TRIPS AGREEMENT FLEXIBILITIES AND THEIR LIMITATIONS: A RESPONSE TO THE UN SECRETARY-GENERAL'S HIGH-LEVEL PANEL REPORT ON ACCESS TO MEDICINES

ERIC M. SOLOVY* AND PAVAN S. KRISHNAMURTHY**

ABSTRACT

Members of the World Trade Organization (WTO) must establish minimum standards of patent protection that are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including for pharmaceutical products. In describing the "flexibilities" accorded pursuant to the TRIPS Agreement, however, the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (HLP Report) strays far from principles of treaty interpretation under the Vienna Convention on the Law of Treaties (Vienna Convention or VCLT).

While the HLP Report correctly identifies and catalogues a number of flexibilities that are explicitly referenced in the patent provisions of the TRIPS Agreement—such as transitional periods for least developed countries or deference relating to patent exhaustion—the HLP Report finds other flexibilities that are derived only from an improper interpretation of the Agreement. Particularly problematic is the HLP Report's encouragement of WTO Members to make use of a broad "freedom to determine"—for themselves—the meaning of substantive requirements of patentability in the interests of advancing short term access to existing medicines.

After describing the principles of treaty interpretation, the Article outlines the patent-related TRIPS flexibilities and their limitations, including (i) ex ante flexibilities, relating to the initial grant of the patent, and (ii) ex post flexibilities, relating to the rights conferred to a patent owner.

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* Partner, International Trade & Dispute Resolution, Sidley Austin, LLP. B.A. 1996, Duke University; J.D. 1999, Harvard Law School. From 2001–2002, Mr. Solovy served as law clerk to the Honorable Pauline Newman, Circuit Judge, U.S. Court of Appeals for the Federal Circuit. From 2008–2010, Mr. Solovy served as an adjunct professor at the American University Washington College of Law, teaching a course on International and Comparative Patent Law.

** Associate, International Trade & Dispute Resolution, Sidley Austin, LLP. B.A. 2012, Northwestern University; MSc 2014, London School of Economics; J.D. 2017, Georgetown University Law Center.

In doing so, the Article highlights instances where the HLP Report inappropriately recommends and encourages WTO Members to disregard substantive requirements of the TRIPS Agreement. Finally, the Article considers TRIPS-plus protections as an additional "flexibility" available to WTO Members.

Introduction

When the World Health Organization (WHO) presents and regularly updates its Model List of Essential Medicines, an interesting paradox is highlighted. While approximately ninety-five percent of essential medicines are not currently protected by patents,[1] organizations advocating for greater access to existing medicines have spent a disproportionate amount of time criticizing international patent protections.

In September 2016, the United Nations Secretary-General's High-Level Panel on Access to Medicine published a much-anticipated report on the promotion of innovation and access to health technologies (HLP Report or Report).[2] The stated motivation for the HLP Report was "to propose ways of incentivizing health technology innovation and increasing access to medicines and treatment."[3] The Report acknowledged that incentives for innovation stem from the pharmaceutical industry's ability to recoup the costs of research and development (R&D), and that such "[i]nnovation is vital to achieving the 2030 Agenda's [Sustainability Development] [G]oal of improving the health and well-being of all people at all ages . . . ."[4] Among other topics, the HLP Report considered

1. *See, e.g.*, Reed F. Beall, *Patents and the WHO Model List of Essential Medicines (18th ed.): Clarifying the Debate on IP and Access*, WIPO Global Challenges Brief (2016) ("Of the 375 items on the 2013 WHO MLEM, 95% are off-patent, meaning that these medicines patents' have expired and that generic equivalents are likely available."); D. Wayne Taylor, Cameron Inst., Pharmaceutical Access in Least Developed Countries: On-the-Ground Barriers and Industry Successes 5 (2010) ("WHO's list of essential medicines is comprised of over 95% off-patent products – the remainder being primarily second-line anti-AIDS medicines."); Steve Brachmann & Gene Quinn, *95 Percent of WHO's Essential Medicines are Off-Patent*, IPWatchDog (Sept. 12, 2016), http://www.ipwatchdog.com/2016/09/12/essential-medicines-off-patent/id=72542/ ("Going back to the early 2000s, the percentage of essential medicines on WHO's MLEM which are off-patent has consistently been between 90 to 95 percent.") [https://perma.cc/696U-JGCS].

2. *See* U.N. Secretary General and Co-Chairs of the High-Level Panel, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicine: Promoting Innovation and Access to Health Technologies* (Sept. 2016) [hereinafter HLP Report or Report]. Only three of the fifteen panelists on the High-Level Panel appear to have been legally trained (Judge Awn Al-Khasawneh, Michael Kirby, and Ruth Okediji). *Id.* at 65; *see also The Panel*, United Nations Sec'y-Gen.'s High-Level Panel on Access to Medicines, http://www.unsgaccessmeds.org/new-page/ (last visited Aug. 28, 2017) (listing the bios of the panel members) [https://perma.cc/7T38-UVC2].

3. *See* HLP Report, *supra* note 2, at 7.

4. *See id.* at 14; *see also* William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law 13 (2003) ("To take an example from intellectual property, a firm is less likely to expend resources on developing a new product if competing firms that have not borne the expense of development can duplicate the product and produce it at the same marginal cost as the innovator; competition will drive price down to marginal cost and the sunk costs of invention will not be recouped."); Stanley M.

literature on the relationship between access to medicines and patent protection, and arrived at recommendations that, like much of the underlying literature, disproportionately targeted international and domestic intellectual property protection as a significant problem.[5]

As its very first solution, the HLP Report proposes that countries can increase short-term access to medicines by taking advantage of the broad "flexibilities" within the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[6] While there are certainly some flexibilities in the TRIPS Agreement that readily flow from proper application of the rules of treaty interpretation, other so-called flexibilities result only from turning a blind eye to those very rules.

Most notably, in recent years, developing countries have been increasingly counseled by certain international organizations and academics that, because certain terms in the TRIPS Agreement may be difficult to understand for countries lacking a long tradition of providing patent protection (particularly for pharmaceutical products), those terms can be interpreted in such a way as to exclude patent protection for broad categories of pharmaceutical products and processes—as they see fit.[7] This view encourages implementing overly strict patent eligibility requirements that will

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Bensen & Leo J. Rasking, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. Econ Persp. 3, 5 (1991) ("[P]rivate producers have an incentive to invest in innovation only if they receive an appropriate return. Whether producers will have the correct incentives depends on their ability to appropriate at least some of the value that users place on those works. If potential innovators are limited in their ability to capture this value, they may not have enough incentive to invest a socially optimal amount in innovative activity.").

5. *See* HLP Report, *supra* note 2, at 9.

6. *Id.* at 6, 9 (defining TRIPS flexibilities as "a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement's obligations, including limits on the exercise of intellectual property rights"); *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement]; HLP Report, *supra* note 2, at 27 (detailing various TRIPS "flexibilities").

7. *See, e.g.*, Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 3 (ICTSD, WHO, UNCTAD, Working Paper, Jan. 2007) [hereinafter Correa Guidelines I] ("[T]he concept of invention as applied in various countries significantly differs. The TRIPS Agreement, however, does not seem to interfere with such diversity."); Carlos M. Correa, UNDP, Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective 12–13 (2016) [hereinafter Correa Guidelines II] ("Most patent laws do not define invention, leaving the specific boundaries of this concept to patent offices and courts to determine. . . . The concept of novelty, [for example], may be applied in different ways, depending on the legislation and interpretation by patent offices and courts.") (footnotes and internal quotations omitted). *See generally* Sisule F. Musungu & Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to

lead WTO Members to violate their international obligation to make good faith, proper interpretations of the ordinary meaning of the terms in the TRIPS Agreement, in light of context, and the object and purpose.[8]

A proper interpretation of the provisions in Part II, Section 5 of the TRIPS Agreement (i.e., the standards concerning the availability, scope, and use of patent rights) must take into account that the TRIPS Agreement is intended to balance (i) the need to provide incentives for the costly R&D necessary to create new medicines over the long-term, with (ii) the desire to enable short-term access to those medicines, once developed and properly tested.[9] More generally, such an interpretation must be performed in line with the rules of treaty interpretation, as detailed below. One cannot simply say, as do the authors of the HLP Report, that the existence of difficult-to-define terms implies that "it is up to countries to define these in their laws and policies" and that Members have "the freedom to determine patentability criteria."[10]

Flexibilities in the patent section of the TRIPS Agreement can be divided into two broad categories: *ex ante* and *ex post*.[11] Rules defining the subject matter eligible for patent protection involve *ex ante* considerations, in that they ask questions arising *before* the grant of patent rights by a country. Once granted, however, the rights accorded to patent holders can be considered *ex post* rules. While the flexibilities proposed by advocates for greater short-term access to medicines include both *ex ante* and *ex post* flexibilities, some of the proposals for *ex ante* flexibilities are particularly problematic, especially the proposals on how to implement the patentability requirements listed in Article 27.1 of the TRIPS Agreement.

The HLP Report provides a "snapshot" of "[p]ublic-health related TRIPS flexibilities,"[12] listing the following categories of flexibilities:

- Parallel imports (citing Article 6 of the TRIPS Agreement);
- Patentability criteria (citing Article 27 of the TRIPS Agreement);

MEDICINES? iii (Aug. 2005) (identifying the flexibility within TRIPs that afford nations the ability to develop patent protection systems that benefit public health).

8. *See* Vienna Convention on the Law of Treaties, art. 31(1), May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT or Vienna Convention].

9. *See infra* Section II.C; TRIPS Agreement, *supra* note 6, arts. 7–8.

10. *See* HLP Report, *supra* note 2, at 6, 8.

11. *See generally* Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (criticizing *ex post* justifications).

12. *See* HLP Report, *supra* note 2, at 18 (Box 4).

- General exceptions to patent rights (citing Article 30 of the TRIPS Agreement);
- Compulsory licensing and government use (citing Article 31 of the TRIPS Agreement);
- Competition/antitrust-related provisions (citing Articles 8, 31(k), and 40 of the TRIPS Agreement);[13] and
- Transition periods (citing Articles 65 and 66 of the TRIPS Agreement, and implicitly subsequent agreements to further extend those periods).

While the flexibilities related to "patentability criteria" and "transition periods" involve *ex ante* flexibilities (permissible at the time of considering whether or not to grant patent protection), the others are *ex post*, relating to rights accorded to patents, only once granted. While a number of the flexibilities promoted by the HLP Report are straight-forward and clear—such as the extended transition period allowing least developed countries (LDCs) until 2033 to protect patents on pharmaceutical products—others are far more controversial.

The remainder of this Article proceeds as follows: Section I provides a backdrop for the policy debate on the relationship between innovation and access. Section II then describes the principles of treaty interpretation and considers how they should be applied to the specific context of the TRIPS Agreement. Section III outlines a WTO Member's obligations, *ex ante*, pursuant to the TRIPS Agreement to grant patents, and considers the *ex ante* flexibilities proposed by, *inter alia*, the HLP Report. The Article concludes that the HLP Report is inappropriately recommending and encouraging WTO Members to disregard the *ex ante* obligations in Part III, Section 5 of the TRIPS Agreement, properly interpreted, in the name of "flexibility" and access. Section IV outlines rights conferred to patent holders, *ex post*, and highlights some of the limitations on the flexibilities accorded by the TRIPS Agreement after a patent has been granted. Section V introduces a flexibility that is both *ex ante* and *ex post*: the flexibility to provide TRIPS-plus protections. The Conclusion follows.

13. This paper does not address the provisions addressing the relationship between competition/antitrust law and intellectual property. *See* TRIPS Agreement, *supra* note 6, arts. 8, 31(k), 40. Members may, consistent with the TRIPS Agreement, adopt measures to remedy or prevent intellectual property-related anti-competitive conduct.

I. Innovation-Access Policy Context

From the outset, the HLP Report acknowledges the competing goals of (i) establishing incentives for innovation, in part through patent protection; and (ii) providing increased short-term access to patented medicines that have previously been created, tested, and approved.[14] Unfortunately, when it came time to issue recommendations on how to provide balance, short-term access goals appear to have far overtaken the goals to provide incentives for innovation through patent protection. While there is nothing unusual about a high-profile report arriving at controversial decisions on the best ways to balance competing policy goals, the HLP Report is particularly problematic in that it justifies those decisions by encouraging countries to effectively overlook their international treaty obligations, particularly those in the TRIPS Agreement.

The HLP Report begins with important recognitions about how far R&D has gone to improve patients' lives:

> Never in the past has our knowledge of science been so profound and the possibilities to treat all manner of diseases so great. Many sources of transmissible and non-transmissible diseases have been identified, and therefore prevention, including the fight against bacteria, viruses and parasites, has improved dramatically. New generations of medicines and their combinations are treating patients whose prognosis some years ago would have been fatal. . . . Progress in fundamental research is nourishing an exceptional phase of development of medicines, vaccines, diagnostics and medical devices.[15]

The Report then goes on to highlight that, despite these advancements, "many people and communities in need of effective prevention methods, life-enhancing and life-saving treatments and rehabilitation do not receive them."[16] To blame, according to the Report, are "unhealthy environments," inaccessible or poorly-equipped health services, lack of medicines that do not yet exist, and "prices that are too high."[17] Then, the Report targets patents as one of the primary causes, if not *the* primary cause, of limited access to medicines.

Notably, the HLP Report's Terms of Reference situates the Report as being consistent "with the findings and recommendations of the Global Commission on HIV and Law," as well as "the post-2015 development agenda and the recently adopted Sustaina-

14. *See* HLP Report, *supra* note 2, at 8, 17.
15. *Id.* at 3.
16. *Id.*
17. *Id.*

ble Development Goals . . . ."[18] Notwithstanding that numerous factors limit access to medicines other than patents, the very first item on the Report's Terms of Reference concerns the "[f]ailure to reduce the costs of *patented* medicines."[19]

At the same time, the HLP Report does not accord sufficient credit for the role of patent protection in creating the medicines that currently exist, or for creating the potential to develop new medicines. While the HLP Report does acknowledge, in passing, that patents and other intellectual property (IP) rights "have enabled right holders to generate the revenues that have contributed to the R&D of medicines, vaccines and diagnostics over the last half century or so that have benefited health and human development,"[20] this acknowledgement is ignored for much of the remainder of the Report and especially in the recommendations. Rather, the Report describes IP rights as *obstacles* to access to medicines. It characterizes IP rights as "temporary, revocable, transferable privileges granted by states [that] *can be suspended or revoked under certain conditions laid out in the TRIPS Agreement when it is in the interest of the state or society.*"[21]

The HLP Report introduces the TRIPS Agreement in its Executive Summary, referring to this agreement as having "ushered in a new and unprecedented era of global intellectual property norms and [having] created a new standard of intellectual property protection and enforcement."[22] Rather than commenting on any positive impact that this "era of global intellectual property norms" could create in terms of new drug development, the Report immediately turns in the very next sentence to the topic of "flexibilities" or "safeguards" that "could be used by signatories to tailor national intellectual property regimes so that countries could fulfil their human rights and public health obligations."[23] This is followed by a critique of free trade agreements with even higher levels of IP protection, as potentially "imped[ing] access to health technologies."[24] In this way, IP, generally, and the TRIPS Agreement, spe-

18. *See* HLP Report, *supra* note 2, at 66; s*ee also* Kristina Lybecker, *UN Panel on Access to Medicines Should Ensure Innovation by Preserving Market Incentives*, IPWatchDog (Feb. 15, 2016), http://www.ipwatchdog.com/2016/02/15/un-panel-access-to-medicines-innovation/id=66095/ (outlining the United Nations' Sustainable Development Goals) [https://perma.cc/2TUL-JLFF].

19. HLP Report, *supra* note 2, at 66 (emphasis added).

20. *See id.* at 21.

21. *Id.* at 20 (emphasis added).

22. *Id.* at 7.

23. *Id.*

24. *Id.*

cifically, are introduced at the very outset of the Report as a threat to public health, rather than as something that is properly credited for establishing standards that help incentivize development of essential medicines. This theme continues throughout the HLP Report, including at the conclusion of the section on "patentability criteria," where the Report instructs that "[g]overnments can adopt legislation to limit *excessive patenting*." [25]

Later in the Report, the authors discuss "a few mechanisms that have been used by governments out of a range of voluntary and non-voluntary mechanisms available to increase access to health technologies and promote the right to health," all of which involve failing to protect IP rights for pharmaceutical products.[26] Specifically, among the "mechanisms" included in their discussion are references to: (1) the Republic of Korea's Patent Act of 1961 which, according to the HLP Report, "excluded foodstuffs, chemicals and pharmaceuticals from patentability and only allowed for 12 years of patent protection on other fields of technologies"; and (2) India's Patent Act of 1970, which excluded pharmaceutical products from patent protection.[27] The Report then goes on to tout the benefits of India having had no patent protection on pharmaceuticals during that time, stating "[t]his reduced the number of patents by as much as 75%, according to some estimates, and paved the way for India's thriving generic medicines industry."[28] What is missing, however, is any consideration of what impact these policies in Korea and India had on innovation, either within those countries or globally. Nor, is there any recognition in the immediate context of this discussion that these "mechanisms . . . to increase access to health technologies" would, without any doubt, violate the TRIPS Agreement if India or Korea were to use them today—irrespective of the flexibilities promoted in the HLP Report.[29]

The HLP Report's Terms of Reference, furthermore, called for the Report to "review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."[30] The concern about policy incoherence is not new, particularly among international organizations. For example, just a year after the TRIPS

25. *Id.* at 23 (emphasis added).
26. *Id.* at 21.
27. *Id.*
28. *Id.* (internal citation omitted).
29. *See id.*; *infra* Section III.C.
30. HLP Report, *supra* note 2, at 66.

Agreement was adopted—1996—the World Health Assembly (WHA), the supreme decision-making body of the WHO, requested the WHO "to report on the impact of the [WTO] with respect to national drug policies and essential drugs . . . ."[31] Since then, reports of the UN Special Rapporteur on the Right to Health,[32] resolutions of the United Nations' Human Rights Council (HRC),[33] reports to the HRC,[34] and a series of WHA resolutions have created—as some have argued—policy incoherence between these international bodies, on the one hand, and the WTO TRIPS Agreement obligations, on the other.[35]

Nevertheless, WTO Members have attempted to reduce policy incoherence, both perceived and real, in several respects, including through declarations by its membership such as the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and a recently-enacted amendment to the TRIPS Agreement.[36] These are discussed in the Sections that follow.

WTO Members, in some instances, have exercised their right to initiate WTO dispute settlement to incentivize compliance with the TRIPS Agreement, including with respect to patents on pharmaceutical products. For example, as discussed below, the European Union launched a dispute against Canada in 1997, challenging a measure that facilitated the early launch of generic pharmaceuticals at the expense of the patent rights on innovative pharmaceuti-

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31. *Revised Drug Strategy*, World Health Assembly Res. WHA49.14 (May 25, 1996).

32. *See, e.g.*, U.N. Human Rights Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, U.N. Doc. A/HRC/17/43 (Mar. 16, 2011) (summarizing discussions before the Human Rights Council regarding access to medicines has a fundamental component of the right to health).

33. *See, e.g.*, Human Rights Council Res. 17/14, U.N. Doc. A/RES/17/14 (July 14, 2011) (declaring "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and calling upon the international community to assist developing countries in realizing that right).

34. *See, e.g.*, U.N. Human Rights Council, *Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria – Report of the Secretary-General*, U.N. Doc. A/HRC/7/30 (Mar. 4, 2008) (discussing access to medicine as a fundamental human right in the context of access of medication to address widespread pandemics).

35. In fact, the HLP Report begins with the assumption that "[p]olicies that have a bearing on access to health technologies that are associated with trade, intellectual property, health and human rights were developed with different objectives and at different periods in history." *See* HLP Report, *supra* note 2, at 16.

36. *See, e.g.*, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/Dec/2, ¶ 5(a) (Nov. 14, 2001) [hereinafter Doha Declaration]; *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Jan. 23, 2017) [hereinafter TRIPS Amendment]; *see also Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Aug. 30, 2003) [hereinafter TRIPS Waiver].

cals.[37] While activists may have today characterized the Canadian measure as containing permissible "flexibilities" given the goal of increasing short-term access to lower-cost medicines, a WTO panel found that one aspect of that measure (allowing stockpiling of generic drugs prior to expiration of the patent) constituted a violation of the TRIPS Agreement.[38] As a result, Canada modified its law within six months, and complied with the panel's ruling.[39]

The HLP Report criticizes the use of "undue political and economic pressure from states and corporations, both express and implied" as a reason why governments have not "used the flexibilities available under the TRIPS Agreement."[40] To the extent the Report is criticizing WTO Members for identifying or challenging certain measures as inconsistent with the TRIPS Agreement, such a critique is misguided.[41] The WTO dispute settlement system is, according to Article 3.2 of the WTO Dispute Settlement Understanding (DSU), "a central element in providing security and predictability to the multilateral trading system."[42] It "serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements."[43] WTO dispute settlement is frequently used by both

37. *See* Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000) [hereinafter Panel Report, *Canada—Pharmaceutical Patents*].

38. *Id.*

39. *See Minutes of Meeting Held in the Centre William Rappard on 23 October 2000*, WTO Doc. WT/DSB/M/91, ¶ 119 (Nov. 30, 2000).

40. *See* HLP Report, *supra* note 2, at 25. Among the cited examples of "undue . . . pressure" was the investor-state arbitration instituted under the North American Free Trade Agreement (NAFTA) in which Eli Lilly alleged that the Government of Canada had expropriated its investment by invalidating several patents on medicines for Strattera and Zyprexa. *See id.* at 45 n.121. Canada successfully defended its position in that case. *See* Eli Lilly and Company v. Canada, ICSID Case No. UNCT/14/2 (Mar. 16, 2017) (Final Award). As a result, Eli Lilly was required to pay a significant portion of Canada's legal fees. This was an instance where a company took advantage of its right to allege a breach of international treaty obligations, and where the arbitrators decided that there was no such breach. The HLP Report's implication that this is an instance of "undue political and economic pressure" used to "dissuade governments from using the flexibilities that could protect public health," *see* HLP Report, *supra* note 2, at 121, is not explained.

41. The HLP Report, in Box 7, refers to a situation involving compulsory licensing in Thailand, which is summarized as sparking "hostility from the manufacturer, Merck, and the United States Government, which *questioned the legality of the compulsory license*." HLP Report, *supra* note 2, at 24 (emphasis added).

42. DSU, Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 3.2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994) [hereinafter DSU].

43. *Id.*

developed and developing countries to assert their rights. It is intended, in part, to prevent unilateral action by individual countries. Thus, rather than "violat[ing] the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement,"[44] as alleged by the HLP Report, recourse to WTO dispute settlement is, in fact, an important component of the WTO system itself.[45] If a Member is exercising a "flexibility" under the TRIPS Agreement that is permitted, based on a proper interpretation of the relevant treaty provisions, then such measure will withstand scrutiny by a WTO panel or the Appellate Body, and that flexibility can persist unabated. However, if that Member's recourse to "flexibility" goes too far, then that too can be clarified through dispute settlement, which likewise creates greater certainty for Members and companies alike.

Importantly, because the WTO dispute settlement system's remedies are prospective, any Member defending against a successful claim of over-using the flexibilities in the TRIPS Agreement will need to modify the challenged measures or actions only after the panel report or, if appealed, the Appellate Body Report has been adopted by the WTO Dispute Settlement Body.[46] If that Member fails to comply within a reasonable period of time,[47] any remedies (which "shall be equivalent to the level of the nullification or impairment" caused by the violation) will be authorized only *after* that reasonable period of time elapses.[48] This limits the criticism

44. *See* HLP Report, *supra* note 2, at 8.

45. In fact, international dispute settlement has been considered the most important development in global trade governance. *See generally* J.H.H. Weiler, *The Rule of Lawyers and the Ethos of Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement*, 35 J. World Trade 191 (2001).

46. *See generally* Patricio Grané, *Remedies under WTO Law*, 4 J. Int'l Econ. Law 755, 760 (2001) ("[R]emedies in the WTO are prospective and forward looking."); Andrew W. Shoyer, Eric M. Solovy & Alexander W. Koff, *Implementation and Enforcement of Dispute Settlement Decisions*, *in* The World Trade Organization: Legal, Economic, and Political Analysis 1342, 1345 (Patrick F. J. Macrory, Arthur E. Appleton & Michael G. Plummer eds. 2005) (noting the perverse incentives in the WTO dispute settlement process, which encourage Members "to appeal panel decisions even if their chances of overturning the decision are low, in order to delay implementation and retaliation measures.").

47. DSU, *supra* note 42, art. 21.3.

48. *Id.* art. 22.4 ("The level of suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment"); *Id.* art. 22.6 ("When the situation described in paragraph 2 occurs [i.e., failure of a Member to bring itself into compliance within the reasonable period of time], the DSB, upon request, shall grant authorization to suspend concessions or other obligations within 30 days of the expiry of the reasonable period of time unless the DSB decides by consensus to reject the request [and pending consideration of a Member's objection to the proposed level of suspension]."); *see also* Patricio Grané, *Remedies under WTO Law*, 4 J. Int'l Econ. Law 755, 760 (2001) ("[R]emedies in the WTO are prospective and forward looking.").

that recourse to WTO dispute settlement proceedings creates undue political and economic pressure, because when Members know that remedies are only prospective, they have little to lose from derogating from their obligations in the meantime. Legally speaking, however, Members should act in accordance with the treaties they have consented to, because "[e]very treaty in force is binding upon the parties to it and must be performed by them in good faith."[49]

II. Interpreting the TRIPS Agreement

Even those who advocate for greater short-term access to medicines often accept that "the policy space that countries have to provide affordable medicines is bound sometimes wholesale by trade rules around intellectual property rights."[50] This is because the text of the TRIPS Agreement must be the starting point of interpretation—only from there can interpreting trade-related IP rights be linked to other considerations.

Frankel and Gervais emphasize the importance of this exercise at the outset of their article on plain packaging of tobacco products (which, *inter alia*, restricts the ability to use trademarks and geographical indications on tobacco packaging) and the TRIPS Agreement.[51] That article explores questions about the relationship between public health objectives and international IP rights. Frankel and Gervais explain as follows:

> The rules of international treaty interpretation are important. They provide a degree of consistency so that those who are part of that rules-based system can use interpretation to predict outcomes not only of potential and existing disputes but also as a guide to the boundaries that international agreements place on the formulation and interpretation of WTO members' laws. The principles of interpretation are thus important for the integrity of the international intellectual property regime. It is crucial to keep these principles intact.[52]

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49. VCLT, *supra* note 8, art. 26.

50. *See* Lisa Forman, Ifrah Abdillahi & Jeannie Samuel, *Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health*, 5 Laws 43, 44 (2016).

51. Australia's plain packaging measures are the subject of a pending dispute before a WTO panel, which has been brought by several developing countries. *See, e.g.*, *Key Facts: Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds467_e.htm [https://perma.cc/NPT8-BRDV].

52. Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 Vand. J. Transnat'l L. 1149, 1151–52 (2013).

While WTO Members are certainly free to make policy decisions in view of concerns over public health, they must nevertheless, "comply with international agreements that they willingly ratified or adhered to. Membership in international agreements almost always curtails some aspects of national autonomy."[53]

A. *The Vienna Convention on the Law of Treaties*

The Vienna Convention on the Law of Treaties (Vienna Convention or VCLT) codifies aspects of the customary international law on treaties. Section 3 of the VCLT concerns the interpretation of treaties.

Article 31 of the VCLT states:

> 1. 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.
>
> 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
>
> 3. There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties.
>
> 4. A special meaning shall be given to a term if it is established that the parties so intended.[54]

Accordingly, there are four primary sources of treaty interpretation: the textual meaning, contextual material, non-contextual material, and object and purpose.

Article 3.2 of the DSU provides that the dispute settlement system clarifies the agreements "in accordance with customary rules of interpretation of public international law."[55] With respect to WTO dispute settlement, as a result, the treaty text shall be inter-

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53. *See id.* at 1152.

54. VCLT, *supra* note 8, art. 31.

55. *See* DSU, *supra* note 42, art. 3.2; *see also* Doha Declaration, *supra* note 36, ¶ 5(a) ("In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement . . . .").

preted pursuant to Article 31 of the VCLT. This obligation has been affirmed by the WTO Appellate Body, itself, which has recognized that Articles 31 to 33 of the VCLT have attained the status of customary rules of interpretation of public international law.[56] The Appellate Body has further explained that "the only rules which may be applied in interpreting the meaning of a concession are the general rules of treaty interpretation set out in the *Vienna Convention*."[57]

Article 31(1) of the VCLT "confirms that there can be no starting point for treaty interpretation other than the actual terms of the text."[58] That text, subsequently, must be given ordinary meaning in context, and in light of the object and purpose of the treaty.

The Vienna Convention specifically provides for interpretation through the use of contextual and non-contextual material. Article 31(2) of the VCLT elaborates on the meaning of context—the text, preamble, annexes, and related treaties made between all the parties in connection with the conclusion of the treaty, and "[a]ny instrument . . . made by one or more parties in connexion [*sic*] with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty."[59]

Next, Article 31(3) of the VCLT allows for the consideration of non-contextual materials, specifically: (1) a subsequent agreement,

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56. *See, e.g.*, Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, 17, WTO Doc. WT/DS2/AB/R (adopted May 20, 1996) (recognizing that the "general rule of interpretation" as set out in art. 31(1) of the VCLT "has attained the status of a rule of customary or general international law"); Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, 10, WTO Doc. WT/DS8/AB/R (adopted Oct. 4, 1996) ("We stressed there that this general rule of interpretation 'has attained the status of a rule of customary or general international law.' There can be no doubt that Article 32 of the Vienna Convention, dealing with the role of supplementary means of interpretation, has also attained the same status."); Appellate Body Report, *United States—Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada*, ¶ 59, WTO Doc. WT/DS257/AB/R (adopted Jan. 19, 2004) (recognizing that art. 33(3) of the VCLT is reflective of a "customary rule of interpretation").

57. Appellate Body Report, *European Communities—Customs Classification of Certain Computer Equipment*, ¶ 84, WTO Doc. WT/DS62/AB/R (adopted June 5, 1998) [hereinafter Appellate Body Report, *EC—Computer Equipment*]; *see also* Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 46, WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997) ("These rules must be respected and applied in interpreting the *TRIPS* Agreement or any other covered agreement . . . . Both panels and the Appellate Body must be guided by the rules of treaty interpretation set out in the *Vienna Convention*, and must not add to or diminish rights and obligations provided in the *WTO Agreement*."). *But see* ISABELLE VAN DAMME, TREATY INTERPRETATION BY THE WTO APPELLATE BODY 50 (2009) (finding some rare use of non-codified principles of interpretation).

58. VAN DAMME, *supra* note 57, at 50.

59. *See* VCLT, *supra* note 8, art. 31(2).

(2) subsequent practice, and (3) relevant rules of international law. For a subsequent agreement to be considered along with the context, it must be "between the parties" and must be regarding "the interpretation of the treaty or the application of its provisions."[60] Second, subsequent practice must be "in the application of the treaty" which "establishes the agreement of the parties regarding its interpretation."[61] The Appellate Body has stated that subsequent practice could be established by "concordant, common and consistent" acts.[62] Finally, regarding relevant rules of international law, the Appellate Body has noted that Article 31(3)(c) of the Vienna Convention contains three elements: (i) rules of international law,[63] which are (ii) relevant, and (iii) applicable in the relations between the parties.[64] For a rule of international law to be relevant, it must "concern the same subject matter as the treaty term being interpreted."[65] While customary international law is by

60. *See id.* art. 31(3)(a); *see also* International Law Commission, *Commentary on the Draft Vienna Convention*, *in* YEARBOOK OF THE INTERNATIONAL LAW COMMISSION, vol. II, ¶ 13 (1966) [hereinafter ILC Draft Articles] ("[A] unilateral document cannot be regarded as forming part of the 'context' . . . unless not only was it made in connexion [*sic*] with the conclusion of the treaty but its relation to the treaty was accepted in the same manner by the other parties.").

61. *See* VCLT, *supra* note 8, art. 31(3)(b). While a subsequent *agreement* applies when the parties intend for a certain interpretation of the treaty, subsequent *practice* applies when the parties have applied a treaty. Subsequent practice necessarily refers to the intention of the parties as a whole. *See* ILC Draft Articles, *supra* note 57, ¶ 15 ("The text provisionally adopted in 1964 spoke of a practice which 'establishes the understanding of all the parties.' By omitting the word 'all', the Commission did not intend to change the rule. It considered that the phrase 'the understanding of the parties' necessarily means the 'parties as a whole'. It omitted the word 'all' merely to avoid any possible misconception that every party must individually have engaged in the practice where it suffices that it should have accepted the practice.").

62. *See* Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, *supra* note 56, at 13; s*ee also* Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶ 192, WTO Doc. WT/DS285/AB/R (adopted Apr. 7, 2005) [hereinafter Appellate Body Report, *US—Gambling*] ("[T]here must be a common, consistent, discernible pattern of acts or pronouncements . . . *and* . . . those acts or pronouncements must imply *agreement* on the interpretation of the relevant provision.").

63. Rules of international law refers to the "sources of international law in Article 38(1) of the Statute of the International Court of Justice [(ICJ)] and thus includes customary rules of international law as well as general principles of law." Appellate Body Report, *United States—Definitive Anti-Dumping and Countervailing Duties on Certain Products from China*, ¶ 308, WTO Doc. WT/DS379/AB/R (adopted Mar. 11, 2011) [hereinafter Appellate Body Report, *US—Anti-Dumping and Countervailing Duties (China)*]. Art. 38(1) of the Statute of the ICJ also refers to international conventions and, as a subsidiary means for determination, judicial decisions and the teachings of the most highly qualified publicists. Statute of the International Court of Justice, June 26, 1945, 59 Stat. 1055, 33 U.N.T.S. 933.

64. *See* Appellate Body Report, *US—Anti-Dumping and Countervailing Duties (China)*, *supra* note 63, ¶ 307.

65. *Id.* ¶ 308.

nature applicable in the relations between parties to a dispute, treaties may not be.[66]

While WTO panels and the Appellate Body have acknowledged Article 31(3)(c), in practice, they have been reluctant to directly integrate extrinsic treaties within WTO jurisprudence. In *EC and certain member States—Large Civil Aircraft*, for example, the Appellate Body determined that the extrinsic agreement in question was not relevant.[67] In another dispute, the Appellate Body ignored alleged North American Free Trade Agreement violations by the complaining party when determining that the rights and obligations of that party had been abridged.[68] WTO panels and the Appellate Body will sometimes venture into extrinsic materials if the terms are ambiguous and were intended to be contextually interpreted. One example is the interpretation of the phrase "exhaustible natural resources" to include endangered species within the Article XX(d) exception to the General Agreement on Tariffs and Trade (GATT).[69] That said, WTO panels and the Appellate Body should be unwilling to entertain relevant rules of international law where they abrogate the ordinary meaning of a treaty text or undermine a substantive right, because such an interpretation would upset the

66. The Appellate Body had a chance to clarify the phrase "the parties" in *EC and certain member States—Large Civil Aircraft*, but generally opted for a balancing approach. *See* Appellate Body Report, *European Communities and certain member States—Measures Affecting Trade in Large Civil Aircraft*, ¶ 845, WTO Doc. WT/DS316/AB/R (adopted May 18, 2011) ("An interpretation of 'the parties' in Article 31(3)(c) should be guided by the Appellate Body's statement that 'the purpose of treaty interpretation is to establish the *common* intention of the parties to the treaty'. . . . In a multilateral context such as the WTO, when recourse is had to a non-WTO rule for the purposes of interpreting provisions of the WTO agreements, a delicate balance must be struck between, on the one hand, taking due account of an individual WTO Member's international obligations and, on the other hand, ensuring a consistent and harmonious approach to the interpretation of WTO law among all WTO Members.").

67. *Id.* ¶ 855.

68. *See generally* Appellate Body Report, *Mexico—Tax Measures on Soft Drinks and Other Beverages*, ¶ 79, WTO Doc. WT/DS308/AB/R (adopted Mar. 6, 2006) ("[W]e agree with the Panel that Article XX(d) is not available to justify WTO-inconsistent measures that seek 'to secure compliance' by another WTO Member with that other Member's international obligations.").

69. *See* Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶ 128–31, WTO Doc. WT/DS58/AB/R (adopted Oct. 12, 1998) (finding that "[t]extually Article XX(g) is *not* limited to conservation of 'mineral' or 'non-living' natural resources" and the parties' intent augmented Article XX despite the fact that its treaty language had not altered—"[w]hile article XX was not modified in the Uruguay Round, the preamble attached to the *WTO Agreement* shows that the signatories to that Agreement were, in 1994, fully aware of the importance and legitimacy of environmental protection as a goal of national and international policy").

"dialectic between the text itself and the legal system from which it draws breath."[70]

When the parties have provided a definition of a term in the treaty, then the panel or the Appellate Body will use it—although definitions themselves are subject to interpretation using the same rules. As indicated in Article 31(4) of the Vienna Convention, a panel or the Appellate Body will attach a "special meaning" to a treaty term (including a technical term) if the parties have so intended.

The reference to context and object and purpose in the VCLT ensures that strict textualism does not lead to unreasonable interpretations.[71] There is no "obligatory legal hierarchy" in the process of treaty interpretation.[72] The rules of interpretation are applied in a "holistic" manner. As the WTO Appellate Body has explained:

> The principles of interpretation that are set out in Articles 31 and 32 are to be followed in a holistic fashion. The interpretative exercise is engaged so as to yield an interpretation that is harmonious and coherent and fits comfortably in the treaty as a whole so as to render the treaty provision legally effective. A word or term may have more than one meaning or shade of meaning, but the identification of such meanings in isolation

70. *See* Campbell McLachlan, *The Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention*, 54 ICLQ 279, 287 (2005) ("'Legal interpretation, and thus legal reasoning, builds systemic relationships between rules and principles . . . .' In this way, the process of interpretation encapsulates a dialectic between the text itself and the legal system from which it draws breath. The analogy with the interpretation of contracts is instructive. For much of the time, interpretation of contracts and treaties alike will be a matter of ascertaining and giving effect to the intention of the parties by reference to the words they have used. It is a natural aspect of legal reasoning to start first with the document under construction and only to look beyond it in hard cases, where reference to the document alone is insufficient or contested.") (internal citations omitted) [hereinafter McLachlan]. McLachlan uses this logic to bring into the fold the legal system from which the text manifests. *Id.* ("But the fact that such an approach is rightly adopted as a starting-point in both contract and treaty interpretation should not be allowed to obscure its equally important counterweight: the impact of the surrounding legal system."). Indeed, some of the "surrounding legal system," such as the contemporaneous version of the Patent Cooperation Treaty, can help an adjudicator to understand patent eligibility baselines. *See infra* Section III.A and accompanying text.

71. *See* Sir Ian Sinclair, The Vienna Convention on the Law of Treaties 130–31 (2d ed. 1984) (warning, however, against the use of teleological methods to deny the intentions of the parties as evidenced by the text).

72. *See* ILC Draft Articles, *supra* note 60, ¶ 9 (discussing Article 27 of the draft articles, which ultimately became Article 31 of the VCLT). Sir Ian Sinclair has argued that object and purpose analysis is implicitly ancillary in treaty interpretation when compared to the ordinary meaning. *See* Sinclair, *supra* note 71, at 130. Ordinary meaning is the natural starting point, and while it is not dispositive, it frames treaty interpretation from start to finish.

> only commences the process of interpretation, it does not conclude it. . . . [A] treaty interpreter is required to have recourse to context and object and purpose to elucidate the relevant meaning of the word or term. This logical progression provides a framework for proper interpretative analysis. At the same time, it should be kept in mind that treaty interpretation is an integrated operation, where interpretative rules or principles must be understood and applied as connected and mutually reinforcing components of a holistic exercise.[73]

There is, however, an explicit hierarchy between the general principle in Article 31 and the secondary principle in Article 32. Article 32 states:

> 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, or to determine the meaning when the interpretation according to article 31: (a) [l]eaves the meaning ambiguous or obscure; or (b) [l]eads to a result which is manifestly absurd or unreasonable.[74]

Article 32, therefore, allows for supplemental means of confirming interpretation through the use of preparatory work and the circumstances of the treaty conclusion, in the circumstances described in that provision.

B. *Treaty Interpretation by WTO Panels and the Appellate Body*

When interpreting treaty terms, the "starting point" for WTO panels and the Appellate Body is the ordinary meaning of the terms, with reference often made to a widely accepted dictionary such as the Shorter Oxford English Dictionary, considered in context and in view of the treaty's object and purpose.[75] This reflects the Appellate Body's practice of applying the rules of treaty interpretation, in line with the Vienna Convention.

The Appellate Body ascertains the "object and purposes" of agreements with reference to the preamble, and other related provisions.[76] When interpreting a treaty, the Appellate Body refers to

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73. *See* Appellate Body Report, *United States—Continued Existence and Application of Zeroing Methodology*, ¶ 268, WT/DS350/AB/R (adopted Feb. 4, 2009).

74. VCLT, *supra* note 8, art. 32.

75. *See* Appellate Body Report, *European Communities—Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 175, WTO Doc. WT/DS269/AB/R (adopted Sept. 12, 2005) (quoting Appellate Body Report, *US—Softwood Lumber IV*, ¶ 59); *see also* Appellate Body Report, *US—Gambling*, *supra* note 62, ¶ 168 (providing an example of such analysis).

76. *See, e.g.*, Appellate Body Report, *EC—Computer Equipment*, *supra* note 57, ¶ 82 (using the DSU to interpret the GATT 1994).

both contextual (Article 31(2) of the VCLT) and non-contextual (Article 31(3) of the VCLT) materials, where available.

Notably, the WTO panel in *EC—Biotech* reaffirmed that the ordinary meaning of a treaty term may be understood by referring to other international agreements—even where not all parties to the dispute are parties to the agreement—because they may "provide evidence of the ordinary meaning of terms in the same way that dictionaries do."[77] As the panel recalled, "the Appellate Body has stated that 'dictionaries are important guides to, not dispositive statements of, definitions of words appearing in agreements and legal documents.'"[78] Ultimately, the *EC—Biotech* panel refused to consider provisions in the Convention on Biological Diversity and of the Biosafety Protocol, on the basis that the "European Communities [had] not explained how these provisions [were] relevant to the interpretation of the WTO agreements at issue in this dispute."[79] However, the *EC—Biotech* panel noted that it had requested several international organizations to identify materials "that might aid [the panel] in determining the ordinary meaning of certain terms used in the definitions provided in" a WTO agreement, and it explained that the materials obtained (reference works, glossaries, official documents of the relevant international organizations, including conventions, standards and guidelines, etc.) "[had] been taken into account . . . as appropriate."[80]

Particularly relevant to our discussion in Section III (regarding patentability standards), below, is the Patent Cooperation Treaty (PCT).[81] The PCT, considered together with its regulations and explanatory guidelines, provides a unified procedure for filing patent applications. Concluded in 1970, the PCT currently (as of March 16, 2017) has 152 contracting states. [82] The PCT is relevant to interpreting the ordinary meaning of the TRIPS Agreement, including the first sentence of Article 27.1 thereof, as it presents definitions of several key patent terms of art (e.g., novelty, inven-

77. Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 7.90–7.94, WTO Doc. WT/DS291/R (adopted Sept. 29, 2006) [hereinafter Panel Report, *EC—Biotech*].

78. *Id.* ¶ 7.92 n.268 (citing Appellate Body Report, *United States—Continued Dumping and Subsidy Offset Act of 2000*, ¶ 248, WTO Doc. WT/DS217/AB/R (adopted Jan. 16, 2003)).

79. *Id.* ¶ 7.95.

80. *Id.* ¶ 7.96.

81. *See* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 (1970) [hereinafter PCT].

82. *The PCT Has 152 Contracting States*, WIPO, http://www.wipo.int/pct/en/pct_contracting_states.html (last visited Aug. 28, 2017) [https://perma.cc/YVY3-NU7U].

tive step, etc.). These definitions have been part of the PCT, and its examination guidelines, since the time of the TRIPS negotiations.

Although, not all WTO Members are parties to the PCT—this is not determinative as to whether or not the PCT can assist with the ordinary meaning of provisions of the TRIPS Agreement. As the panel in *EC—Biotech* reaffirmed: "[T]he mere fact that one or more disputing parties are not parties to a convention does not necessarily mean that a convention cannot shed light on the meaning and scope of a treaty term to be interpreted."[83]

Having reviewed the applicable rules of treaty interpretation, it becomes clear that there is no basis—either in public international law or in WTO practice—for the HLP Report's proposition that WTO Member governments are "free" to interpret terms in the WTO agreements as they see fit in the absence of a specific definition of that term in the treaty.[84] The fact that granting such "freedom" might make it easier for a Member, for example, to provide short-term access to a medicine does not somehow change the fundamentals of treaty interpretation.

The absence of an explicit definition in a treaty, including for a term of art, may not be taken as an invitation by an individual WTO Member to interpret the treaty as if it were solely an instrument of national law. Rather, the term in question must be interpreted using the ordinary meaning of those terms, interpreted in their context, and in view of the object and purpose of the TRIPS Agreement. This is irrespective of Article 1 of the TRIPS Agreement, which provides, in relevant part: "Members shall give effect to the provisions of this Agreement." While Members are free to determine the *method* of domestic treaty execution (i.e., the how), they are not free to determine the matter to be incorporated into their own legal system (i.e., the what).[85]

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83. *See* Panel Report, *EC—Biotech*, *supra* note 77, ¶ 7.94.

84. *See* HLP Report, *supra* note 2, at 6, 8.

85. *See* Thomas Cottier, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*, *in* THE WORLD TRADE ORGANIZATION: LEGAL ECONOMIC AND POLITICAL ANALYSIS 1041, 1059 (Patrick F. J. Macrory, Arthur E. Appleton & Michael G. Plummer eds. 2005) ("The Agreement therefore does not prescribe the status of the norms of the TRIPs Agreement in domestic law. Members are free to limit the impact of these rules to the process of domestic legislation in the dualist tradition of international law which clearly separates the spheres of national and international law. Countries operating under monist doctrines, which integrate international law into domestic law, may grant more extensive, immediate effect to the norms of the Agreement. Yet, the nature and definition of private rights in the TRIPs Agreement has not altered the freedom of members to choose their own methods of implementation.").

C. *The Object and Purpose of the TRIPS Agreement*

The self-stated object and purpose (principles) of the TRIPS Agreement are set out in Articles 7 and 8. While the HLP Report characterizes Articles 7 and 8 as "safeguards in the TRIPS Agreement that could be used to promote the right to health," and quotes some of the language in these provisions, it does not actually consider the meaning of those terms on balance, or their interpretative role.[86]

Article 7 of the TRIPS Agreement 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.[87]

Consequently, Article 7 clarifies the intent of the drafters to "balance"—to the "mutual advantage" of producers *and* users—the need to establish incentives for creation and promotion of new technology, without unduly restricting the dissemination of that technology once created. Thus, the very essence of the innovation-access debate is crystallized in the terms of Article 7 of the TRIPS Agreement, itself, with WTO Members urged to find "balance." That "balance" is currently reflected in the TRIPS Agreement, itself, with its combination of obligations and exceptions.

Article 8.1 of the TRIPS Agreement states: "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."[88]

Importantly, Article 8.1 concludes that any measures "to protect public health and nutrition" or "to promote the public interest" must be "consistent with the provision of [the TRIPS] Agreement."[89] The use of the word "necessary" in the phrase "necessary to protect public health and nutrition" indicates that it is imperative to consider whether a measure achieves the legitimate objective of protecting public health, and whether there may be a

86. *See* HLP Report, *supra* note 2, at 17.

87. TRIPS Agreement, *supra* note 6, art. 7.

88. *Id.* arts. 8.1, 8.2 (relating to anti-competitive practices and providing that Members may implement measures curbing such practices so long as they are consistent with the TRIPS Agreement).

89. *Id.* art. 8.1.

reasonably available, less IP-restrictive alternative for achieving that same objective.[90]

Thus, the TRIPS Agreement explicitly espouses a balance between innovation and access in these two provisions. Nevertheless, measures taken to protect public health must be "consistent with the provisions of this Agreement."[91] Thus, while Article 8.1 provides relevant context for interpreting other provisions of the TRIPS Agreement, by its clear terms it is not an exception to the TRIPS Agreement, including the patent obligations thereof.

D. *The Doha Declaration on the TRIPS Agreement and Public Health*

The Doha Declaration further articulates the relationship between the TRIPS Agreement and public health. The Declaration, which "affirm[s] that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and in particular, to promote access to medicines for all," was adopted by the WTO Ministerial Conference of 2001 in Doha, Qatar.[92] For the reasons set out in this Section, it is unlikely that a WTO panel or the WTO Appellate Body would find that the Doha Declaration creates legal rights or obligations distinct from the TRIPS Agreement.

While the Doha Declaration has clear political and practical implications, there has been much debate about the formal role it

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90. The term "necessary" has most frequently been interpreted in the context of disputes involving defenses under the exception in Article XX of the GATT 1994, including Article XX(b), which provides an exception for certain measures "necessary to protect human, animal or plant life or health." *See* General Agreement on Tariffs and Trade, art. XX, Oct. 30 1947, 55 U.N.T.S. 194 [hereinafter GATT]; *see also, e.g.*, Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶¶ 58, 178–83, 210–12, WTO Doc. WT/DS332/AB/R (adopted Dec. 3, 2007) (finding that an import ban of used tires was necessary to protect human, animal or plant life or health, within the meaning of Article XX(b)); Appellate Body Report, *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶ 165, WTO Doc. WT/DS161/AB/R (adopted Dec. 11, 2000) [hereinafter Appellate Body Report, *Korea—Various Measures on Beef*] (finding that a measure is not "necessary" within the meaning of GATT art. XX(b) "if an alternative measure which [a Member] could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it") (citing Panel Report, *US—Section 337 of the Tariff Act of 1930*, ¶ 5.26 (adopted Nov. 7, 1989)).

91. This type of legalism is characteristic of the transformation of the GATT diplomatic-functionalism to the WTO technocratic-formalism. *See generally* Sol Picciotto, *The WTO's Appellate Body: Legal Formalism as a Legitimation of Global Governance*, 18 Governance 477 (2005); Andrew Lang, World Trade Law After Neoliberalism: Reimagining the Global Economic Order 4 (2011); Pavan S. Krishnamurthy, *Effective Enforcement: A Legalistic Analysis of WTO Dispute Settlement*, 5 Nw. Interdisc. L. Rev. 191, 201 (2012).

92. *See* Doha Declaration, *supra* note 36, ¶ 4.

should play in an interpretation of the TRIPS Agreement.[93] The text and negotiating history, however, suggest that the Doha Declaration was intended to be a legally non-binding statement of intent.

On its face, the Doha Declaration represents a reaffirmation that the TRIPS Agreement does not prevent Members from taking certain actions to protect public health. In addition, the Declaration "instruct[s]" Members to take two specific types of actions.

First, Paragraph 6 "recognize[s] that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."[94] Compulsory licensing, formally referred to as "other use without authorization of the right holder" in Article 31 of the TRIPS Agreement, occurs when "the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government."[95] Paragraph 6 of the Declaration instructs the TRIPS Council to find "an expeditious solution to this problem" of WTO Members that are unable to make effective use of compulsory licensing due to insufficient manufacturing capacity, a direction which ultimately led to the amendment of the TRIPS Agreement. Second, Paragraph 7 of the Declaration instructs Members to continue to extend certain transition periods for least-developed country Members, an instruction that was also acted upon by the Members, as discussed below in Section III.B.1.

To the extent the Doha Declaration has some contextual value for interpreting the TRIPS Agreement, it is important to point out that this type of ministerial declaration is not an authoritative interpretation, within the meaning of Article IX:2 of the Marrakesh Agreement Establishing the WTO.[96] Pursuant to that provision,

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93. *See generally* James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 Harv. J.L. & Tech. 292 (2002) (suggesting the need to examine the extent to which the Doha Declaration resolves divergent interpretations of the TRIPS Agreement).

94. *See* Doha Declaration, *supra* note 36, ¶ 6.

95. TRIPS Agreement, *supra* note 6, art. 31 (footnote omitted). *See infra* Section IV.B.3.

96. *See* Cottier, *supra* note 85, at 1078; *see also* Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health 44 (World Health Organization, EDM Series No. 12, 2002) [hereinafter Correa, Implications of Doha] (noting that the Doha Declaration "has no specific legal status in the framework of WTO Law; it is not strictly an authoritative interpretation in terms of Article IX:2 of the Marrakesh Agreement Establishing the WTO."). Correa, however, suggests that the Doha Declaration could be argued to have "the same *effects* as an authoritative interpretation." *Id.* at 44 (footnote omitted). Any argument that a Declaration could have the same interpreta-

the WTO has a process in place designed to establish an authoritative definition beyond that which was developed by a panel or the Appellate Body.[97]

WTO Members were cognizant that the Article 31(f) requirement—that compulsory licenses be predominantly for supply of the domestic market of an authorizing Member—may prevent Members that could not themselves produce pharmaceuticals from benefitting from compulsory licensing. Subsequent to the Declaration, in August 2003, the WTO's General Council adopted the "Decision [on the] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health."[98] This waiver removed the limitation on exports under a compulsory licensing regime to countries that cannot manufacture the necessary pharmaceuticals themselves, subject to numerous safeguards to prevent diversion of the products. Canada was the first and only country so far to have taken advantage of the decision, when it issued a compulsory license for HIV/AIDS medicines for export to Rwanda.[99]

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tive power as an authoritative interpretation would appear to conflict with proper treaty interpretation. The drafters of the WTO outlined a *specific* manner to establish authoritative interpretation—these procedures are well known, and to derogate from them would make art. IX:2 superfluous. "Any interpretation that would render parts of the treaty superfluous or diminish their practical effects is to be avoided." VIENNA CONVENTION ON THE LAW OF TREATIES: A COMMENTARY 545 (Oliver Dörr & Kirsten Schmalenbach eds., 2012) (citing *Constitution of the Maritime Safety Committee of the Inter-Governmental Maritime Consultative Organization* (Advisory Opinion) [1960] ICJ Rep 150, 160–61, 166).

97. *See* WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization art. IX.2, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Marrakesh Agreement]. In *US—FSC*, the Appellate Body articulated the difference between an authoritative interpretation under article IX:2 and general interpretations (e.g., those conducted by a panel):

> Under the WTO Agreement, an authoritative interpretation by the Members of the WTO, under Article IX:2 of that Agreement, is to be distinguished from the rulings and recommendations of the DSB, made on the basis of panel and Appellate Body Reports. In terms of Article 3.2 of the DSU, the rulings and recommendations of the DSB serve only "to clarify the existing provisions of those agreements" and "cannot add to or diminish the rights and obligations provided in the covered agreements."

Appellate Body Report, *United States—Tax Treatment for "Foreign Sales Corporations,"* at 40 n.127 WTO Doc. WT/ DS108/AB/R (adopted Feb. 24, 2000).

98. *See* TRIPS Waiver, *supra* note 36.

99. *See Canada is First to Notify Compulsory License to Export Generic Drug*, WTO (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health _notif_oct07_e.htm [https://perma.cc/KF8N-4MSB]; *TRIPS: Special Compulsory Licenses for Export of Medicines*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (clicking on "view notifications" shows only one (Canada's) notification thus far) (last visited Aug. 28, 2017) [https://perma.cc/X5ZP-ZZRU].

By December 6, 2005, the General Council permanently incorporated the 2003 waiver into the TRIPS Agreement, subject to the acceptance of two-thirds of WTO Members. With the notifications of Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates, and Viet Nam, the TRIPS Agreement was officially amended in January 2017.[100] This marks the first time a WTO agreement has been amended, and reveals that where Members come to a common understanding that there may be an inconsistency between the TRIPS Agreement and public health concerns, such an inconsistency can be overcome through an amendment.

Thus, if Members are unsatisfied with certain obligations in the TRIPS Agreement or in any other WTO agreement, they can attempt to convince other Members to amend the agreement. Any other process would give the judicial branch of the WTO—a panel or the Appellate Body—far more authority in determining WTO obligations than the drafters had intended. This is sound policy. It ensures that declarations do not easily rise to the level of authoritative interpretation, because "it would be theoretically possible for a panel or the Appellate Body to find an inconsistency between the Doha Declaration and the TRIPS Agreement itself."[101] Because the Doha Declaration merely reaffirms rights previously enumerated in the TRIPS Agreement or urges future solutions to selected problems, however, it is unlikely that one could find a conflict, in the strict sense, between the Doha Declaration and the TRIPS Agreement.

Moreover, there would be difficulties in demonstrating that the Doha Declaration should be squarely understood as a subsequent agreement, under Article 31(3)(a) of the Vienna Convention, due to the strong objections suggesting it is not itself a decision on the interpretation of the TRIPS Agreement.[102] The history and prac-

100. *See Amendment of the TRIPS Agreement*, WTO, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Aug. 28, 2017) [https://perma.cc/U5XW-EZ5Z].

101. *See* Correa, Implications of Doha, *supra* note 96, at 45. Correa argues that theoretically a conflict is possible, but practically unlikely because "Members have exercised their exclusive competence to interpret a WTO agreement." *Id.* at n.130 (citing DSU, *supra* note 42, art. 3.2). Correa suggests that a panel or Appellate Body can only "'clarify' the provisions of the WTO agreements; they 'cannot add to or diminish the rights and obligations provided in the [covered] agreements.'" *Id.* The Doha Declaration is not an instance of the Members exercising their competence to interpret a WTO agreement.

102. *But see* Gathii, *supra* note 93, at 314 ("[E]ven if a country concluded that the Doha Declaration is not legally binding, it still constitutes soft law with substantial hortatory authority that puts political pressure on governments and international institutions to comply.").

tice of the Doha Declaration is beset with statements by the United States, the European Communities, and Switzerland objecting to the Declaration's use to alter the TRIPS Agreement.[103] In fact, "[t]he United States in particular would have been unwilling to sign the Declaration had it suspended the legal obligations of developing countries under TRIPS."[104] Proposals for the Declaration were bifurcated: developing countries provided their own proposal,[105] while developed countries proposed another.[106]

The Doha Declaration does not "generate specific rights and obligations for the WTO, which can be enforced through WTO dispute settlement."[107] However, the WTO Agreement does envision a process through which the covered agreements can be changed, and that is through formal amendments.[108]

Returning to the content of the Doha Declaration, Paragraph 4 states:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. *In this connection, we reaffirm the right of WTO members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility.*[109]

Reviewing the terms of the Doha Declaration, three conclusions about its role and its content surface. First, the Doha Declaration does not, itself, purport to add any TRIPS flexibilities that are not already evident in the TRIPS Agreement; rather, Paragraph 4 makes it clear that the Doha Declaration is merely a "reaf-

103. *See, e.g.*, *id.* at 315 ("The United States has maintained that Doha was a political declaration with no legal authority. The United States Trade Representative's Fact Sheet summarizing the results of the Doha meeting refers to the Doha Declaration on TRIPS and Public Health as a political declaration. From this perspective, the Declaration is not a fait accompli for countries seeking to facilitate access to essential medicines. Rather, it is an implicit reciprocation by the West to developing countries for their implementation of the TRIPS Agreement and their acquiescence to a new round of WTO talks.").

104. *Id.*

105. *See Draft Ministerial Declaration: Proposal from a Group of Developing Countries*, WTO (Oct. 4, 2001), https://www.wto.org/english/tratop_e/trips_e/mind ecdraft_w312_e.htm [https://perma.cc/3HNZ-6MYM].

106. *See id.* (lacking the word "interpret" in the draft proposal, but including the "reaffirm" language eventually kept in the final draft).

107. *See* Peter Van den Bossche & Werner Zdouc, The Law and Policy of the World Trade Organization 50 (3d ed. 2013).

108. *See* Marrakesh Agreement, *supra* note 97, art. X.

109. Doha Declaration, *supra* note 36, ¶ 4 (emphasis added).

firm[ation]" of rights already provided by the TRIPS Agreement.[110] The chapeau of Paragraph 5 further confirms that any TRIPS flexibilities can be implemented only "while maintaining [WTO] commitments in the TRIPS Agreement."[111]

Second, interpretation must comport with the "commitment to the TRIPS Agreement,"[112] and ultimately does not allow a WTO Member to interpret matters of patent eligibility in any manner it sees fit.

Third, interpretation and implementation "in a manner supportive of WTO members' right to protect public health" is ultimately value-laden and empirically controversial.[113] One set of advocates calls for a short-term access to medicines, while another set argues that long-term innovation requires patent protection—both claiming that their interpretation and implementation better supports public health policy. The TRIPS Agreement negotiators were keenly aware of this dialectic, but ultimately chose minimum standards of protection—"TRIPS defined the scope of a patent."[114]

III. Patentability

Article 27.1 of the TRIPS Agreement provides the basic agreed-upon patent eligibility requirements for all WTO Members: "[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[115] In other words, if an applicant for a patent in a WTO Member seeks to register any invention, whether product or process, in any field of technology, which is "new," "involve[s] an inventive step," and is "capable of industrial application," then the WTO Member is obligated to grant a patent on that invention (subject to the disclosure and procedural requirements, and the exceptions, all discussed below).[116]

As Daniel Gervais has explained, "the scope and coverage of the Section are comprehensive, and makes TRIPS the most important multilateral instrument in this field. The TRIPS Agreement overcame the main weakness of the Paris Convention in this regard,

110. *Id.*
111. *See id.*
112. *Id.*
113. *See supra* note 4 and accompanying text.
114. *See* Daniel J. Gervais, The TRIPS Agreement: Drafting History and Analysis ¶ 2.256 (2003).
115. TRIPS Agreement, *supra* note 6, art. 27.
116. *Id.*

and *instead of relying on domestic law, TRIPS defined the scope of a patent.*"[117] Nevertheless, the HLP Report purports to effectively turn this significant accomplishment on its head, by asserting that WTO Members have the inherent authority to define standards governing patentability, as they see fit, within their respective national laws.

The Report misstates the general principle of treaty interpretation when it explains that WTO Members have the "freedom to determine patentability criteria."[118] Any determination of these concepts cannot be more stringent than permitted by the TRIPS Agreement, as it would result in Members denying patents on inventions that must, pursuant to Article 27.1 of the TRIPS Agreement, be granted.

The HLP Report concludes its comments on patentability by encouraging governments to adopt legislation to limit patent eligibility, and specifically states: "The application of public health-sensitive guidelines in country patent offices may be an important policy tool to improve health technology access."[119] The footnote to the quoted language refers to a 2016 document authored by Carlos Correa, entitled "Guidelines for Pharmaceutical Patents Examination: Examining Pharmaceutical Patents from a Public Health Perspective" (2016 Correa Guidelines), and published by the United Nations Development Programme.[120] These and related guidelines rest on the faulty assumption that Members are free to strategically interpret the TRIPS Agreement.

Before turning to the substantive patentability requirement, it is important to note that patent applicants are subject to the "conditions on patent applications" listed in Article 29 of the TRIPS Agreement, which requires clear and complete disclosure so that the invention can be carried out by a person skilled in the art. In addition, pursuant to Article 62.1 of the TRIPS Agreement, Members may require, as a condition of acquiring patents, "compliance

117. *See id.* (emphasis added) (footnote omitted).

118. HLP Report, *supra* note 2, at 8; *see also* Sisule F. Musungu & Cecilia Oh, Comm'n on Intell. Prop. Rights, Innovation and Public Health, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? 34 (2005) ("Although there appears to be a general principle of eligibility to be patented where these criteria are satisfied, there is still some degree of flexibility for countries in their national implementation. Since the TRIPS Agreement does not define the terms 'novelty, inventiveness and industrial applicability', WTO Members may determine how these criteria should be interpreted and applied, and hence, the scope of patentability of pharmaceutical inventions.").

119. HLP Report, *supra* note 2, at 23.

120. *See* Correa Guidelines II, *supra* note 7.

with reasonable procedures and formalities" that are "consistent with the provisions of this Agreement."[121]

The TRIPS Agreement also provides several procedural safeguards related to acquisition of a patent, or of other forms of IP. In particular, Article 62.4 provides that such application procedures "shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41."[122] In turn, Article 41.2 requires that procedures shall be "fair and equitable," and not "unnecessarily complicated or costly."[123] Article 41.3 provides, *inter alia*, that decisions on the merits of a case "shall preferably be in writing and reasoned" and "shall be based only on evidence in respect of which parties were offered the opportunity to be heard."[124] The implication of these procedural protections is that decisions, including with respect to patentability, should be made on a case-by-case basis, based on a fair consideration of the evidence supporting a claim that an invention is new, "involve[s] an inventive step," and is "capable of industrial application."[125]

The HLP Report does not appear to encourage any manipulation of these procedures and formalities to obstruct the issuance of patents. Instead, the focus of the HLP Report's patentability discussion is on the substantive standards listed in Article 27.1 of the TRIPS Agreement.

A. *Obligations Concerning Patent Eligibility*

As highlighted above, the HLP Report suggests that WTO Members have the "freedom to determine patentability criteria."[126] The Report also acknowledges, however, that the TRIPS Agreement requires that "an invention must be novel, involve an inventive or non-obvious step and be industrially applicable or useful."[127]

Using "secondary patents" as an example, the Report outlines the contours of the "policy space"[128] that it understands to be properly accorded to WTO Members:

> At one end of the spectrum are national authorities who either do not undertake substantive patent examination or who interpret the criteria broadly, granting secondary patents that in

121. TRIPS Agreement, *supra* note 6, art. 62.
122. *Id.*
123. *Id.* art. 41.
124. *Id.*
125. *Id.* art. 27.
126. *See* HLP Report, *supra* note 2, at 8.
127. *See id.* at 22.
128. *See id.* at 27.

> effect extend the original patent based on varying methods of use, formulations, dosages and forms of constituent chemicals. At the other end of the spectrum are national authorities with provisions stating that a mere discovery of a new form of a known substance that does not improve efficacy is not patentable.[129]

However, the practices of certain states, particularly those states "at the other end of the spectrum" that automatically deny patent protection on new forms of known substances, are not dispositive of the meaning of the TRIPS Agreement. These exceptional practices cannot constitute subsequent practice because they do not establish "the agreement of the parties regarding [the TRIPS Agreement's] interpretation."[130] The HLP Report has put the cart in front of the horse—instead of looking at the TRIPS Agreement to determine the meaning of the terms, it looks to current state practice, emphasizing those Members that have made the policy choice to provide less, rather than more, patent protection, and encouraging other Members to follow their lead.

This strategy is ultimately tautological because it begs the question of what is patentable. Indeed, the HLP Report itself suggests "[s]imilar to the use of flexibilities in general[,] countries applying a public health-based interpretation of patentability criteria have faced pressure against such an interpretation and application in their national laws."[131] If such broad patentability interpretations are being challenged domestically—who is to say that these guidelines followed by certain states are TRIPS-consistent to begin with? A simple assertion that one interpretation is more "public health-based" does not somehow immunize that interpretation from claims that it is inconsistent with the TRIPS Agreement.

The TRIPS Agreement sidesteps this quandary through textual reference to minimum standards. Article 27.1 of the TRIPS Agreement requires WTO Members to grant patents on "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[132] The "any" and "all" language reflects the

129. *See id.* at 22.

130. *See* VCLT, *supra* note 8, art. 31(3)(b).

131. *See* HLP Report, *supra* note 2, at 22 (internal citations omitted).

132. TRIPS Agreement, *supra* note 6, art. 27. Footnote 5 of the TRIPS Agreement equates the "inventive step" and "industrial application" requirements with the "non-obviousness" and "useful" requirements, respectively. *Id.* n.5.

possibility of new scientific fields and establishes "a general principle of eligibility."[133]

Article 29.1 provides that WTO Members shall condition the grant of patents on otherwise eligible inventions on the filing of an application that discloses:

> [T]he invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.[134]

Thus, Articles 27.1 and 29.1 together require all WTO Members to grant patents on inventions that are new (i.e., "novel"), involve an inventive step, and are capable of industrial application, provided those inventions are adequately described in the patent disclosure.

Each of the criteria of patentability specified in the TRIPS Agreement had a common and/or well-accepted meaning as of the date the TRIPS Agreement was concluded. These meanings would be taken into account by a WTO panel or the Appellate Body, as discussed in Section II.B, above.

Thus, WTO Members have specific obligations to grant patents under well-established international standards for determining patentability and patent eligibility. WTO Members may not justify use of TRIPS-inconsistent standards and practices within their domestic intellectual property system under a broad rationale of protecting public health. As detailed above in Section II.C, while Article 8.1 of the TRIPS Agreement provides that: "Members may, in formulating or amending their laws and regulations, adopt measures *necessary* to protect public health and nutrition," this is subject to the provision in the very same sentence that "*such measures are consistent with the provisions of this Agreement.*"[135] Again, it is important to recall the objective mentioned in Article 7 of the TRIPS Agreement, which is to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to

133. *See* GERVAIS, *supra* note 114 ("[T]he drafting of [Article 27] was inspired in part by art.10 of an early draft of the WIPO Patent Law Treaty, [and] requires that patents be available in *all fields of technology* . . . . Combined with the explicit inclusion of both product and process inventions and the part of the last sentence, which prohibits any distinction concerning the field of technology, one might say that a general principle of eligibility to be patented is established. Any exclusion from patentability would therefore be looked upon as an exception to that rule.") (footnotes omitted) (emphasis added).

134. TRIPS Agreement, *supra* note 6, art. 29.1.

135. *Id.* art. 8.1 (emphasis added).

the mutual advance of producer and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[136] This reflects the fact that innovation is chilled when Members adopt unjustifiably strict patent eligibility standards.

Returning for a moment to the negotiating history, Cottier (the lead TRIPS negotiator for the Government of Switzerland) suggests that developing countries were progressively more open to higher levels of protection in the negotiating process of the TRIPS Agreement. He has explained that: "The educational process in the first phase [of negotiations] led to a change in the attitude of a majority of developing countries toward the . . . approach of regarding higher protection of intellectual property as detrimental to the development of those countries."[137] Ultimately, "developing countries eventually recognized the importance of intellectual property protection as a prerequisite, albeit not the only one, for foreign direct investment and transfer of technology."[138] To suggest that developing countries were not cognizant of these concerns would serve to discredit their agency and capacity.[139]

The remainder of this Section will interpret the TRIPS obligations governing patentability (i.e., novelty, inventive step, and industrial application), with reference to the ordinary meaning of those terms, interpreted in their context, and in view of the object and purpose of the TRIPS Agreement.

1. Novelty

The first of the three patentability criteria listed in Article 27.1 is a requirement that the invention be "new." Following the ordinary meaning, an invention is "new" if it "differs from what existed in the past . . . ; [was] not existing before."[140] Moreover, WTO panels and the Appellate Body may ascertain ordinary meaning by looking beyond dictionaries, including by considering contemporaneous international agreements relating to the same subject matter.[141] For example, the *EC—Biotech* panel noted that "other relevant rules of international law may . . . be considered for their informa-

136. *Id.* art. 7.

137. Cottier, *supra* note 85, at 1055.

138. *Id.* at 1056.

139. *See* James Thuro Gathii, *The Neoliberal Turn in Regional Trade Agreements*, 86 WASH. U.L. REV. 421, 473 (2011) (arguing that developing countries voluntarily liberalize, because "such reforms signal that a country is 'safe' for investment.").

140. *New*, OED Online (Oxford University Press, June 2017).

141. *See supra* Section II.B.

tive character" when ascertaining "the ordinary meaning of treaty terms."[142]

The meaning of novelty, additionally, can be ascertained based in part on the understanding of the proponents and drafters of the patentability language eventually agreed to during negotiations. Such understanding may also constitute the concluding circumstances of the treaty and inform the analysis of the *travaux preparatoires* documents.[143]

The term "novelty" had been expressly defined in the PCT before the TRIPS Agreement was concluded. Specifically, Article 33 of the PCT provided that "a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the [PCT] Regulations."[144] The PCT Regulations, in turn, defined the prior art to be:

> [E]verything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (*i.e.*, that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date.[145]

Drafts of the TRIPS Agreement never failed to include the novelty standard.[146] The intent of the parties was to continue the use of the novelty standard roughly as it was understood at the time—as a term of art, subject to some minor variations. Thus, an invention is "new" within the meaning of TRIPS Article 27.1 if it is differ-

142. Panel Report, *EC—Biotech*, *supra* note 77, ¶ 7.92.

143. *See* VCLT, *supra* note 8, art. 32.

144. PCT, *supra* note 81, art. 33(2).

145. WIPO, Regulations under the Patent Cooperation Treaty, r. 33 (July 1, 2017), http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_regs.pdf [https://perma.cc/Y3XW-AN9R]; *see also* WIPO, History of the PCT Regulations: June 19, 1970 – July 1, 2016, 171–73, http://www.wipo.int/export//www/pct/en/texts/pdf/pct_regulations_history.pdf (showing that the text of Rule 33 has remained the same since 1970) [https://perma.cc/5NXS-MDYF]; PCT Examination Guidelines, 35 PCT/GL/3 (Mar. 1, 1993). The PCT Examination Guidelines reinforce this well-accepted meaning of "novel." As the PCT Examination Guidelines explain, "[a] claimed invention shall be considered novel if it is not anticipated by the prior art." *Id.* at 35.

146. *See, e.g.*, Gervais, *supra* note 114, ¶ 2.253 (referring to the novelty standard under the Brussels Draft); Chairman's Report to the GNG, *Status of Work in the Negotiating Group: Chairman's Report to the GNG*, MTN.GNG/NG11/76, at 29 ("Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.") (brackets in original).

ent than what is described in the prior art, defined by reference to the effective filing date of the claimed invention.

2. Inventive Step ("Non-Obviousness")

The second patentability requirement set forth in Article 27.1 is that an invention "involve an inventive step." According to footnote 5 of the TRIPS Agreement, the term "inventive step" can be considered synonymous with the term "non-obvious." Like the meaning of "new," the meaning of "involve an inventive step" and "non-obvious" was well-established at the time that the TRIPS Agreement was negotiated.

Beginning with the ordinary meaning, the Oxford English Dictionary defines "obvious," when used as a legal term related to "an article, system, etc., for which a patent application is made," as follows: "conceptually apparent, without substantial research, to any expert in the field (and hence not capable of being protected by a patent)."[147] Thus, adjudging obviousness must be done from the perspective of an expert in the field in which the invention was made. Based on that perspective, the question is whether that expert would find the invention "conceptually apparent, without substantial research." While this is certainly a standard that, when applied, may yield different conclusions by different fact-finders (whether patent examiners or judges), it is nevertheless a standard that Members must, in good faith, attempt to apply.

The term "inventive step" had a well-established meaning at the time that the TRIPS Agreement was negotiated, which is consistent with the dictionary definition. In particular, Article 33(3) of the PCT provided that "a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art."[148] This definition is consistent with the longstanding laws of many WTO Members.

Importantly, both the dictionary definition and the PCT definition imply that any decision on "inventive step" or non-obviousness should be made on a case-by-case basis. Determining whether someone of ordinary skill in the art in the relevant field would have found an invention obvious, in view of the information and technology that came before, is a highly fact-based question. And, in view of Article 62.4 of the TRIPS Agreement, incorporating by ref-

147. *Obvious,* OED Online (Oxford University Press, June 2017).

148. PCT, *supra* note 81, art. 33; *see also* PCT Examination Guidelines, *supra* note 145, at 37.

erence the principles set out in paragraphs 2 and 3 of Article 41, the supporting evidence must be considered in a "fair and equitable" manner, and on a case-by-case basis.[149]

Given the fact-intensive inquiry required for this aspect of patentability, there is no place for generalized cross-cutting rules requiring denial of patentability on grounds of non-obviousness for broad categories of technologies or improvements, similar to those that are advocated in the HLP Report.

3. Industrial Application ("Usefulness")

The third substantive patentability requirement listed in Article 27.1 of the TRIPS Agreement specifies that an invention must be "capable of industrial application" to justify the grant of a patent by a WTO Member. Footnote 5 of the TRIPS Agreement explains that the requirement for an invention to be "useful" may be deemed synonymous with "capable of industrial application."[150]

As was the case with novelty and inventive step, this third requirement of patentability was expressly defined in the PCT, and well-understood by the drafters of the provision, at the time of the TRIPS negotiations. Specifically, PCT Article 33(4) provided that "a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. 'Industry' shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property."[151]

4. Case Study on Substantive Patentability Requirements: "Secondary Patents"

The HLP Report references "secondary patents" as an example of the type of patent rights that Members can freely choose to accept or reject, making use of the "flexibilities" in Article 27.1.[152] The Report uses the term "secondary patents" to refer broadly to

149. *See* PCT Examination Guidelines, *supra* note 145, at 37–38 ("In considering inventive step or non-obviousness, the examiner should take into consideration the relation of any particular claim to the prior art as a whole. He should take into consideration the claim's relation not only to individual documents or parts thereof taken separately but also to combinations of such documents or parts of documents, where such combinations are obvious to a person skilled in the art.").

150. *See id.* at 14 ("A claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry."); TRIPS Agreement, *supra* note 6, art. 27.1.

151. *See* PCT, *supra* note 81, art. 33(4).

152. *See* HLP Report, *supra* note 2, at 22.

"patents that in effect extend the original patent based on varying methods of use, formulations, dosages and forms of constituent chemicals."[153] Others, such as the 2007 Correa Guidelines, refer to these as "incremental innovations," and similarly argue against their patentability along similar lines.[154]

While asserting that such patents can "prolong exclusivity (commonly known as 'evergreening')" and thereby limit "patient access to health technologies," the HLP Report nevertheless acknowledges the benefits of encouraging such "secondary" patents:

> In some instances, however, changes to existing medicines may add important therapeutic value by, for example, helping patients to tolerate the medicine better. This, in turn, could promote competition with the original medicine. Secondary patents may also be important for the development of safer, less toxic and more effective health technologies.[155]

Pharmaceutical inventions reflecting "follow-on" innovation provide immense benefits to patients in the form of new, safe, and more effective formulations; new and useful combinations of products; and new treatments to address unmet medical needs. Many such "incremental" innovations materially improve the safety or effectiveness of existing pharmaceutical products, or offer new hope to patients who previously had no available options for treatment. For example, World Intellectual Property Organization has lauded Abbott Laboratories' improvement patent on Ritonavir (claiming a heat-stable formulation of a Ritonavir tablet), an antiretroviral drug used to treat HIV infection and AIDS, as having "particular importance for developing countries with elevated ambient temperatures."[156]

Nevertheless, at the end of the discussion of "secondary patents," the HLP Report encourages governments to "adopt legislation to

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153. *Id.*

154. *See* Correa Guidelines I, *supra* note 7, at 4 & n.24.

155. HLP Report, *supra* note 2, at 22.

156. *See* WIPO, Patent Landscape Report on Ritonavir 7 (Oct. 2011), http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946.pdf [https://perma.cc/3MSC-DFXG]. Other incremental innovation has made similarly significant impacts on patient care worldwide. For example, new formulations for a malaria drug decreased dosage from eight tablets per day to only two tablets per day, the combination of two medications into a single dosage form (in the face of difficult obstacles to such a combination) eased the strict treatment regimen for type 2 diabetes, and an anti-fungal medication was adapted for treatment of chagas disease. *See* Int'l Fed'n of Pharm. Mfrs. & Ass'ns, Incremental Innovation: Adapting to Patient Needs 8–14 (2013), http://www.ifpma.org/wp-content/uploads/2016/01/_Incremental_Innovation_Feb_2013_Low-Res.pdf (discussing these examples and overall benefits of incremental innovation as improving therapeutic quality, safety and efficacy of existing medicines) [https://perma.cc/K8XF-4KVC].

limit *excessive patenting* that stifles health technology R&D and access."[157] The negative views toward patentability of these "incremental" inventions reflect a failure to appreciate the *limited scope of rights* accorded to these types of patents. Specifically, the scope of "follow-on" patents invariably will be narrower than first-in-class pharmaceutical innovations because these later-filed patents must define an invention that is not obvious over, and does not literally encompass, the older pharmaceutical product. Simply stated, improvement patents do not block use of known and previously existing pharmaceutical products. Granting patents on improvements to prior formulations of a product encourages pharmaceutical companies to innovate, creating new products with improved safety and/or effectiveness over existing pharmaceutical products, but *without removing older and less expensive variants from the market.* This provides greater choice for patients, while preserving competition for the older product.

A patent cannot be rejected simply because it relates to an invention that can be classified by a Member—or an activist—as a "secondary patent" on an "incremental innovation." Rather, it must be evaluated on an individualized basis, particularly in view of Article 62.4 of the TRIPS Agreement, incorporating by reference the principles set out in paragraphs 2 and 3 of Article 41. If it is determined that the applicant has created an invention that is "new," "involve[s] an inventive step," and is "capable of industrial application," within the meaning of Article 27.1 of the TRIPS Agreement, and it does not fall within the scope of the exceptions and permissible exclusions under Articles 27.2 and 27.3 (discussed below), then a Member is obligated to grant a patent on that invention.

B. *Ex Ante Patentability-Related Flexibilities and Limitations Thereof*

While the HLP Report ignores the proper rules of treaty interpretation in emphasizing the freedom that Members have to define for themselves the substantive patentability rules in Article 27.1 of the TRIPS Agreement, it also overlooks aspects of the TRIPS Agreement that do specifically accord WTO Members important *ex ante* flexibilities when it comes to deciding whether or not to grant a patent.

First, the HLP Report mentions, but neglects to highlight, that WTO Members have provided LDC Members of the WTO with transition periods that provide them with the flexibility to continue

157. HLP Report, *supra* note 2, at 23 (emphasis added).

to exclude pharmaceutical products from the scope of patentable subject matter.[158] The current transition period extends through the year 2033. There is no greater "flexibility," when it comes to pharmaceutical patents, than permitting certain Members to simply refuse to provide patents on such products. Second, the HLP Report fails to mention Article 27.2 of the TRIPS Agreement, which provides for permitted exclusions from patentability of inventions. For reasons discussed below, however, it is difficult to envision how such an exception could justify refusing patents on pharmaceutical products or processes. Third, the HLP Report ignores Article 27.3, which permits Members to refuse to grant patents on certain specifically-referenced types of inventions, including some that directly impact public health.

1. Transition Periods

The WTO has unburdened LDCs from certain TRIPS obligations through various transition periods. Indeed, the transition periods appear to be one of the broadest flexibilities permitted by the TRIPS Agreement.

Among other transition periods included at the outset of the TRIPS Agreement, Article 66.1 of the TRIPS Agreement provided that:

> [i]n view of the special needs and requirements of [LDC] Members, their economic, financial and administrative constraints, and their need for *flexibility* to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65.[159]

The transition period for LDCs has been subject to multiple renewals by the TRIPS Council. The most recent extension provided that LDCs "with respect to pharmaceutical products" need not "implement or apply Sections 5 and 7 of Part II of the TRIPS

158. The WTO recognizes as LDCs those countries designated by the United Nations, thirty of which are WTO Members: Angola; Bangladesh; Benin; Burkina Faso; Burundi; Central African Republic; Chad; Congo, Democratic Republic of the; Djibouti; Gambia; Guinea; Guinea Bissau; Haiti; Lesotho; Madagascar; Malawi; Maldives; Mali; Mauritania; Mozambique; Myanmar; Niger; Rwanda; Senegal; Sierra Leone; Solomon Islands; Tanzania; Togo; Uganda; Zambia. *See Towards Free Market Access for Least-Developed Countries*, WTO, https://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief03_e.htm (last visited Aug. 28, 2017) [https://perma.cc/M883-T5KW].

159. TRIPS Agreement, *supra* note 6, art. 66.1 (emphasis added); *see* GERVAIS, *supra* note 114, ¶ 2.513 ("The TRIPS Agreement is a minimum standard agreement where the same obligations are applicable to all members, with the exceptions of transitional provisions . . . .").

Agreement or to enforce rights provided under these Sections until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier."[160] Section 5 of Part II is the entire section on substantive patent protection, while Section 7 relates to undisclosed information, including pharmaceutical test data required for marketing approval.

Thus, with respect to LDCs, there is no question that they continue to have the maximum flexibility in terms of their protection of patents on pharmaceutical products.

2. Exclusions for Reasons of *Ordre Public* or Morality

The TRIPS Agreement permits certain exclusions from patentability of invention. Article 27.2 states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, *including to protect human, animal or plant life or health* or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[161]

TRIPS Article 27.2, therefore, permits countries to deny patent protection for subject matter in order "to protect *ordre public* or morality." This flexibility includes the protection of human health. For example, the United States does not grant patents for any invention or discovery that is useful exclusively in the utilization of special nuclear material or atomic energy in an atomic weapon.[162]

However, Article 27.2 has two key limitations. First, the focus of the exception is on the potential harm from "commercial exploitation" of an invention, and therefore the risk in question "must not come from the invention as such, but from its commercial exploitation and the impact that can be invoked is only within the territory of the country concerned."[163] This conclusion is strengthened by the fact that the previous Brussels Draft "referred to a broader standard, namely any exploitation *or* publication."[164] Through Article 27.2, the drafters of the TRIPS Agreement acknowledged that, in some instances, protection of public health is more important than

160. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. No. IP/C/73 (Nov. 6, 2015).

161. TRIPS Agreement, *supra* note 6, art. 27.2 (emphasis added).

162. *See* 42 U.S.C. § 2181(a) (2012).

163. *See* Gervais, *supra* note 114, ¶ 2.261.

164. *See id.*

granting patents on a dangerous product or process that, if commercially exploited, could cause great harm.

Second, exclusions to patentability made merely because the exploitation is prohibited by domestic law are not allowed.[165] The exploitation must be prohibited for reasons "necessary to protect ordre public or morality," within the meaning of Article 27.2 of the TRIPS Agreement. The language of *ordre public* (referring to public policy or public order)[166] and morality is relatively open-textured and Member-specific. One state's morality will not necessarily be the same as another state's morality. Evolutive interpretation of such terms has been affirmed by a WTO panel.[167]

Similar to certain exceptions under Article XX of the GATT 1994, Article 27.2 contains a necessity test, which creates a significant burden on the Member taking advantage of this exception.[168] The WTO jurisprudence on the "necessity" test makes clear that

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165. *See, e.g.*, Ping Xiong, An International Law Perspective on the Protection of Human rights in the TRIPS Agreement: An Interpretation of the TRIPS Agreement in Relation to the Right to Health 113, 171 (2012) (footnotes omitted) ("The proviso restricts the mere invocation of domestic laws and it echoes the restrictions and limitations resulting from domestic law in terms of the grant of patent in the Article 4*quater* of Paris Convention.").

166. *See* Gervais, *supra* note 114, ¶ 2.261 ("[T]he negotiators rightly replaced the term 'public order or morality' with '*ordre public* or morality.' The reference to public order was inappropriate as a translation of the French concept of '*ordre public*,' whose meaning is closer to 'public policy.'"). *But see* Xiong, *supra* note 165, at 174–76 ("Does the term *ordre public* only refer to 'public policy' or also refer to police power or 'public order' in TRIPS? One view is that it refers to public policy [citing Gervais]. The other view takes a narrow interpretation and refers the term to security issues such as riots or public disorder."). Regardless of how *ordre public* is defined, and here even a broader definition is assumed, the necessity test of Article 27.2 is quite a limiting principle. Nevertheless, it seems unlikely that *ordre public* refers only to security interest such as "riots or public disorder." *See id.* (citing Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries: TRIPS and Policy Option 14 (2000)). It seems unlikely that *ordre public* refers to such a narrow matter, not only because its enumerative reference to human, animal, or plant life seems to imply the contrary, but because the TRIPS Agreement articulates a separate security exception. *See id.*

167. *See, e.g.*, Panel Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶ 6.468, WTO Doc. WT/DS285/R (adopted Nov. 10, 2004).

168. One WTO panel has noted that the word "necessary" has the identical meaning in Article XX(b) and XX(d) of the GATT 1994, despite the fact that the subject matter of Article XX(d) is unrelated to health policy. *See* Panel Report, *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, ¶ 74, WTO Doc. DS10/R - 37S/200 (adopted Nov. 7, 1990) ("The Panel could see no reason why under Article XX the meaning of the term 'necessary' under paragraph (d) should not be the same as in paragraph (b). In both paragraphs the same term was used and the same objective intended: to allow contracting parties to impose trade restrictive measures inconsistent with the General Agreement to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable. The fact that paragraph (d) applies to inconsistencies resulting from the enforcement of GATT-consistent laws and regulations while paragraph (b) applies to those

necessity does not amount to indispensability. However, the Appellate Body "consider[s] that a 'necessary' measure is, in this continuum, located significantly closer to the pole of 'indispensable' than to the opposite pole of simply 'making a contribution to.'"[169] A complaining party can defeat an allegation of necessity by presenting a reasonably available, less trade restrictive alternative that similarly mitigates the risk to *ordre public* or morality.[170]

3. Permissible Exclusions for Specifically-Referenced Subject Matter

In contradiction to the case-by-case analysis otherwise required by Article 27.1, and the requirement that patents be available without discrimination as to the field of technology (discussed below), Article 27.3 lists several types of subject matter that Members may, in their own discretion, decide not to protect with patents:

> Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

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resulting from health-related policies therefore did not justify a different interpretation of the term 'necessary.'").

169. *See* Appellate Body Report, *Korea—Various Measures on Beef*, *supra* note 90, ¶ 161.

170. Under the necessity test doctrine in the WTO, a responding party initially has the burden when invoking an exception, but the burden shifts to the complaining party to show that there are less trade-restrictive alternatives. If shown, the burden then shifts back to the responding party to show that the alternatives are unreasonable or do not mitigate the risk to *ordre public* or morality. *See* Appellate Body Report, *China—Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, ¶ 319, WTO Doc. WT/DS363/AB/R (adopted Dec. 21, 2009) ("[A] responding party invoking Article XIV(a) of the GATS bears the burden of demonstrating that its GATS-inconsistent measure is 'necessary' to achieve the objective of protecting public morals. This burden does not imply that the responding party must take the initiative to demonstrate that there are no reasonably available alternatives that would achieve its objectives. When, however, the complaining party identifies an alternative measure that, in its view, the responding party should have taken, the responding party will be required to demonstrate why its challenged measure nevertheless remains 'necessary' in the light of that alternative or, in other words, why the proposed alternative is not a genuine alternative or is not 'reasonably available.' If a responding party demonstrates that the alternative is not 'reasonably available,' in the light of the interests or values being pursued and the party's desired level of protection, it follows that the challenged measure must be 'necessary.'").

Article 27.3 enumerates *per se* exclusions. As a threshold matter, it is important to note that "this exception is much narrower than that proposed by some members."[171] Indeed, the Brussels Draft, a precursor to the TRIPS Agreement, had included as a possible exclusion from patentability, "[c]ertain products, and processes for the manufacture of those products, on the grounds of public interest, national security, public health or nutrition, including food, chemical and pharmaceutical products and processes for the manufacture of pharmaceutical products,"[172] but it was ultimately rejected. By encouraging Members to freely and flexibly define "new," "inventive step," and "industrial application" as they see fit, in view of public health concerns, the HLP Report is effectively trying to bring back aspects of this rejected exception.

The first paragraph of Article 27.3 privileges WTO Members with the ability to exclude the patentability of diagnostic, therapeutic, and surgical *methods* for the treatment of humans or animals.[173] This exception, which has been implemented by most WTO Members, has been criticized for over-deterring innovation.[174] The second paragraph permits WTO Members to exclude from patentability plants and animals other than micro-organisms, and certain "essentially biological processes for the production of plants or animals."[175] While the TRIPS Agreement allows this flexibility with respect to patents on plants, it requires Members to provide for the protection of *plant varieties* either by patents or by an effective *sui generis* system (a system created to protect plant varieties). One example of an effective *sui generis* system is the International Union for the Protection of New Varieties of Plants. A number of WTO Members choose to provide both plant variety protection and patents on plant inventions.

C. *Non-Discrimination Obligation*

In interpreting the TRIPS Agreement and any potential flexibilities thereunder, the non-discrimination principle acts as a particularly important limitation for WTO Members. Article 27.1, second sentence, provides that "patents shall be *available* and patent rights

171. *See* Gervais, *supra* note 114, ¶ 2.263.

172. *See* Uruguay Round, *Draft final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, MTN.TNC/W/35/ Rev.1, 209 (Dec. 3, 1990) [hereinafter Brussels Draft].

173. *See* TRIPS Agreement, *supra* note 6, art. 27.3(a).

174. *See* Xiong, *supra* note 165, at 177 (citing Pat Loughlan, *Of Patents and Patients: New Monopolies in Medical Methods*, 6 AIPJ 5 (1995)).

175. TRIPS Agreement, *supra* note 6, art. 27.3(b).

enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[176]

The non-discrimination principle broadly considers the place of invention, field of technology, or whether products are imported or locally produced. In evaluating the recommendations of the HLP Report, the field of technology language in Article 27.1 is important. Pharmaceuticals represent a specific field of technology—discrimination unique to such a field is barred. Article 27.1 of the TRIPS Agreement, furthermore, privileges both patent availability and enjoyment, meaning that a WTO Member cannot immunize itself against claims of discrimination by merely issuing a patent—enjoyment of the rights accorded to the patent owner (i.e., the ability of a patent holder to exercise its rights against unauthorized third parties) are unambiguously specified.

Both *de jure* (as a matter of law) and *de facto* (as a matter of fact) forms of discrimination are prohibited, as found by the *Canada—Pharmaceutical Patents* panel.[177] In addition, the *Canada—Pharmaceutical Patents* panel clarified that the non-discrimination principle applies not only to the positive obligations outlined in the TRIPS Agreement, but also to any limitations, restrictions, or exceptions:

> The text of the TRIPS Agreement offers no support for [the interpretation that the non-discrimination principle does not extend to the exceptions]. Article 27.1 prohibits discrimination as to enjoyment of "patent rights" without qualifying that term. Article 30 exceptions are explicitly described as "exceptions to the exclusive rights conferred by a patent" and contain no indication that any exemption from nondiscrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as is discrimination in the basic rights themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-

176. *Id.* art. 27.1 (emphasis added). The non-discrimination obligation is limited by certain procedural and transitional provisions. *See id.* (providing that the principle of non-discrimination is "[s]ubject to paragraph 4 of Article 65 [transitional arrangements for developing countries], paragraph 8 of Article 70 [procedures related to transitional periods] and paragraph 3 of this Article [*per se* exclusions to patent eligibility]").

177. *See* Panel Report, *Canada—Pharmaceutical Patents*, *supra* note 37, ¶ 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 standards by which the justification for differential treatment is measured are a subject of infinite complexity.").

> discrimination rules as applicable to Article 30. Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30.[178]

The use of TRIPS flexibilities must therefore be even-handed.

Yet, a review of the 2016 Correa Guidelines, which have been endorsed by the HLP Report,[179] reveals recommendations that WTO Members deny patents on many types of inventions simply *because* they are *pharmaceutical* inventions. The Guidelines, like the HLP Report, emphasize the public health priorities of developing nations in suggesting that patentability criteria be applied differently to pharmaceutical inventions than other classes of inventions.[180] Specifically, the 2016 Correa Guidelines include a summary of recommendations listing classes of patents for pharmaceutical products that they suggest should be unworthy of patent protection, including *inter alia*, pharmaceutical compositions (formulations); chemical combinations intended for use as pharmaceuticals; and active metabolites.[181] This type of *per se* exclusion from patentability of pharmaceutical inventions would appear to be inconsistent with a WTO Member's obligations under the TRIPS Agreement, particularly the prohibition on non-discrimination as to the field of technology pursuant to Article 27.1.

Under TRIPS Article 27.1, WTO Members may not refuse to grant a patent on a "pharmaceutical" invention that is new, involves an inventive step, and is industrially applicable, while continuing to grant patents on comparable inventions not intended for use in the pharmaceutical sector. Specifically, under TRIPS Article 27.1, WTO Members may not refuse to grant patents on chemical compounds, compositions of those compounds, or methods of producing those compounds or compositions, simply because the compound, composition, or method is intended for use as a pharmaceutical agent. Yet, many aspects of the 2016 Correa Guidelines suggest precisely this—precluding the issuance of patents on inventions that are to be used as pharmaceuticals, while permitting patents on similar inventions that are not. Moreover, the differential practices suggested by the 2016 Correa Guidelines and the HLP Report are, on their face, limited to pharmaceutical applications of the inventions. This would arguably make the stan-

178. *Id.* ¶ 7.91 (footnote omitted).

179. *See supra* note 120 and accompanying text.

180. *See* Correa Guidelines II, *supra* note 7, at 18.

181. *See id.* at 9–10.

dards suggested by the Guidelines, if enacted, a *de jure* discriminatory practice prohibited by Article 27.1 of the TRIPS Agreement.

IV. Rights Accorded to Registered Patents

While the focus of this Article is on *ex ante* flexibilities, with respect to patentability of inventions, the HLP Report also discusses several *ex post* flexibilities that may be accorded after a patent has been granted. In this Section, the Article first briefly summarizes the core rights accorded to owners of patents, and then considers related flexibilities.

A. *Core Rights Accorded to Patent Owners*

Article 28.1 of the TRIPS Agreement requires that patent owners in WTO Members be granted exclusive rights to prevent all third parties from "making, using, offering for sale, selling, or importing" a patented product.[182] For process patents, the patent owner has the right to prevent third parties from using the process, itself, as well as the right to prevent use, offering for sale, sale, or import of the product directly obtained from the patented process. Pursuant to Article 33, the term of protection available shall not end before the expiration of a period of twenty years, counted from the filing date.[183]

Perhaps because they are not technical terms that can be easily understood by all Members, the HLP Report does not propose that there are any "flexibilities" that Members can take advantage of based on ambiguity of the terms used in Article 28.1, such as "making," "using," or "selling." As detailed in the next Section, the flexibilities encouraged are generally more straightforward and justifiable.

B. *Ex Post Flexibilities to Patent Rights*

WTO Members have the ability to take advantage of several "flexibilities" to the baseline patent rights listed in Article 28, consistent with the TRIPS Agreement. In particular, these flexibilities include (1) the Members' discretion with respect to "exhaustion" of intellectual property rights, including patent rights; (2) the general exception to rights conferred under Article 30 of the TRIPS Agree-

182. *See* TRIPS Agreement, *supra* note 6, art. 28.1(a). Further, Article 28.2 provides that patent owners must have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. *Id.* art. 28.2.

183. *Id.* art. 33.

ment; and (3) the provision providing for compulsory licensing of patents in certain circumstances. With respect to compulsory licensing, as discussed above, the WTO Members decided that the flexibilities in the TRIPS Agreement did not go far enough, which eventually led to an amendment to the TRIPS Agreement enabling compulsory licensing for exports in certain limited circumstances.[184]

Before proceeding, it is important to recall that the non-discrimination obligation in Article 27.1 (second sentence) applies not just to availability of patent rights, but also to "enjoy[ment]" of those rights, once granted. Thus, Members may not discriminate against the enjoyment of patent rights because they cover pharmaceutical products or processes. This is an important limitation on the "flexibilities" of the patent rights accorded by WTO Members.

1. Exhaustion of Patent Rights

The first *ex post* flexibility discussed by the HLP Report relates to patent exhaustion, which the Report refers to as "parallel imports." According to the HLP Report, "[g]oods legitimately placed on another market may be imported from another market without permission of the right holder because of the exhaustion of the patent holder's exclusive marketing rights."[185] This flexibility is indeed envisioned by Article 6 of the TRIPS Agreement, through which WTO Members agreed to disagree on the principle of patent exhaustion, as well as exhaustion of other types of intellectual property rights.[186]

The issue of IP exhaustion relates to the question of when, after a patented product has been lawfully sold for the first time, the patent holder's rights to prevent further sale of that product expire. Exhaustion can be delimited at the national, international, or regional level, or some combination of the three.[187] If a patented product has been lawfully sold with the authorization of a patent holder in one country, and then imported into another country (without the express authorization of the patent holder), that is termed a "parallel import."

In a country that provides for international patent exhaustion, parallel importation cannot be prevented, based on the understanding that the patent owner's rights expired at the point that

184. *See supra* Section II.D.
185. *See* HLP Report, *supra* note 2, at 18.
186. *See* Cottier, *supra* note 85, at 1070.
187. For a review of national, international, and regional exhaustion policies, see *id.* 85

the patented product was lawfully sold in the first country. National IP exhaustion, by contrast, considers only the sale of the product within the same country, and can disregard the first lawful sale outside the country. Given the analytical difficulties in determining where IP ends after first sale, even within and among Members with a long tradition of IP protection,[188] the decision to provide this flexibility was not a particularly surprising development.[189]

Article 6 specifically provides: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[190] The ordinary meaning of the text suggests a deference to WTO Members on the issue of exhaustion, as long as they comply with the obligations of national treatment and most-favored nation treatment (prohibiting discrimination based on the nationality of the right holder). The deference on issues of exhaustion was reaffirmed in the Doha Declaration, where it was stated that Members can deal with exhaustion pursuant to their own domestic policy priorities.[191]

2. Exceptions to Rights Conferred and Limitations Thereof

Article 30 of the TRIPS Agreement provides a general exception to patent rights, which states as follows: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

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188. *See, e.g.*, Lexmark Int'l, Inc. v. Impression Prods., Inc., 816 F.3d 721 (Fed. Cir. 2016) (en banc), *rev'd* 137 S. Ct. 1523 (2017) (finding that patent rights are exhausted upon first sale).

189. *See* Cottier, *supra* note 85, at 1069 ("Intellectual property rights are of an 'ubiquitous' nature. They exist independently of the specific material good in which they might be incorporated. Intellectual property rights conceptually follow the product downstream, and potentially control the use of the product. Logically, they could expand endless over time, interfering in downstream markets indefinitely. It therefore is necessary to put an end, at some point . . . .").

190. *See* TRIPS Agreement, *supra* note 6, art. 6.

191. *See* Doha Declaration, *supra* note 36, ¶ 5(d) ("The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the [most-favored nation] and national treatment provisions of Articles 3 and 4.").

The language in this exception is in line with, and uses similar terminology as, general exceptions in the TRIPS Agreement for other forms of IP rights, such as trademarks and copyrights.[192]

As a threshold matter, the exception to a patent owner's exclusive rights must be "limited," which according to the panel in *Canada—Pharmaceutical Patents* "is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed."[193] Moreover, exceptions cannot unreasonably conflict with a normal exploitation of the patent, with exploitation referring to "the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent."[194]

Nor, pursuant to the terms of Article 30, should exceptions unreasonably prejudice the legitimate interests of the patent owner, which have been found to include interests broader than legal interests.[195] According to the *Canada—Pharmaceutical Patents* panel, legitimate interests involve "a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."[196] Legitimate interests of third parties are also taken into account in determining whether an exception properly falls within the scope of Article 30.

At issue in *Canada—Pharmaceutical Patents* were two exceptions for patent protection provided in Canada's patent law. First, a "regulatory review exception" allowed companies, without the permission of a patent holder, to use a patented invention to develop information required for marketing approval of a new drug.[197] Second, a "stockpiling exception" allowed companies, without the permission of a patent holder, to manufacture and stockpile unlimited quantities of a patented drug during the six months before the patent expired, which could then be sold when the patent

192. *See, e.g.*, TRIPS Agreement, *supra* note 6, 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."); *id.* 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.").

193. Panel Report, *Canada—Pharmaceutical Patents*, *supra* note 37, ¶ 7.31.

194. *Id.* ¶ 7.54.

195. *Id.* ¶ 7.68.

196. *Id.* ¶ 7.69.

197. *Id.* ¶¶ 7.2–7.6.

expired.[198] The panel split the decision. It found that the regulatory review exception fell within the permitted scope of Article 30, because (i) it was "limited," in that products used for regulatory review were used "solely for regulatory purposes and no commercial use is made of resulting final products"; and (ii) the European Union did not put forward evidence or argument demonstrating that the exception unreasonably conflicted with a normal exploitation of the patent or unreasonably prejudiced the legitimate interests of the patent holder.[199] As for the stockpiling exception, however, the panel found that this was not a "limited exception," because it allowed unlimited "making" and "using" of the patented products during the last six months of the patent term, without authorization of the patent holder; this removed the right accorded under Article 28.1 of the TRIPS Agreement to prevent the "making" and "using" of the patented product.[200]

The *Canada—Pharmaceutical Patents* panel's analysis is instructive on the broader issues addressed in the HLP Report. While finding that Members were accorded some discretion in limiting the rights accorded to patents, in that case pharmaceutical-related patents, that discretion was bound by the terms of Articles 28 and 30, as properly interpreted pursuant to the VCLT. The panel did not, as the HLP Report appears to propose, begin with the proposition that the TRIPS Agreement is "flexible," and find that, in a situation involving efforts to accelerate access to generic medicines, the many ambiguous terms in Article 30 must be interpreted in a way that allowed all of Canada's exceptions to continue. Terms such as "unreasonable," "normal," and "legitimate" are certainly difficult to interpret, but nevertheless the WTO panel opined on the proper interpretation, as it was required to do in order to effectuate a settlement of the dispute. It did so while bearing "in mind" "the goals and limitations stated in Articles 7 and 8.1" of the TRIPS Agreement.[201]

3. Compulsory Licensing and Restrictions Thereof

At the same time that the TRIPS Agreement established minimum standards of protections for patent rights, it "strengthened rather than weakened the compulsory licensing regime" by outlin-

198. *Id.* ¶¶ 7.7–7.10.
199. *Id.* ¶¶ 7.39–7.83.
200. *Id.* ¶¶ 7.34–7.36.
201. *Id.* ¶ 7.26.

ing the procedural contours of the regime.[202] To recall, compulsory licensing refers to a government "allow[ing] for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government."[203]

The HLP Report argues that "[a]t a time of increased political commitment to enhancing local pharmaceutical production in developing countries, attention should be paid to incorporating efficient, *easy to use* compulsory licensing provisions into domestic legislation."[204] Similarly, in its recommendations, the HLP Report urges Members to "adopt and implement legislation that facilitates the issuance of compulsory licenses," and to effectuate "*quick*, fair, predictable and implementable compulsory licenses for legitimate public health needs." [205]

By emphasizing a desire for efficiency and ease in issuing compulsory licensing, but neglecting to recall the actual text of Article 31 of the TRIPS Agreement, the HLP Report overlooks that Article 31 is, in reality, a carefully crafted and highly detailed legal provision, with numerous sub-paragraphs. Curiously, while the Doha Declaration is quoted in full in the HLP Report, there are just a few passing references to Article 31, itself.[206] Indeed, in the "recommendations," the HLP Report provides that the "use of compulsory licensing must be based on the provisions found in the Doha Declaration," thereby de-emphasizing the relevance of the requirements in Article 31.[207]

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202. *See* Omar Serrano & Mira Burri, *Making use of TRIPS flexibilities: Implementation and diffusion of compulsory licensing regimes in Brazil and India* 3 (World Trade Inst., Working Paper No. 1, 2016) (citing J. H. Reichman & C. Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS, and an Overview of the Practice in Canada and the U.S.A*, UNCTAD/ICTSD (Project on IPRS and Sustainable Dev. Issue, Paper no. 5, 2003)).

203. TRIPS Agreement, *supra* note 6, art. 31 (footnote omitted).

204. *See* HLP Report, *supra* note 2, at 23 (emphasis added) (footnote omitted); *see also* Andrew D. Mitchell & Tania Voon, *The TRIPS Waiver as a Recognition of Public Health Concerns in the WTO*, *in* Incentives for Global Public Health: Patent Law and Access to Essential Medicines 56 (Thomas Pogge et al. eds., 2010) (discussing the lingering complexity faced by less developed countries in complying with the TRIPS Agreement); Frederick M. Abbot, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469 (2002) (providing background on the Doha Declaration and discussing the need for less developed countries to focus on building legal infrastructure that will help ensure patent protection).

205. HLP Report, *supra* note 2, at 27 (emphasis added).

206. *See id.* at 6, 18–19 (Box 5) (quoting Doha Declaration), 23, 60–61.

207. *See id.* at 27.

Turning to those Article 31 requirements, WTO Members may, in certain circumstances, authorize the use of a patented invention without the consent of the patent owner. Article 31 contains no less than twelve distinct paragraphs, subparagraphs (a) through (l), primarily detailing conditions and restrictions on issuing such compulsory licenses. This constitutes, by far, the longest list of specific considerations for any single limitation or exception to substantive IP rights in the TRIPS Agreement. Thus, while compulsory licenses are explicitly permitted, Members taking advantage of their availability must comply with the specific requirements listed in Article 31.

Procedurally, there are numerous limiting principles and requirements. First, consultation is generally required to "obtain authorization from the right holder on reasonable commercial terms and conditions."[208] Members are required to consult for a reasonable period of time.[209] However, Members "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" may waive the reasonable period of consultation requirement, but the right holder shall nevertheless be notified "as soon as reasonably practicable."[210] It is likely that a national emergency or other circumstances of extreme urgency would be interpreted broadly, not only because they are open-textured terms, but also because the Doha Declaration reaffirmed that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency."[211]

Second, "the scope and duration" of the compulsory license "shall be limited to the purpose for which it was authorized."[212] This is coupled with the requirement in Article 31(g) that authori-

208. TRIPS Agreement, *supra* note 6, art. 31(b).

209. *Id.*

210. *Id.*

211. *See* Doha Declaration, *supra* note 36, ¶ 5(c); *see also* Dianne Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicine*, 91 Bull. World Health Organ. 533, 534 (2013) ("Article 5 of the Doha Declaration confirms that WTO Member States have the freedom to determine the grounds for compulsory licensing and that public health crises, including those linked to the epidemics human immunodeficiency virus (HIV) infection, tuberculosis, malaria and other diseases, can represent a national emergency or other circumstance of extreme urgency.").

212. *See* TRIPS Agreement, *supra* note 6, art. 31(c). However, for semi-conductors, the use of compulsory licensing is further limited to those instances of "non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive." *Id.*

zation of compulsory licensing terminates when the circumstances leading to its issuance "cease to exist and are unlikely to occur."[213]

Third, there is a clear obligation of "adequate remuneration" to the right holder to compensate for the compulsory license.[214] The adequate remuneration requirement presents an economic limitation to the use of compulsory licenses. What amount of remuneration is "adequate" is the subject of much debate.[215]

Fourth, Article 31(f) provides that the use of the compulsory license should be "authorized predominantly for the supply of the domestic market of the Member authorizing such use."[216] However, the newly adopted TRIPS Amendment, Article 31*bis*, modifies this obligation to satisfy the concern expressed in Paragraph 6 of the Doha Declaration regarding Members that do not have manufacturing capacity to benefit, themselves, from compulsory licensing:

> The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

Such modification is subject to numerous safeguards set out in the amendment, including provisions intended to prevent trade diversion of the compulsory-licensed pharmaceutical products.

Further, Article 31 provides that any authorization for use without right holder authorization "shall be considered on its individual merits," and that any such use should be "non-exclusive" and generally non-assignable.[217] Any decision to provide a compulsory license (including the decision on remuneration) must, according to Articles 31(i) and (j), be subject to judicial review or other independent review by a higher authority.

Thus, while the HLP Report correctly points to the flexibility that Members have in issuing compulsory licensing, it misleads by focusing on the importance of "easy" issuance, at the cost of

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213. *See id.* art. 31(g).

214. *See id.* art. 31(h).

215. GERVAIS, *supra* note 114, at 252 n.17 ("In Brussels, negotiators were still hesitating between 'adequate' (supported by the US) and 'fair and equitable' . . . . This section is among the most controversial (and ambiguous) sections of the TRIPS Agreement. One commentator noted, that the interpretation of this requirement 'necessitates the strongest use of he [sic] balancing test to weigh the economic concerns of the patent holder against the economic capabilities of the licence grantor.'") (citations omitted).

216. *See* TRIPS Agreement, *supra* note 6, art. 31(f).

217. *See id.* art. 31(a), (d)–(e).

obscuring the extensive requirements in Article 31 of the TRIPS Agreement.

Finally, from a policy perspective, it is important to note that if a country or group of countries overuses compulsory licenses, or the threat thereof, this may serve to lower the overall credibility of that country's patent system, and the incentives to innovation that this system may create. This would have long term implications for access to medicines, particularly medicines that might be tailored to the particular medical conditions in that country or group of countries.

V. Flexibility to Provide TRIPS-Plus Protections

Before concluding, there is one more TRIPS "flexibility" that should be addressed. It is one that is not, however, referenced by the HLP Report as a "flexibility." Unlike the flexibilities listed at the outset of its report, this is a type of flexibility that the HLP Report very much *discourages*.

In particular, Article 1.1 of the TRIPS Agreement provides that "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."[218] This flexibility is both *ex ante* and *ex post* because WTO Members can structure both the grant of the patent, and the rights conferred, to whatever policy goal is intended—provided that grant and conferral do not otherwise violate the TRIPS Agreement.

The HLP Report is critical, at least implicitly, of those WTO Members that take advantage of this particular flexibility by, for instance, entering into and complying with free trade agreements (FTAs) with protections for patents and test data that go beyond those required by the TRIPS Agreement.[219] According to the HLP Report, such FTAs include "provisions [that] significantly reduce the scope of measures that national governments can use to pursue public health priorities and fulfil the right to health," and this increases the policy "incoherence" between "trade agreements and

218. *Id.* art. 1.1 (emphasis added).

219. Recall, the HLP Report defines "TRIPS flexibilities" as a term "used broadly to describe a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement obligations." HLP Report, *supra* note 2, at 6. Thus, the idea that a Member may provide greater-than-required patent protection for pharmaceuticals falls within the HLP Report's own definition of "TRIPS flexibilities."

the human right to health."[220] Among the provisions highlighted by the HLP Report are those in recent U.S. bilateral and multilateral FTAs,[221] including provisions that provide, *inter alia*, (i) clarity as to the period required for test data exclusivity (required by Article 39.3 of the TRIPS Agreement); (ii) patent term extensions for unreasonable regulatory or marketing delays; (iii) limits on parallel importation; and (iv) additional enforcement obligations.[222]

Thus, when discussing the balance between health and intellectual property, the HLP Report takes the position that decisions by WTO Members to meet or exceed the patent-related obligations of the TRIPS Agreement, without creative and extensive use of flexibilities to lower the standards, is necessarily the wrong choice.[223] However, that position again fails to appreciate the critically important balance between incentives to innovation that will, in the longer-term, increase access to medicines, and decisions to provide immediate access to medicines that have already been developed (which may restrict incentives for further R&D). WTO Members have some flexibility to make different policy choices about how best to achieve this balance, with some focused more on long-term access and others on short-term access. WTO Members that provide more extensive protection of patent rights for pharmaceuticals than what is required by the TRIPS Agreement may, therefore, be doing so in the name of public health by focusing on long-term access.

While it is not surprising that, given the conclusions and recommendations of the HLP Report, the right accorded in Article 1.1 of the TRIPS Agreement is not listed as a relevant "flexibility," it is certainly an important flexibility that must be considered by WTO Members as they make policy decisions on balancing incentives to innovation (and therefore long-term access to medicines) with short-term access.

Conclusion

WTO Members are required to determine patentability and patent owner rights according to the standards set forth in the TRIPS Agreement, using the ordinary meaning of those terms, interpreted in their context, and in view of the object and purpose of the TRIPS Agreement.

220. *See id.* at 19.
221. *Id.* at 25–26 (Box 8).
222. *Id.*
223. *See id.* at 20.

Analytically, TRIPS flexibilities relate to *ex ante* and *ex post* requirements. *Ex ante*, Members must grant patents based on the substantive standards of patentability listed in Article 27.1 of the TRIPS Agreement. *Ex post*, Members must provide right holders with the minimum standards of protection of their exclusive rights. Any TRIPS flexibilities espoused by the Agreement must be interpreted in the same manner as the positive obligations themselves. Finally, they must be applied consistent with the non-discrimination principles in Article 27.1.

The proposition advanced by the HLP Report, that Members have the "freedom" to define for themselves the substantive requirements of patentability, is contrary to well-accepted principles of treaty interpretation. More importantly, to the extent Members take advantage of these "flexibilities" without carefully weighing the "balance of rights and obligations" referenced in Article 7 of the TRIPS Agreement, they may be providing short-term access to medicines at the risk of foreclosing long-term access to medicines for conditions that cannot yet be treated.