes of lawmaking. In short, rather than looking to the unorthodox reading or interpretation of the Declaration, we should look at the Declaration not for what it says but as a rallying point or catalyst to utilize these other forms of lawmaking. We can lean on these to open the door for legal change. We can do so by looking for new connections (as was done with services) or new multinational agents (as was done with access to medicines), and by employing the fragmented IIP process (as was done with TRIPS). Ironically, and importantly, the Declaration can serve this purpose.

In sum, the fight is not over. We can borrow from the rare and hard fought successes, such as Doha and Marrakesh, and translate these successes to the Declaration's struggle. It is with renewed hope that I join this struggle.

297. Hubbard, *Reimagining Workers' Human Rights*, *supra* note 211, at 27–28, 42.