

SLOUCHING TOWARDS DEVELOPMENT IN INTERNATIONAL INTELLECTUAL PROPERTY†

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INTRODUCTION

“Development” is increasingly one of the pressing purposes of the international legal regimes within which intellectual property operates. From skirmishes during the G8 Summit over whether promoting public health along with innovation should be among the goals of intellectual property¹ to consensus on recommendations for a WIPO Development Agenda (WIPO Development Agenda),² development is now an

1. Group of Eight (G8), Joint Statement by the German G8 Presidency and the Heads of State and/or Government of Brazil, China, India, Mexico and South Africa on the Occasion of the G8 Summit in Heiligendamm, Germany 1-2 (June 8, 2007), http://www.g-8.de/nsc_true/Content/EN/Artikel/_g8-summit/anlagen/o5-erklaerung-en,templateId=raw,property=publicationFile.pdf/o5-erklaerung-en; see also Ravi Kanth Devarakonda, *G8: Health Over Intellectual Property Rights, Says G5*, IPS, June 8, 2007, <http://ipsnews.net/news.asp?idnews=38098>.

2. World Intellectual Property Organization [WIPO], Provisional Committee on Proposals Related to a WIPO Development Agenda [PCDA], Fourth Session Draft Report, at 29-30, Annex I, PCDA/4/3/Prov.2 (June 11-15, 2007) [hereinafter *PCDA Final Recommendations*], available at http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_4/pcda_4_3_prov_2.pdf.

unmistakable and ubiquitous feature of international intellectual property. Yet, like other areas of international trade law, the design of international intellectual property law lags behind the development rhetoric of international institutions.³ Accordingly, we propose several non-mutually-exclusive, non-exhaustive methods for pursuing the goal of development within international intellectual property regimes:

- (1) Exploring principles of treaty interpretation to maximize the potential of TRIPS articles 7 and 8⁴ as balancing mechanisms within World Trade Organization (WTO) jurisprudence;⁵
- (2) Positing “development” as a key legal term of art through a substantive equality principle within the World Intellectual Property Organization (WIPO), to link intellectual property and innovation to human development; and⁶
- (3) Recognizing emerging rules of customary international law and maximizing international law principles of non-derogation and

3. Tomer Broude, *The Rule(s) of Trade and the Rhetos of Development: Reflections on the Functional and Aspirational Legitimacy of the WTO*, 45 COLUM. J. TRANSNAT'L L. 221, 250 (2007) (“Form follows function, and function follows purpose, but in the WTO the ostensible shift in telos from trade to development is incomplete and risks superficiality, [and] is not supported by a corresponding change in its actual workings.”). See generally Sungjoon Cho, *Doha's Development*, 25 BERKELEY J. INT'L L. 165 (2007); Lan Cao, *Culture Change*, 47 VA. J. INT'L L. 357 (2007).

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, arts. 7-8, 33 I.L.M. 1125, 1200-01 (1994) [hereinafter TRIPS], available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

5. See *infra* Part I; see also Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *Patenting Science: Protecting the Domain of Accessible Knowledge*, in THE FUTURE OF THE PUBLIC DOMAIN: IDENTIFYING THE COMMONS IN INFORMATION LAW 191, 220-21 (Lucie Guibault & P. Bernt Hugenholtz eds., 2006) (noting the need for more elaboration of articles 7 and 8 to preserve balance and a robust international public domain); Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 389-92 (2006) (advocating the exploration of public interest safeguards in TRIPS such as articles 7 and 8); MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 411 (3d ed. 2005) (noting that “Part I [of TRIPS] . . . acknowledges that a balance of legitimate (potentially competing interests) must be struck in determining the appropriate level and kind of intellectual property protection guaranteed by the GATT.”); Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 884, 893-94 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

6. See *infra* Part II; see also Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2828 (2006); Broude, *supra* note 3, at 253 (development “is nevertheless a yet-undefined but operative term in some of its legal texts, such as the Special and Differential Treatment provisions of Articles XII:3(d) and XVIII of the GATT, Article 21.2 of the DSU, Articles 3(c), 5 and 6 of the Enabling Clause, and Article 27.4 of the Agreement on Subsidies and Countervailing Measures (SCM).”).

freedom of implementation, to maintain national policy space and flexibility for social welfare objectives in the context of post-TRIPS bilateral and regional treaties.⁷

These illustrative proposals reflect the growing complexity of international intellectual property norm-setting and norm-interpretation activities, which take place in multiple fora and jurisdictions, globally and domestically. Nuanced approaches differentiating among countries, technologies, and social policies for purposes of furthering development goals require serious attention in intellectual property.

Before elaborating upon our proposed methods, we first unpack the concepts of development and trade, respectively. They signify quite different goals and values for industrialized versus developing countries and are often relatively a “black box” to intellectual property lawyers unaccustomed to thinking about balance in the global intellectual property context. After exploring the different dimensions of development and trade relevant to intellectual property, we then situate them within a larger conceptual framework. We discuss the evolving nature and purpose of the WTO; the desirability of linking intellectual property to trade, and therefore inevitably to public health, and other aspects of development; and the consequences of understanding international intellectual property law and policy-making as a regime complex that includes development as a goal (or “function”) of innovation.

We join the growing discussion about the appropriate mix of development and trade,⁸ given the foundational balance in intellectual

7. See *infra* Part IV.

8. Other extant proposals to address asymmetries in the international intellectual property system include Margaret Chon, *A Substantive Equality Principle in International Intellectual Property Norm-Setting*, in *TRADE, DEVELOPMENT AND INTELLECTUAL PROPERTY: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA* (Daniel Gervais ed., forthcoming 2007); Dinwoodie & Dreyfuss, *supra* note 5, at 220-21 (advocating the use of “substantive maxima” to preserve an international public domain of knowledge); Yu, *supra* note 5, at 387-89 (engaging in the “constructive ambiguit[y]” of TRIPS so as to maximize the possibility of a “pro-development” presumption in norm-interpretation, and suggesting several other directions); Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 *FORDHAM L. REV.* 505, 528-34 [hereinafter Gervais, *Intellectual Property*] (suggesting that developing countries utilize the “normative elasticity” of TRIPS to formulate policy responsive to their needs); Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME* 3, 33-41 (Keith E. Maskus & Jerome H. Reichman eds., 2005) (suggesting a moratorium on stronger intellectual property standards and an institutional infrastructure for reconciling existing standards with national systems of innovation); Ruth L. Okediji, *Sustainable Access to Copyrighted Digital Information Works in Developing Countries*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME* 181-86 (Keith E. Maskus & Jerome H. Reichman eds., 2005) (suggesting a number of proposals, including an international fair use doctrine); Rochelle Cooper Dreyfuss, *TRIPS-Round II: Should Users Strike Back?*, 71 *U.*

property between rights to exclude and access to a robust public domain.⁹ Within U.S. intellectual property scholarship, however, questions of “development” tend to be segregated within scholarship about developing countries, and “balance” tends to be situated within the context of industrialized countries.¹⁰ What might a pro-development international intellectual property balance look like? Balance is rarely analyzed within the context of the development mandates of the WTO and the WIPO, and other institutions that together constitute the so-called international intellectual property regime complex. While the rhetoric of development (according to the Doha Development Round, on the WTO side, and the WIPO Development Agenda and United Nations Millennium Development Goals (UNMDG), on the WIPO side) is au courant now within international intellectual property institutions, development concerns have not been integrated into the dialogue about intellectual property balance. This Article seeks to redress these omissions as well as to disrupt the dichotomy between developed and developing country conversations on these foundational policy issues.

I. THE GLOBAL FRAMEWORK FOR DEVELOPMENT IN INTELLECTUAL PROPERTY

A. A Development Divide and Two Trade Puzzles

1. *Development: Freedom and Growth*

From a development perspective, international intellectual property laws have narrowed available options for regulating knowledge goods for purposes of domestic capacity-building based on the enhancement of human development. We refer to this model of development as a “development as freedom” model, to contrast it with the predominant model based upon “development as growth.” The relationship between intellectual property

CHI. L. REV. 21, 21-22 (2004) [hereinafter Dreyfuss, *TRIPS-Round II*] (calling for the articulation of a user right in the context of TRIPS); Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 249-54, 289-92 (2003) (urging developed countries to expand the exhaustion/first sale doctrines and refuse to enforce one-sided license agreements).

9. See Dinwoodie & Dreyfuss, *supra* note 5, at 220-21 (“But even if the constraints of international law are lifted or loosened, it can be argued that international intellectual property law should be framed to do more, that it should be viewed not only as an obstacle to be overcome, but also as an *affirmative protection* of the public domain against encroachments by member states.”) (emphasis added).

10. Cf. EUROPEAN PATENT OFFICE, SCENARIOS FOR THE FUTURE (2007), available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/\\$File/CPO_scenarios_bookmarked.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/CPO_scenarios_bookmarked.pdf) (forecasting four global scenarios of intellectual property balance across countries with different levels of development).

and the model of development as freedom has received relatively little attention in intellectual property circles.

By human development (or capability), we refer primarily to the concept advocated by Amartya Sen¹¹ and Martha Nussbaum. According to the latter, there are “certain basic functional capabilities at which societies should aim for their citizens, and which quality of life measurements should measure.”¹² This list includes:

- (1) LIFE. Being able to live to the end of a human life of normal length
- (2) BODILY HEALTH. Being able to have good health, including reproductive health; to be adequately nourished
- (4) SENSES, IMAGINATION, AND THOUGHT. Being able to use the senses; being able to imagine, to think, and to reason—and to do these things in a “truly human” way, a way informed and cultivated by an adequate education, including, but by no means limited to, literacy and basic mathematical and scientific training. . . .¹³

The development as freedom model figures prominently in the UNMDG.¹⁴ The United Nations Development Programme (UNDP) has propounded the model of development as freedom since 1991.¹⁵ The human development index (HDI) approach, as opposed to the gross domestic product (GDP) approach standing alone, emphasizes the distribution of human capability opportunities in measuring development.¹⁶ It includes not

11. See AMARTYA SEN, *DEVELOPMENT AS FREEDOM* (1999).

12. Martha C. Nussbaum, *Human Capabilities, Female Human Beings*, in *WOMEN, CULTURE, AND DEVELOPMENT: A STUDY OF HUMAN CAPABILITIES* 61, 82 (Martha C. Nussbaum & Jonathan Glover eds., 1995).

13. Martha C. Nussbaum, *Capabilities and Human Rights*, 66 *FORDHAM L. REV.* 273, 287 (1997). This list is slightly different from the version published earlier in *Human Capabilities*, in note 12 above, and was apparently revised as a result of recent visits to development projects in India. See *id.* at 286.

14. United Nations Millennium Declaration, G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 18, 2000), available at <http://www.un.org/millennium>. Philip Alston claims that these have arguably attained the status of customary international law. Philip Alston, *Ships Passing in the Night: The Current State of the Human Rights and Development Debate Seen Through the Lens of the Millennium Development Goals*, 27 *HUM. RTS. Q.* 755, 771-75 (2005). The 2002 report by the UK Government’s Commission on Intellectual Property Rights was an early attempt to link intellectual property to the UNMDG. See DUNCAN MATTHEWS, *NGOS, INTELLECTUAL PROPERTY RIGHTS AND MULTILATERAL INSTITUTIONS* 3-4 (2006), <http://www.ipngos.org/Report/IPNGOs%20final%20report%20December%202006.pdf>.

15. See MAHBUB UL HAQ, *REFLECTIONS ON HUMAN DEVELOPMENT: HOW THE FOCUS OF DEVELOPMENT ECONOMICS SHIFTS FROM NATIONAL INCOME ACCOUNTING TO PEOPLE-CENTERED POLICIES, TOLD BY ONE OF THE CHIEF ARCHITECTS OF THE NEW PARADIGM* (1995).

16. See U.N. Dev. Programme, *Human Development Report 1991*, at 15-18, <http://hdr.undp.org/reports/global/1991/en> (inaugurating new criterion of development, the Human Development Index (HDI), which measures development through longevity, knowledge and income sufficiency). This is a highly simplified index; in fact, HDI is more than about education and health. Selim Jahan, *Evolution of the Human Development Index*, in *READINGS IN HUMAN DEVELOPMENT: CONCEPTS, MEASURES, AND POLICIES FOR A*

only the standard of living measure of per capita GDP, but also literacy and health measures. Other intergovernmental organizations, including the World Health Organization, increasingly rely upon HDI as a development metric.¹⁷

By contrast, international intellectual property law institutions, such as the WIPO and the WTO, tend to rely on a “development as growth” model. This approach, often shared by policymakers from developed countries with well-entrenched intellectual property industries, tends to view the goal of international intellectual property as encouraging economic growth, increasing trade liberalization, promoting foreign direct investment, and ultimately, enhancing innovation through resulting technology transfer.¹⁸ The development as growth framework was initially set by international development agencies such as the International Monetary Fund and the World Bank.¹⁹ This framework has nonetheless influenced other institutions—including the WTO and the WIPO—which do not view development as their central mandate, but which are increasingly under pressure to consider development in their norm-setting and norm-interpreting activities.

The contrasting, and indeed often clashing, understandings of development lead to very different normative visions of international intellectual property. The freedom model of development emphasizes not just the innovation mandate of intellectual property, but also its relation to other human capability-enhancing social welfare measures, such as access to education or health,²⁰ which in turn build national capacities for innovation and growth. The growth model of development, on the other hand, ties intellectual property unilaterally to its capacity to encourage innovation through technology transfer, irrespective of intellectual property’s function in other economic and social sectors. The various

DEVELOPMENT PARADIGM 128, 134 (Sakiko Fukuda-Parr & A.K. Shiva Kumar eds., 2003); see also Richard Jolly, *Human Development and Neo-liberalism: Paradigms Compared*, in READINGS IN HUMAN DEVELOPMENT: CONCEPTS, MEASURES, AND POLICIES FOR A DEVELOPMENT PARADIGM 82 (Sakiko Fukuda-Parr & A.K. Shiva Kumar eds., 2003).

The standard of living of people is commonly measured by the total amount of goods and services produced per head of the population, or what is called Gross Domestic Product (GDP) per capita (or Gross National Product (GNP) per capita if net income from abroad is added). This, in turn, is determined by the number of people who work, and their productivity.

A.P. THIRLWALL, DEVELOPMENT AS ECONOMIC GROWTH IN THE COMPANION TO DEVELOPMENT STUDIES 41 (Vandana Desai and Robert B. Potter, eds., 2002).

17. See, e.g., WHO, *Strategic Resource Allocation*, EB188/7, at 14 (May 11, 2006), available at http://www.who.int/gb/ebwha/pdf_files/EB118/B118_7-en.pdf.

18. Gervais, *Intellectual Property*, *supra* note 8, at 516-20; Maskus & Reichman, *supra* note 8, at 8-11.

19. See JOSEPH E. STIGLITZ, *GLOBALIZATION AND ITS DISCONTENTS* (2002).

20. See Jennifer Prah Ruger, *Health, Capability, and Justice: Toward a New Paradigm of Health Ethics, Policy and Law*, 15 CORNELL J.L. & PUB. POL’Y 101 (2006).

debates about the key term “development” within the WTO and the WIPO underscore the differences between these two models of development.²¹

Throughout the remainder of this Article, we expand upon the insights of the development as freedom approach for intellectual property. Intellectual property not only stimulates innovation, but also protects knowledge goods that enhance human capabilities, which in turn build national capacities for innovation. Thus, intellectual property should be deployed as a part of a robust regulatory mix of regulatory approaches towards various global public goods, including knowledge goods, rather than as an end in itself.

2. *The First Trade Puzzle: What Form of Global Governance?*

A debate exists in trade scholarship over the WTO’s proper role. Should it adhere strictly to its original mandate of trade liberalization, or engage in some form of global governance? Sometimes referred to as the “constitutionalizing of the WTO,”²² the governance question is about the proper evolution of the global trade regime, from its origins in the GATT to its current incarnation (at least multilaterally) as the WTO.²³ As recently observed,

the global trading system has come to require a new *telos* capable of transcending the narrow purpose of antiprotection while at the same time connoting a much broader idea of “integration” that ensures that both trade values and social values are upheld in a coherent and synergetic, rather than competing fashion. Reflecting this new teleology, the Preamble of the WTO Charter expresses the ideals of an “integrated, more viable and durable multilateral trading system” and “sustainable development,” which certainly go beyond the narrow antiprotectionist motto that was embedded in the old GATT. In the same context, the Doha Ministerial Declaration recently reaffirmed the Members’ commitment to the objective of “sustainable development” under which a dual goal of open markets and adequate social regulation must be “mutually supportive.” . . . This “trade constitution,” which is embedded in the very concept of linkage, also reveals a new horizon in the field of international trade: “distributional issues.”²⁴

21. Chon, *supra* note 6.

22. Jeffrey L. Dunoff provides a summary of the debate and some recent positions in the scholarly literature. See Jeffrey L. Dunoff, *Constitutional Concepts: The WTO’s ‘Constitution’ and the Discipline of International Law*, 17 EUR. J. INT’L L. 647 (2006). The WTO itself is preoccupied with questions of its role and legitimacy, as evidenced by the so-called Sutherland Report. See PETER SUTHERLAND ET AL., THE FUTURE OF THE WTO: ADDRESSING INSTITUTIONAL CHALLENGES IN THE NEW MILLENNIUM: REPORT BY THE CONSULTATIVE BOARD TO THE DIRECTOR-GENERAL SUPACHAI PANITCHPAKDI (2004), available at http://www.wto.org/English/thewto_e/10anniv_e.pdf.

23. JOHN H. BARTON ET AL., THE EVOLUTION OF THE TRADE REGIME: POLITICS, LAW, AND ECONOMICS OF THE GATT AND THE WTO 2-5 (2006).

24. Sungjoon Cho, *Linkage of Free Trade and Social Regulation: Moving beyond the Entropic Dilemma*, 5 CHI. J. INT’L L. 625, 646-47 (2005) (citations omitted).

The governance question includes the debate over the scope of regulatory harmonization. Should the WTO's mandate include issues other than the liberalization of trade, or so-called "non-trade issues?"²⁵ The most contentious of these are environmental, human rights, and labor standards (sometimes referred to as "fair trade issues"). Intellectual property is often mentioned as a prototypical example of a domain that involves deep or positive integration of standards, rather than reduction of tariffs. Intellectual property was the first of the non-tariff issues to be actually incorporated within the WTO legal framework, and has now been institutionalized within the WTO through TRIPS for more than ten years. Nevertheless, some question whether it is an authentic aspect of the WTO's core mandate. We discuss this at greater length later on in this Article. We simply note here that this question of linkage to intellectual property is a narrow framing of the constitutional question. The Doha Development Round included within its scope discussions of competition policy and investment, which are also arguably non-trade-related.²⁶

Points of view about the WTO's capacity to take on a global governance role fall across a broad spectrum, ranging from celebratory²⁷ to critical.²⁸ In the middle are somewhat skeptical views of constitutionalizing impetuses within trade scholarship,²⁹ suggesting that, at the end of the day, there is little support for any actual constitutionalization of the WTO. Nonetheless, even the discourse of constitutionalism may create not only heightened expectations, but also an incipient reality of global governance.³⁰ Perhaps this is a claim that the WTO's jurisdiction over non-trade issues is

25. Andrew T. Guzman, *Global Governance and the WTO*, 45 HARV. INT'L L.J. 303, 306 (2004) ("The non-trade concerns at issue—sometimes referred to as 'trade and . . . ' issues or 'fair trade' issues—include (at least for the purposes of this Article) human rights, environmental issues, labor, investment, competition policy, and intellectual property.") (footnotes omitted).

26. *Id.*

27. *See, e.g., id.* (pointing to the TRIPS Agreement as a particularly salutary example of the WTO's institutional capacity and competence to engage in non-trade areas).

28. FRANK J. GARCIA, *TRADE, INEQUALITY, AND JUSTICE: TOWARD A LIBERAL THEORY OF JUST TRADE* 3-4 (2003) (describing literature inveighing against linkages).

29. Dunoff provides a taxonomy of the different aspects of scholarship in this area: John Jackson (constitutionalism as institutional architecture); Ernst-Ulrich Petersmann (constitutionalism as a set of normative values); Deborah Cass (constitutionalism as judicial mediation). *See* Dunoff, *supra* note 22, at 651-56.

30. *Id.* at 673-74 (quoting Neil Walker, *Late Sovereignty in the European Union*, in *SOVEREIGNTY IN TRANSITION* 3, 4 (Neil Walker ed., 2003)) (invoking the term "constitutional pluralism," coined by Neil Walker, which is "a position which holds that states are no longer the sole locus of constitutional authority, but are now joined by other sites, or putative sites of constitutional authority, most prominently . . . and most relevantly . . . those situated at the supra-state level, and that the relationship between state and non-state sites is better viewed as heterarchical rather than hierarchical").

inevitable given the lacunae that exist within and among competing forms of global regulatory interventions.³¹

Regardless of the debate, it is surely not possible now (if it ever was) to compartmentalize trade and/or intellectual property from other concerns, including social issues. This may be just a reality of globalization.³² Global regulation behind domestic borders, such as the minimum intellectual property standards required by TRIPS, leads directly to consideration of other social welfare policies.³³

Thus, we adopt Thomas Cottier's pragmatic definition of constitutionalism: constitutionalizing the WTO means "an attitude and a framework capable of reasonably balancing and weighing different, equally legitimate and democratically defined basic values and policy goals of a polity dedicated to promote liberty and welfare in a broad sense."³⁴ This definition of global governance amplifies the need to balance and weigh the knowledge goods encouraged by intellectual property with the production of other global public goods important for human development. In a related vein, Ernst-Ulrich Petersmann argues for principles of justice to animate the heretofore formalist interpretations of economic treaties such as the WTO.³⁵

31. See John O. McGinnis & Mark L. Movsesian, *Against Global Governance in the WTO*, 45 HARV. INT'L L.J. 353, 359 (2004) (citations omitted), for a view that

[a]s a practical matter, too, the TRIPs Agreement stands apart from other attempts to expand the WTO into substantive regulation. Further progress in the trade regime could not have been made if exporters of intellectual property knew their property would be taken upon export; these exporters would have had no interest in having tariffs reduced abroad if their goods could simply be pirated. Yet intellectual property exporters were key in battling against protectionist groups, such as textile producers, in the developed world. The TRIPs Agreement was thus central to the "grand bargain" of the Uruguay Round that made the WTO possible. In contrast, members of the WTO today seem reluctant to add new subject matters to the organization.

As the next Subsection of this Article demonstrates, not all commentators agree that TRIPS belongs in the WTO. See *infra* Subsection I.A.3.

32. See Ernst-Ulrich Petersmann, *Justice in International Economic Law? From the 'International Law Among States' to 'International Integration Law' and 'Constitutional Law'* 4-7 (European University Institute Working Paper LAW No. 2006/46, 2006), available at <http://ssrn.com/abstract=964165>; see also S. Hobe, *Globalisation: A Challenge to the Nation State and to International Law*, in TRANSNATIONAL LEGAL PROCESSES: GLOBALISATION AND POWER DISPARITIES 378, 378-79 (Michael Likosky ed., 2002); L. M. Friedman, *One World: Notes on the Emerging Legal Order*, in TRANSNATIONAL LEGAL PROCESSES *supra*, at 28-30.

33. See Sean Pager, *TRIPS: A Link Too Far? A Proposal for Procedural Restraints on Regulatory Linkage in the WTO*, 10 MARQ. INTELL. PROP. L. REV. 215, 237 n.96 (2006) ("Regulatory harmonization can impact a broad gamut of domestic actors having little or no direct connection to trade. Unlike tariff policies, which primarily affect input prices, regulatory policies can affect the ability of ordinary citizens to engage in economic and non-economic activities on many levels.").

34. Thomas Cottier, *Limits to International Trade: The Constitutional Challenge*, 94 AM. SOC'Y INT'L L. PROCS. 220, 221 (2000).

35. Petersmann, *supra* note 32, at 7-12.

As stated at the outset, this Article is written from the development as freedom lens. Understanding intellectual property's innovation mandate as one of many cross-cutting development goals has been under-emphasized within international intellectual property legal frameworks at the global and domestic levels. We develop this further in the next Subsection.

3. *The Second Trade Puzzle: Linking Trade to Intellectual Property*

What kind of development should the WTO prioritize through TRIPS?³⁶ Related to this question is the degree of intrusion upon domestic sovereignty to which member states agreed in TRIPS, in return for greater access to markets. As mentioned above,³⁷ the debate about whether TRIPS belongs in trade occurred in part because TRIPS represented the first instance of a deep integration of standards behind borders (rather than shallow integration, where the focus is on trade barriers at the borders)³⁸ in what was arguably a non-trade linkage.

Given the pragmatic observation that non-trade linkages are inevitable, are they good or bad for development, specifically a model of development as freedom? Predictably again, there are a variety of perspectives, but unpredictably, we find interesting inconsistency among the positions. Some highly critical of the WTO on the access to medicines issue have nonetheless posited that intellectual property linkages to trade are themselves positive for development because they highlight the question of intellectual property's purpose in relation to social welfare goals other than innovation.³⁹ Alternatively, this linkage, otherwise dubious, might legitimize other social or fair trade linkages, which are seen as more desirable.⁴⁰ Others view trade's links to intellectual property as appropriate,

36. See James Thuo Gathii, *Process and Substance in WTO Reform*, 56 RUTGERS L. REV. 885 (2004).

37. See *supra* Subsection I.A.2.

38. Nancy Birdsall & Robert Z. Lawrence, *Deep Integration and Trade Agreements: Good for Developing Countries?*, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 128 (Inge Kaul et al. eds., 1999); Denis Borges Barbosa, *TRIPs art. 7 and 8, FTAs and Trademarks*, at 3 nn.7-8, Mar. 9, 2006, available at <http://www.wcl.american.edu/pijip/documents/Presentation-DenisBorgesBarbosa.pdf?rd=1>.

39. Sisule F Musungu, *Rethinking Innovation, Development and Intellectual Property in the UN: WIPO and Beyond* 22 (Quaker U.N. Office TRIPS Issues Papers No. 5, 2005), available at <http://www.qiap.ca/pages/documents/TRIPS53.pdf>.

From a strategic standpoint, the WTO and TRIPS may have been a blessing in disguise. Because of TRIPS and the bluntness given to its rules due to the use of trade-based retaliation measures, civil society has emerged to play a critical role in the debate on intellectual property and development. . . . The trade-related concept introduced by TRIPS has helped other institutions, especially within the UN such as WHO, to make a relatedness argument as a basis of their work.

Id. (footnote omitted).

40. JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 221 (2000).

seeing no problem with the trade-relatedness of intellectual property, while decrying any other trade linkages.⁴¹ Others are more critical of the intellectual property linkage, seeing no normative justification from a trade standpoint, but accepting it nonetheless.⁴² Still others view the intellectual property linkage as unacceptable. From their perspectives, intellectual property is simply not trade-related (in the memorable words of neoliberal economist Jagdish Bhagwati, TRIPS turns the WTO “into a royalty collection agency”),⁴³ has an undeniably negative impact on developing countries by way of innovation and overall social welfare measures, and should be excised from the WTO.⁴⁴

Our perspective is informed by the development as freedom approach. Implicit in the WTO’s current trade emphasis is a particular view of development, heavily dominated by the model of development through economic growth, rather than alternatives such as the development as freedom model.⁴⁵ Among the various and not insignificant dangers of linkage is that the domestic intellectual property balance in member states is being subverted to global trade ends, such as balance of trade concerns for intellectual property rich states.⁴⁶ We also recognize structural concerns and systemic asymmetry in the dispute resolution process within the WTO.⁴⁷

TRIPS is the only case of ‘positive’ linkage of non-trade regulatory standards to the GATT - where states are required to enforce specified minimum standards. All other linkages in the history of the GATT have been ‘negative.’ . . . Whatever we think of TRIPS, . . . the TRIPS principle is right: positive linkage is sometimes justified. In the contest of law between the GATT and environmental treaties that are enforceable by trade sanctions, we must accept that some regulatory minimums are more important than free trade, for us to survive and flourish. Failure to honour them is an unfair trade advantage that responsible states should not have to accept.

Id. (citations omitted).

41. McGinnis & Movsesian, *supra* note 31, at 359.

42. Cho, *supra* note 24, at 631.

43. JAGDISH BHAGWATI, IN DEFENSE OF GLOBALIZATION 182 (2004) (“But pharmaceutical and software companies muscled their way into the WTO and turned it into a royalty-collection agency simply because the WTO can apply trade sanctions.”); *see also* José E. Alvarez & Jagdish Bhagwati, *Afterword: A Question of Linkage*, 96 AM. J. INT’L L. 126, 127 (2002).

44. BHAGWATI, *supra* note 43, at 182; JOSEPH E. STIGLITZ & ANDREW CHARLTON, FAIR TRADE FOR ALL: HOW TRADE CAN PROMOTE DEVELOPMENT 11-46 (2005).

45. Chon, *supra* note 6, at 2885.

46. Dreyfuss, *TRIPS Round-II*, *supra* note 8, at 21 (describing how “the free traders who negotiated the GATT worked in an environment in which the core concern, reducing market barriers, was viewed as producing . . . unmitigated welfare gains, [and thus] they were not likely to appreciate the social importance, in TRIPS, of balancing proprietary interests against public access needs”); *see also* Peter Gerhart, *The Tragedy of TRIPS*, 2007 MICH. ST. L. REV. 143; Chon, *supra* note 8.

47. Daniel Drache, *Trade, Development and the Doha Round: A Sure Bet or a Train Wreck?* 6 (Centre for Int’l Governance Innovation, Working Paper No. 5, 2006), available at http://www.igloo.org/igloo/community.igloo?r0=communitydownload&r0_script=/scripts/do

Perhaps most significantly, free trade agreements (FTAs) and other bilateral and regional agreements are inexorably increasing intellectual property minimum standards set through TRIPS.⁴⁸

Nonetheless, the jurisprudence of intellectual property within the WTO may evolve to accommodate intellectual property and development, understood from a human development perspective. Noting that the “tension between trade and regulatory failure . . . lies at the center of all linkage issues,”⁴⁹ Sungjoon Cho concludes that “[w]hen confronting a legitimate regulatory concern, one might reasonably posit that domestic governments should be able to maintain their own regulatory autonomy and diversity.”⁵⁰ Adopting this approach, any interpretation of TRIPS thus should give great weight to its built-in flexibilities to address domestic development concerns, so long as these flexibilities are not being used primarily as a cover for trade protectionism.⁵¹ Moreover, the WTO dispute settlement panels have looked outside of WTO law to other sources of law for guidance on the meaning of “sustainable development” in the preamble to the WTO Agreement.⁵² Thus, part of our proposed methodology focuses on WTO jurisprudence. Part II focuses on some underutilized principles of treaty interpretation that can give fuller effect to the different values struck in the original TRIPS bargain.⁵³

We also note that a shift from the WIPO to the WTO for the enunciation of international intellectual property norms has generated some positive pressure on the WIPO for norm-setting based on a development as freedom model.⁵⁴ Accordingly, in Section I.B, we shift our focus away from the WTO to other intellectual property institutions.

B. A Development as Freedom Approach to the International Intellectual Property Regime Complex

The WTO, however important, is only one of several major players impacting international intellectual property norm-setting and interpretation. Thus, before analyzing balance from a development perspective, the overall

cument/download.script&r0_pathinfo=%2F%7B7caf3d23023d494b865b84d143de9968%7D%2FPublications%2Fworkingp%2Ftrade_de&r0_output=xml&s=cc.

48. TREBILCOCK & HOWSE, *supra* note 5, at 437-38, Tbl. 13.1 (“TRIPS-plus obligations in bilateral and regional agreements”); *see also infra* Part IV.

49. Cho, *supra* note 24, at 639.

50. *Id.* at 643.

51. *Id.* at 655 (citing John O. McGinnis & Mark L. Movsesian, *The World Trade Constitution*, 114 HARV. L. REV. 511, 566-72 (2000)).

52. Gabrielle Marceau, *A Call for Coherence in International Law: Praises for the Prohibition against “Clinical Isolation” in WTO Dispute Settlement*, J. WORLD TRADE, Oct. 1999, at 87-152 (arguing in favor of incorporating non-WTO law in WTO DSU decisions).

53. *See infra* Part II.

54. *See infra* Part III.

global landscape should be considered. This legal landscape has been termed (perhaps infelicitously) the international intellectual property regime complex (IIPRC). As introduced into the intellectual property academic literature, the terms “regime” and “regime complex” are, respectively:

Regimes, a term taken from international relations theory, refer to “implicit or explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations.” More concisely and narrowly, regimes have been defined as “institutions with explicit rules, agreed upon by governments, that pertain to particular sets of issues” in international relations. At the core of most regimes is an international treaty. A *regime complex*, by contrast, is a collective of partially overlapping and even inconsistent regimes that are not hierarchically ordered, and which lack a centralized decisionmaker or adjudicator. Regime complexes may comprise many agreements and many institutions.⁵⁵

Although the WTO and the WIPO each could be considered a regime complex by itself, by virtue of administering multiple treaties,⁵⁶ together they form an IIPRC. In addition to the WTO and the WIPO (which is a UN agency as of 1974), many other UN agencies are implicated in or have an explicit mandate with respect to intellectual property norm-setting, innovation, and development.⁵⁷ Current important examples include the Convention on Biological Diversity (CBD), which oversees the intellectual property-related work on access and benefit-sharing (ABS),⁵⁸ the World Health Organization (WHO), which includes the Commission on Intellectual Property Rights, Innovation, and Public Health (CIPRH),⁵⁹ and the International Telecommunications Union (ITU), which administers the work of the World Summit on Information Society (WSIS).⁶⁰ These are only a few of the many intersecting mandates among UN agencies that touch upon intellectual property.⁶¹ However, until TRIPS, the WIPO had

55. Kal Raustiala, *Density & Conflict in International Intellectual Property Law*, 40 U.C. DAVIS L. REV. 1021 (2007) (citation omitted), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=914606; see also Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 408-17 (2004); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 42 n.186 (2004).

56. Indeed, perhaps the WIPO could be regarded as a regime complex in and of itself, as it administers multiple treaties and has had multiple incarnations over its one hundred year existence, if one counts its initial incarnation as BIRPI. Sisule F Musungu & Graham Dutfield, *Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO) 4-10* (Quaker U.N. Office, TRIPS Issues Papers No. 3, 2003), available at http://www.iprsonline.org/ictsd/docs/WIPO_Musungu_Dutfield.pdf.

57. Musungu, *supra* note 39.

58. *Id.* at 34.

59. *Id.* at 28.

60. *Id.* at 29.

61. *Id.* at 25-35 (listing eighteen “UN bodies and the mandates relevant to innovation, development, and intellectual property”).

successfully cast itself as the premier, if not the only legitimate, intellectual property standard-setting organization within the IIPRC.

Related to the concepts of regime and regime complex is that of “regime-shifting,” which is “an attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another.”⁶² The WIPO-WTO institutional division of labor is in flux.⁶³ Arguably TRIPS threw the WIPO’s hegemony into doubt by allowing developed countries with powerful intellectual property interests to shift to a more favorable regime (the trade regime) for norm-setting.⁶⁴ However, TRIPS has paradoxically increased the WIPO’s visibility with respect to norm-spreading, if not norm-setting, through its 1995 technical cooperation agreement with the WTO to provide technical assistance to developing countries under article 67 of the TRIPS agreement.⁶⁵ Moreover, the WIPO has more financial resources than the WTO to engage in intellectual property norm-setting activities of any stripe, by virtue of its revenue from filing fees from the various treaties it administers. Since the Marrakesh meeting, the WIPO has successfully concluded the WIPO Copyright Treaty,⁶⁶ the WIPO Performances and Phonograms Treaty,⁶⁷ the Patent Law Treaty,⁶⁸ and, most recently, the Singapore Treaty on the Law of Trademarks.⁶⁹

Both developed and developing countries appear to be shifting regimes back again from the WTO to the WIPO. On the one hand, the International Bureau of the WIPO is moving forward in what could be

62. Helfer, *supra* note 55 (describing regime-shifting from WIPO to other agencies; using examples of TRIPs and food, agriculture, public health, biodiversity, and human rights); Yu, *supra* note 55, at 408-17 (describing multilateral to bilateral regime shifting as well as shifting between the WTO and WIPO); Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights*, 21 AUSTRIAN J. DEV. STUD. 1, 7 (2005) (shifting from UNCTAD to WIPO); cf. BRAITHWAITE & DRAHOS, *supra* note 40, at 571 (defining forum-shifting and suggesting that it is a game that only the powerful states can play).

63. JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 396-402 (2001) (forecasting institutional matters of relevance to implementation of TRIPS, such as division of authority and competence between the WTO and WIPO); Musungu & Dutfield, *supra* note 56, at 16 (focusing on the role of WIPO post-TRIPS).

64. Raustiala, *supra* note 55; Yu, *supra* note 55, at 408-17; Helfer, *supra* note 55, at 42 n.186.

65. Agreement Between the WIPO and the WTO, Dec 22, 1995, 35 I.L.M. 754 (1995).

66. WIPO, Copyright Treaty, Dec. 20, 1996, 36 I.L.M. 65 (1997).

67. WIPO, Performances and Phonograms Treaty, Dec. 20, 1996, 36 I.L.M. 76 (1997).

68. WIPO, Patent Law Treaty, June 2, 2000, 39 I.L.M. 1047 (2000).

69. WIPO, Singapore Treaty on the Law of Trademarks, March 27, 2006, TLT/R/DC/30, available at http://www.wipo.int/treaties/en/ip/Singapore/pdf/Singapore_treaty.pdf.

viewed as TRIPS-plus norm-setting initiatives, such as the draft substantive patent law treaty in the patent domain through the Standing Committee on the Law of Patents;⁷⁰ the draft broadcasting treaty discussions within the WIPO's Standing Committee on Copyright and Related Rights (SCCR);⁷¹ as well as soft law norm-setting activities in the Standing Committee on the Law of Trademarks, Industrial Designs, and Geographical Indications.⁷²

On the other hand, a group of developing countries introduced the WIPO Development Agenda proposal in 2004.⁷³ After often contentious discussion, the WIPO member states agreed in June 2007 to forward forty-five development mandates to the WIPO General Assembly for consideration at its September 2007 meeting.⁷⁴ Thus, the WIPO continues to occupy a major role in intellectual property norm-setting with respect to development, at least vis-à-vis any other alternative contender within the international UN agency system.⁷⁵ Part III focuses on the potential of the WIPO Development Agenda as viewed through the development as freedom lens.⁷⁶

Simultaneously, regime-shifting is occurring between multilateral and bilateral treaty-making settings. The success and legitimacy of the current

70. WIPO Draft Substantive Patent Law Treaty [Clean Text], Sept. 30, 2003, SCP/10/4, available at http://www.wipo.int/edocs/mdocs/scp/en/scp_10_4.pdf.

71. WIPO Revised Draft Basic Proposal for the WIPO Treaty on the Protection of Broadcasting Organizations, July 31, 2006, SCCR/15/2, available at http://www.wipo.int/edocs/mdocs/scr/en/scr_15/scr_15_2.pdf.

72. These soft law norm-setting activities have culminated in the adoption by the WIPO General Assembly and the Assembly of the Paris Union of three Joint Recommendations: (1) Concerning Provisions on the Protection of Well Known Marks (1999); (2) Concerning Trademark Licenses (2000); and (3) Concerning Provisions on the Protection of Marks, and Other Industrial Property Rights in Signs, on the Internet (2001). WIPO, Trademark Joint Recommendations, http://www.wipo.int/about-ip/en/development_iplaw/index.html (last visited Oct. 19, 2007).

73. WIPO, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11 (Aug. 27, 2004) [hereinafter *Proposal by Argentina and Brazil*], available at http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf; see also *infra* Part III (discussing the Development Agenda); WIPO, *Report*, WO/GA/31/15 (Oct. 5, 2004), available at http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_15.pdf.

Originally submitted in 2004 by Argentina and Brazil on behalf of the Friends of Development, it was joined by twelve other member states, including Bolivia, Cuba, the Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela.

74. *PCDA Final Recommendations*, *supra* note 2; see also Viviana Munoz Tellez, *The WIPO Development Agenda: The Campaign to Reform International Intellectual Property Policy-Making 1*, available at <http://www.ipngos.org/NGO%20Briefings/The%20WIPO%20Development%20Agenda.pdf>.

75. Sisule F. Musungu, *WIPO Development Agenda – As the Dust Settles, Pondering What is in the Agenda, Whether it is Success or Hot Air*, July 9, 2007, <http://thoughtsincolours.blogspot.com/2007/07/wipo-development-agenda-as-dust.html>. But see Helfer, *supra* note 55, at 42.

76. See *infra* Part III.

Doha Development Round at the WTO (and perhaps of the multilateral efforts of the WTO more broadly) are in question.⁷⁷ Given the disagreements of the Doha Round thus far, the United States and other intellectual property-rich nations increasingly rely upon bilateral “solutions” to trade issues, including intellectual property. The WTO’s multilateral solutions, while imperfect, have been giving way to Berne-Plus, TRIPS-plus,⁷⁸ and even U.S.-plus⁷⁹ intellectual property standards negotiated through FTAs.⁸⁰ As many have noted, these turn the non-discrimination most-favored nation (MFN) principle of TRIPS into a ratchet-upwards for rights holders.⁸¹ Thus, instead of acting as a ceiling, as had been expected by many in developing countries, the multilateral instrument of TRIPS is now a floor for harmonized standards. FTAs are used as a vehicle for elevating the so-called “minimum standards” of TRIPS. Widespread recognition of this one-way process has resulted in calls for “substantive

77. See Sungjoon Cho, *The WTO Doha Round Negotiation: Suspended Indefinitely*, AM. SOC’Y INT’L L. INSIGHTS, Sept. 5, 2006, <http://www.asil.org/insights/2006/09/insights060905.html>; Sandra Polaski, *The Future of the WTO 2* (Carnegie Endowment for Int’l Peace, Sept. 2006), available at http://www.carnegie-endowment.org/files/Polaski_WTO_final_formatted.pdf.

78. “TRIPS-Plus” refers to bilateral agreements or regional multilateral agreements, often denominated as “free trade agreements,” in which minimum standards that exceed the TRIPS minimum standards are negotiated, which often have the effect of reducing the flexibilities and policy space of developing countries. Examples of this include article 17.5 of the U.S.-Chile Free Trade Agreement, which requires copyright term of life of the author plus seventy years. This exceeds the requirements of article 9 of TRIPS (incorporating Berne Convention article 7(1)), which establishes a term of life of the author plus fifty years. U.S.-Chile Free Trade Agreement, U.S.-Chile, Art. 17.5, June 6, 2003, 42 I.L.M. 1026 (2003), available at http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html; see generally Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 31-33 (Pedro Roffe et al. eds., 2006) (describing various restrictions in regulatory flexibility resulting from free trade agreements negotiated by the U.S.).

79. Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law* 1, 9, 11 (Int’l Centre for Trade and Sustainable Dev., Issue Paper No. 12, Feb. 2006), available at http://www.unctad.org/en/docs/iteipc20064_en.pdf (describing several examples of U.S.-plus standards adopted by other countries because of the narrower scope of exceptions to the U.S. standard allowed by the bilateral agreement than would be available under U.S. law).

80. See *supra* text accompanying notes 59-68.

81. See, e.g., Drahos, *supra* note 62, at 7. Professor Drahos explains:

Each new bilateral agreement that sets higher standards of intellectual property is picked up by the MFN principle of TRIPS. The savings of MFN become significant as more states enter into agreements with the US. If, for example, 29 states each enter into a bilateral agreement with the US that contains the same provisions on intellectual property, the MFN principle spreads those standards amongst all the states. Without MFN, 435 [separate] agreements would be needed.

Id.

maxima”⁸² or international exceptions and limitations,⁸³ in order to maintain some sort of overall balance between the interests of intellectual property producers and users. Part IV addresses this phenomenon of “upwardly mobile minimum standards” through a discussion of emerging international law human rights norms, as well as the full application of the non-derogation and freedom of implementation principles to limit the impact of FTAs on the original bargain struck in TRIPS.⁸⁴

Of course, no discussion of the IIPRC is complete without acknowledging that non-nationalization⁸⁵ and private ordering⁸⁶ contribute to the proliferation of international lawmaking sites.⁸⁷ Increasingly as well, international intellectual property norms influence national intellectual property norm development, and vice versa, creating a law-making reflexivity across territorial boundaries.⁸⁸ Finally, the increasingly important role of NGOs is overwhelmingly obvious in light of the debate over access to pharmaceuticals and the Doha Declaration on TRIPS and Public Health.⁸⁹

82. Dinwoodie & Dreyfuss, *supra* note 5, at 220-21 (advocating the use of “substantive maxima” to preserve an international public domain of knowledge).

83. WIPO, PCDA, *Proposal by Chile*, PCDA/1/2 (Jan. 12, 2006), available at http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_1/pcda_1_2.pdf; WIPO, Standing Committee on Copyright and Related Rights [SCCR], *Proposal by Chile on the Analysis of Exceptions and Limitations*, SCCR/13/5 (Nov. 22, 2005), available at http://www.wipo.int/edocs/mdocs/copyright/en/sccr_13/sccr_13_5.pdf; WIPO, SCCR, *Proposal by Chile on the Subject “Exceptions and Limitations to Copyright and Related Rights”*, SCCR/12/3 (Nov. 2, 2004), available at http://www.wipo.int/edocs/mdocs/copyright/en/sccr_12/sccr_12_3.pdf.

84. *See infra* Part IV.

85. Yu, *supra* note 55, at 401-02 (describing non-nationalization as a “network model [that] has now replaced the patchwork model that countries traditionally used to structure international intellectual property norms in the past century” and discussing the Uniform Dispute Resolution Policy as an example).

86. Graeme B. Dinwoodie, *Private Ordering and the Creation of International Copyright Norms: The Role of Public Structuring*, 160 J. INSTITUTIONAL & THEORETICAL ECON. 161, 178 (2004).

87. *See* Graeme B. Dinwoodie, *The International Intellectual Property System: Treaties, Norms, National Courts, and Private Ordering*, in INTELLECTUAL PROPERTY, TRADE & DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA (D. Gervais ed., 2007).

88. GRAEME B. DINWOODIE, FOREIGN AND INTERNATIONAL INFLUENCES ON NATIONAL COPYRIGHT POLICY: A SURPRISINGLY RICH PICTURE (2007), available at http://works.bepress.com/graeme_dinwoodie/43/; Daniel Gervais, *The Role of International Treaties in the Interpretation of Canadian Intellectual Property Statutes*, in THE GLOBALIZED RULE OF LAW: RELATIONSHIPS BETWEEN INTERNATIONAL AND DOMESTIC LAW (Oonagh Fitzgerald ed., 2006).

89. *See* MATTHEWS, *supra* note 14; Susan K. Sell, Books, Drugs and Seeds: The Politics of Access 53, 59 (Mar. 20, 2006) (unpublished paper presented to Trans Atlantic Consumer Dialogue, available at <http://www.tacd.org/events/intellectual-property/index.htm>).

Thus, the success of intellectual property-rich countries in implementing specific intellectual property strategies is due not only to their ability to shift back and forth between the WTO and the WIPO frameworks, but also between the multilateral and bilateral frameworks. It also depends heavily on the insularity of all norm-setting organizations towards foundational understandings of development. Many developing countries, in particular, contend with a lack of policy coordination within and between the national and international levels, combined with growing complexity and fragmentation of policy-making venues.⁹⁰ This is part of what has been termed a “knowledge trap” for poor countries, which are severely and systematically penalized by the knowledge-intensity demanded by the deep integration of standards within the IIPRC.⁹¹ Opportunities have increased for meaningful developing country participation in the IIPRC, whether through intergovernmental organizations⁹² or NGOs.⁹³ At the same time, international level efforts may be disconnected from national level implementation of TRIPS or other intellectual property treaties; from national level coordination of intellectual property policy-making with other relevant ministries; or even from negotiation of bilateral trade agreements within national capitals.⁹⁴ As Sisule Musungu and Graham Dutfield recently stated, “it is imperative, if developing countries are going to influence negotiations at WIPO towards a development orientation, that the issue of representation in WIPO negotiations and coordination both nationally and in Geneva (WTO and WIPO) be discussed and resolved.”⁹⁵

Given this flux, a re-examination of institutional roles, structures, and legal tools from the perspective of development is timely. For example, one of the WIPO Development Agenda recommendations includes “[t]o request WIPO to intensify its cooperation on IP related issues with UN agencies, according to Member States’ orientation, in particular UNCTAD, UNEP, WHO, UNIDO, UNESCO and other relevant international organizations, especially WTO in order to strengthen the coordination for maximum efficiency in undertaking development programs.”⁹⁶ This echoes earlier

90. Ahmed Abdel Latif, *Developing Country Coordination in International Intellectual Property Standard-Setting* 1 (South Centre, Working Papers No. 24, June 2005), available at <http://www.southcentre.org/publications/workingpapers/wp24.pdf>.

91. Sylvia Ostry, *After Doha: Fearful New World?*, BRIDGES, Aug. 2006, at 3, available at <http://www.ictsd.org/monthly/bridges/BRIDGES10-5.pdf>.

92. BARTON ET AL., *supra* note 23, at 172-74.

93. MATTHEWS, *supra* note 14.

94. See Denis Borges Barbosa, *New Semiconductor Chip Protection Act in Brazil*, Mar. 8, 2007, <http://www.mondaq.com/article.asp?articleid=46352&lastestnews=1>.

95. Musungu & Dutfield, *supra* note 56, at 22.

96. *PCDA Final Recommendations*, *supra* note 2, annex ¶ 40.

reform proposals made by those with a deep understanding of Geneva-based norm-setting.⁹⁷

This Article does not focus on global institutional reform *per se* to address development and IIPRC balance.⁹⁸ Nonetheless, to encourage development-oriented intellectual property, multiple macro (structural) and micro (legal doctrinal) approaches are necessary. This observation relates back to the previous Section, which addressed the question of WTO global governance. We posit that a global governance approach not just by the WTO, but also by the entire IIPRC, is required in order to adequately address intellectual property-driven development.

C. Locating the International Intellectual Property Balance: Towards Development in International Intellectual Property

The WIPO Development Agenda explicitly embraces the classic domestic balance between exclusive rights and access to knowledge goods, in its nine “Cluster B” recommendations on “Norm-Setting, Flexibilities, Public Policy and Public Domain.” For example, references to “the public domain,” “flexibilities” and “access to knowledge” appear.⁹⁹ On the WTO side of the IIPRC, however, Graeme Dinwoodie claims that there are currently three types of balance in international intellectual property:

TRIPS still relied heavily on national political processes to ensure appropriate balance. If one is to find balance embedded in the TRIPS context, it can only be found by recognizing that in return for accepting restrictions on national autonomy to maintain unduly low levels of intellectual property protection, developing countries secured benefits in terms of market access and technology transfer. That is, the balance embodied in the 1994 WTO agreements was not a balance intrinsic to intellectual property law, which we find in the domestic political context, nor

97. Musungu & Dutfield, *supra* note 56, at 18-24 (advocating, among other things, operationalizing the Agreement between WIPO and the UN, specifically the language of article One (“WIPO’s role is subject to the competence and responsibilities of the UN and its organs particularly UNCTAD[,] . . . UNDP[,] . . . UNIDO[,] . . . [and] UNESCO”), manifesting a deeper commitment to its role as a UN specialized agency whose “purposes must be compatible with those of the UN and its agencies,” and making far greater efforts to consult and cooperate with other UN organs and agencies).

98. *Cf.* Gerhart, *supra* note 46.

99. *PCDA Final Recommendations*, *supra* note 2, annex ¶¶ 15-22. *See also* Part III and text accompanying note 237. This language of balance was explicitly invoked in the WCT preamble: “Recognizing the need to maintain a balance between the rights of authors and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention.” WORLD INTELLECTUAL PROPERTY ORGANIZATION COPYRIGHT TREATY, S. TREATY DOC. NO. 105-17, at 4, 36 I.L.M. 65, 68 (1996). As Dinwoodie astutely points out, the Berne Convention does not refer to balance and probably historically was not much concerned with balance, at least on the international level. Graeme B. Dinwoodie, *The Global Politics of Intellectual Property* 3 (June 2006) (unpublished manuscript, on file with author) (“Implicit in the celebration of that balance language in 1996 is the fact that international intellectual property treaties historically did not explicitly seek to strike a particular substantive balance.”).

even a balance that also figured in the right mix of universal standards versus national autonomy, which we find in the classical international intellectual property. Rather, TRIPS added a third vector: policy objectives secured by a balance of intellectual property rights and other tools of economic development.¹⁰⁰

If this is an accurate assessment, then this third type of balance, the non-classical international one, requires the greatest theoretical and doctrinal exposition at this historical moment. Does it simply mean that any particular developing country may simply choose to balance the adoption of greater standards of intellectual property in exchange for greater market access to textiles and food, in the pursuit of overall social welfare? Or does the third vector include a balance of the innovation goal of intellectual property against various other social welfare goals, such as public health, on a global level?

We argue here that international intellectual property balance must be calibrated to assist in the achievement of global human development goals. Given that TRIPS could just as easily be characterized as a rule of law project as a free trade agreement,¹⁰¹ its minimum standards ought to be interpreted in a manner that recognizes the obstacles posed by overly high and rigid intellectual property standards to human development. As recently stated,

As viewed by proponents, TRIPS prohibits nations from “free riding” by acquiring at low cost the products developed in other nations, and thus not paying the higher prices that allow for recovery of research or development cost. As seen by critics it threatens development by slowing the spread of technology, hampering the ability of developing countries to compete in markets where the industrial world already has an advantage, and failing to stimulate innovation in the world’s poorer countries. But both agree that the main effect of the agreement is to protect rents in profitable activities. The thrust of the TRIPS is therefore very different from the notion of “driving out” rents by the steady reduction of protection at the border.¹⁰²

TRIPS not only was a turning point with respect to linkage bargaining, allowing states to bargain intellectual property for other trade “chips,” such as access to agricultural markets (for example, DVD protection for apples).

100. Dinwoodie, *supra* note 99, at 3; *see also* Dinwoodie, *supra* note 87.

101. BARTON ET AL., *supra* note 23, at 142; *see also* DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 81 (2d ed. 2003).

Several paragraphs of the preamble thus confirm the need for achieving a balance, or, perhaps more accurately, the need to arrive at a series of equilibriums between intellectual property protection and free trade (*bearing in mind that, prior to the Uruguay Round, intellectual property was viewed as an exception to free trade in Art. XX(d) in GATT*); between highly industrialized and developing nations; between the private rights of intellectual property owners and cases where the public interest may trump some aspects of the protection of intellectual property; and more broadly as a reflection of the ‘contract’ that intellectual property represents

Id. (emphasis added) (citation omitted).

102. BARTON ET AL., *supra* note 23, at 142.

TRIPS also clearly articulates the space for member states to balance internally the innovation goal of intellectual property along with other development goals, such as promotion of public health, through articles 7 and 8. The TRIPS preamble clearly references “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”¹⁰³ As Graeme Austin has argued in a slightly different context, intellectual property values are an instantiation of domestic self-determination that ought to be expressed as “aspects of much broader issues of public policy. . . . that help ensure that populations get fed, enjoy the benefits of literacy, are healthy, have viable agricultural bases, and can participate in technological and cultural development”¹⁰⁴

TRIPS, via articles 7 and 8, was intended to import a normative “balance” approach into international intellectual property law.¹⁰⁵ The explicit “Objectives” of TRIPS, articulated in article 7, include:

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.¹⁰⁶

This article 7 “balance” language has now been incorporated by reference in the WIPO Development Agenda,¹⁰⁷ and as Barbosa has previously argued, article 7 should:

be read as an interpretative tool before everything, in a way conducive to the technology transfer; but . . . stress[ing] especially the balanced nature of the overall agreement. . . . The necessary balancing to the constitutionality of the IPRs as it is developed in the Constitutional discourse in many relevant countries appears in TRIPS, preventing the exclusive protection of the interests of the IPRs owners.¹⁰⁸

Furthermore, among the “Principles” of TRIPS articulated by article 8 is the ability of members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital

103. TRIPS, *supra* note 4, pmb1.

104. Graeme W. Austin, *Valuing “Domestic Self-Determination” in International Intellectual Property Jurisprudence*, 77 CHI.-KENT L. REV. 1155, 1193 (2002).

105. GERVAIS, *supra* note 101, at 81.

106. TRIPS, *supra* note 4, art. 7.

107. PCDA *Final Recommendations*, *supra* note 2, annex ¶ 45 (“To approach intellectual property enforcement in the context of broader societal interests and especially development oriented concerns, with a view that ‘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,’ in accordance with Article 7 of the TRIPS Agreement.”).

108. Barbosa, *supra* note 38, at 5-6 (emphasis omitted) (citations omitted); *see also infra* note 145.

importance to their socio-economic and technological development.”¹⁰⁹ Referring to articles 7 and 8, Moncayo von Hase has stated that local “freedom to introduce exceptions or limitations on public ground or to adopt measures to counter abuses on the part of IPRs rightsholders w[as] partly conceived to attenuate the social costs that developing countries must absorb in order to bring their national IPRs system in line with TRIPS standards.”¹¹⁰

One might argue that member states accepted intrusions on sovereignty accompanying the deep linkages of intellectual property minimum standards, without demanding corresponding shields on this intrusion through, for example, the language of “rights of development”¹¹¹ or through mandatory exceptions and limitations. Articles 7 and 8, which reference the developmental objectives of TRIPS, are couched in the less definite language of “should” or “may” whereas the minimum standards of TRIPS are stated in the mandatory language of “shall.”¹¹²

For several reasons, we find this position to be less than compelling. Pre-existing international intellectual property treaties upon which the TRIPS treaty was modeled, such as the Berne Convention, specified the rights associated with intellectual property but left the ambit of other rights associated with the public interest up to the discretion of member states to mold as they see fit within certain broadly outlined parameters.¹¹³ However, it does not follow that a balance of development goals within the TRIPS treaty structure is irrelevant, particularly when specific treaty text referencing balance and development exists.

Furthermore, the negotiating history indicates that the preambular language, as well as articles 7 and 8, were the product of vigorous debate about the role of intellectual property in development. The initial text was suggested by the so-called “Group of 14” developing countries.¹¹⁴ The

109. TRIPS, *supra* note 4, art. 8.

110. Moncayo von Hase, *The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 137 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

111. See generally Stephen Marks, *The Human Right to Development: Between Rhetoric and Reality*, 17 HARV. HUM. RTS. J. 137 (2004).

112. See, e.g., TRIPS, *supra* note 4, art. 9 (“Members shall comply with Articles 1 through 21 of the Berne Convention”); TRIPS, *supra* note 4, art. 27 (“[P]atents shall be available”).

113. Ruth L. Okediji, *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries 2*, (Int’l Centre for Trade and Sustainable Dev., Issue Paper No. 15, Mar. 2006), available at http://www.unctad.org/en/docs/iteipc200610_en.pdf.

114. Adronico O. Adede, *Origins and History of the TRIPS Negotiations*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY* 25, 28 (Christophe Bellmann et al. eds., 2003); Daniel J. Gervais, *Intellectual Property*, *supra* note 8, at 508-09.

Group of 14 pushed to include this language referencing development after it became inevitable that intellectual property rights were to be included in the global trading framework.¹¹⁵ By presenting their own text, these countries wanted

to highlight the importance of the public policy objectives underlying national IPR [Intellectual Property Rights] systems, the necessity of recognizing those objectives at the international level and . . . the need to respect and safeguard national legal systems and traditions on IPRs, in view of the diverse needs and levels of development of states participating in the IPR negotiations.¹¹⁶

Finally, and perhaps most significantly, the interpretative context for these articles has changed significantly since 1996 when TRIPS came into force and indeed even since the initial DSU decisions interpreting articles 7 and 8.¹¹⁷ According to the Vienna Convention on the Law of Treaties, “any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions”¹¹⁸ or “any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation”¹¹⁹ shall be taken into account in treaty interpretation. The Doha Declaration on TRIPS and Public Health,¹²⁰ the

[T]he emerging outline of a possible TRIPS result had essentially been at the level of principles, not legal texts. The draft legal texts, which emanated from the European Community, the United States, Japan, Switzerland, and Australia, foreshadowed a detailed agreement covering all IP rights then in existence. . . . As a reaction, more than a dozen developing countries proposed another “legal” text, much more limited in scope, with few specific normative aspects. They insisted on the need to maintain flexibility to implement economic and social development objectives. In retrospect, some developing countries may feel that the Uruguay Round Secretariat did them a disservice by preparing a “composite” text, which melded all industrialized countries’ proposals into what became the “A” proposal, while the developing countries’ text became the “B” text. The final Agreement mirrored the “A” text. As such, it essentially embodied norms that had been accepted by industrialized countries. The concerns of developing countries were reflected in large part in two provisions—Articles 7 and 8.

Daniel J. Gervais, *Intellectual Property*, *supra* note 8, at 508 (footnotes omitted).

115. Abdulqawi A. Yusuf, *TRIPS: Background, Principles and General Provisions*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 3, 10-14 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

116. Adede, *supra* note 114, at 28.

117. See, e.g., Appellate Body Report, *Canada-Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000) (discussed *infra* Part II).

118. Vienna Convention on the Law of Treaties, art. 31(3)(a), 1155 U.N.T.S. 331 (May 23, 1969) [hereinafter Vienna Convention]; see also ANTHONY AUST, *MODERN TREATY LAW AND PRACTICE* 191 (2000).

119. Vienna Convention, *supra* note 118, art. 31(3)(b); AUST, *supra* note 118, at 194-95.

120. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration on TRIPS and Public Health] (affirming “WTO members’ right to protect public health and, in particular, to promote access to medicines for all”) (emphasis added).

Doha Declaration,¹²¹ the 2003 General Council Decision,¹²² and proposed article 31bis¹²³ all comprise subsequent legal agreements or practices that highlight the importance of “development” as a key legal term of art within the original TRIPS text. The new WIPO Development Agenda reinforces even more profoundly this development tilt in global intellectual property. Moreover, the overall context for interpretation should arguably account for the development focus of the Doha Round itself,¹²⁴ and even the explicit human development approach of the UN Millennium Development Goals.¹²⁵ In Part II below, we discuss a principle of evolutive interpretation that takes into account this changing context.

Yet at the same time, balance of any kind in the IIPRC seems increasingly elusive, both as an empirical and even a normative matter. Intellectual property, as the *de jure* and *de facto* form of regulation of innovative activity, connects powerfully to an often one-sided rhetoric of exclusionary rights.¹²⁶ The previous Section described regime-shifting moves by industrialized countries to instruments such as FTAs, or venues such as the G8, which have exacerbated the lack of balance in the IIPRC. While developing countries have responded by shifting regimes to human rights frameworks, this does not automatically counteract the powerful property rights discourse wielded by intellectual property rights holders.¹²⁷

121. Note that two separate Doha Ministerial Declarations were issued on November 14, 2001. The one referenced herein as the “Doha Declaration on TRIPS and Public Health” was specific to the issue of TRIPS and public health. The other, referenced herein as the “Doha Declaration,” more generally addressed the objectives of the so-called “Doha development round.” See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 ¶¶ 17-19 (2002) [hereinafter Doha Declaration]. Paragraph 19 of the Doha Declaration explicitly links the TRIPS Council review of specific activities to “the objectives and principles set out in articles 7 and 8 of the TRIPS Agreement and” directs the TRIPS Council to “take fully into account the development dimension.” *Id.* ¶ 19.

122. Decision of the General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WT/L/540 (Aug. 30, 2003), http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [hereinafter General Council Decision] (last visited Oct. 19, 2007).

123. Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/41 (Dec. 6, 2005).

124. BARTON ET AL., *supra* note 23, at 168-69.

125. “Target 12. Develop further an open, rule-based, predictable, non-discriminatory trading and financial system [sic] Includes a commitment to good governance, development, and poverty reduction — both nationally and internationally.” UN Millennium Development Goals, Targets, and Indicators, Goal 8, Target 12, <http://www.undp.org/mdg/goallist.shtml> (last visited Oct. 19, 2007).

126. See generally KEITH E. MASKUS, *REFORMING U.S. PATENT POLICY: GETTING THE INCENTIVES RIGHT* (Council on Foreign Relations, CSR No. 19, 2006).

127. Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039 (2007); Laurence R. Helfer, *Toward a*

Indeed, there is a certain similarity between the rhetoric of balance within the IPRC and the way development functions rhetorically as part of the WTO's mandate. International intellectual property "balance" and international "development" both are nominally recognized. But in both cases, they are embedded within a model of economic growth, which then makes any alternative interpretations (based, for example, on a human development model) difficult to articulate. Within trade law generally, recognizing the special problem of development has traditionally been a challenge.¹²⁸ Yet any development-oriented approach necessitates differentiating among differently situated member states.¹²⁹

Regulatory harmonization of intellectual property rules across countries varying widely in their levels of development demonstrates the very real costs, and somewhat dubious benefits, of implementation.¹³⁰ From the perspective of many developing countries, capacity building has been about building capacity for compliance with top-down intellectual property legal regimes, not about building capacity from the bottom up, that is, from the local context for innovation based on human development needs.¹³¹ Two primary tools for development within the traditional trade framework are special and differential treatment (S&DT), endorsed by the developed countries, and technical assistance, typically endorsed by developing countries.¹³² These two tools have neither been sufficient, nor sufficiently implemented, for purposes of development within the intellectual property context.¹³³ S&DT is implemented in TRIPS solely through the transition

Human Rights Framework for Intellectual Property, 40 U.C. DAVIS L. REV. 971 (2007) (analyzing General Comment 17, which interprets ICESCR Article 15(1)(c)); Rochelle Cooper Dreyfuss, *Patents and Human Rights: Where is the Paradox?* (N.Y. Univ., Law and Economics Research Paper No. 06-38, forthcoming 2007), available at <http://ssrn.com/abstract=929498>.

128. Broude, *supra* note 3, at 6.

129. Broude, *supra* note 3, at 35.

130. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 137, ch. 7 (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter INTEGRATING INTELLECTUAL PROPERTY RIGHTS]; STIGLITZ & CHARLTON, *supra* note 44, at 48 (reporting that US \$30 million was required for Mexico to implement an IPR enforcement system with questionable benefits).

131. INTEGRATING INTELLECTUAL PROPERTY RIGHTS, *supra* note 130, at 137, ch. 7; Michel Kosteci, *Intellectual Property and Economic Development: What Technical Assistance to Redress the Balance in Favor of Developing Nations?* (ICTSD Issue Paper No. 14, Mar. 2006), available at <http://www.iprsonline.org/resources/docs/Kosteci%20-%20IP%20Economic%20Development%20-%20Blue%2014.pdf>.

132. Daniel D. Bradlow, *Differing Conceptions of Development and the Content of International Development Law*, 21 S. AFR. J. HUM. RTS. (2005), available at [www.ssrn.com, abstract=788070](http://www.ssrn.com/abstract=788070).

133. TRIPS, *supra* note 4, art. 66.1 ("Least-Developed Country Members"). S&DT is implemented in TRIPS via the transition periods for the LDCs to implement their obligations under Article 66.2; the TRIPS General Council extended this time to 2016.

periods for the LDCs to implement their obligations under article 66; the TRIPS General Council extended this time to 2016.¹³⁴ This Uruguay Round model departs from the traditional S&DT of non-reciprocal trade concessions by developed countries; TRIPS establishes uniform regulatory baselines that are modifiable by time of acceptance, but are not otherwise subject to differentiation.¹³⁵ Technical assistance has received relatively little attention in the literature, and arguably has not been operationalized beyond the exporting of intellectual property norms, although it has been institutionalized within the TRIPS framework.¹³⁶ Under the development as growth model, technology transfer is supposed to occur as a by-product of foreign direct investment, encouraged by the adoption of intellectual property minimum standards and aided by technical assistance. Yet, so far the evidence is mixed at best.¹³⁷

Current approaches to trade and development, even outside of intellectual property, emphasize *balanced* rules. This means assessments of costs and benefits, preservation of flexibility, and transparency of development impact.¹³⁸ By contrast to what is demanded by these new approaches, however, there seems to be a hardening of the arteries within the international intellectual property framework. Formalistic norm-setting and norm-interpretation is a problem, even for developed countries with

134. Press Release, WTO, Council approves LDC decision with additional waiver (June 28, 2002), http://www.wto.org/english/news_e/pres02_e/pr301_e.htm (last visited Oct. 19, 2007).

135. TREBILCOCK & HOWSE, *supra* note 5, at 34-35, 501-502.

136. TRIPS, *supra* note 4, at art. 66.2, 67 (“Technical Cooperation”), and 69 (“International Cooperation”) address technical assistance and technology transfer. See Duncan Matthews & Viviana Munoz-Tellez, *Bilateral Technical Assistance and TRIPS: The United States, Japan and European Communities in Comparative Perspective*, 9 J. WORLD INTELL. PROP. 629, 649-50 (2006) (analyzing article 67 technical assistance efforts from 1996-2005; concluding that while subtle differences exist among the U.S., the EU and Japanese approaches to technical assistance, relatively few activities focus on articles 7 and 8, or on flexibilities.); Kristen M. Koepsel, *How Do Developed Countries Meet Their Obligations Under Article 67 of the TRIPS Agreement?* 44 IDEA 167 (2004) (describing difficulty in meeting reporting requirements of Article 67 as well as technology transfer requirements under article 66.2); Okediji, *supra* note 113, at 5 (“The failure to obtain an international agreement on technology transfer occasioned acknowledgements within TRIPS of the freedom of countries to interfere with abuses of intellectual property rights that adversely affect, *inter alia*, technology transfer.”) (footnotes omitted).

137. Gervais, *Intellectual Property*, *supra* note 8, at 516-20; Maskus & Reichman, *supra* note 8, at 8-11.

138. Faizel Ismail, *Mainstreaming Development in the World Trade Organization*, 39 J. WORLD TRADE 11, 12 (2005). This type of balanced development approach seems to have been endorsed within the new WIPO Development Agenda. *PCDA Final Recommendations*, *supra* note 2, annex ¶ 15 (“Norm-setting activities shall: be inclusive and member driven; take into account different levels of development; take into consideration a balance between costs and benefits; . . .”).

well-established intellectual property industries.¹³⁹ Intellectual property is represented as being in the social welfare interests of all countries, in a formal equality sense. Yet any robust innovation policy should consider other means and forms of regulation. Developing countries arguably need the most flexibility in this regard.

The remainder of this Article outlines three specific legal proposals to mainstream meaningfully development and balance within the IIPRC. Part II focuses on expanding the role of TRIPS articles 7 and 8 within WTO jurisprudence. Part III examines the potential impact of a substantive equality principle¹⁴⁰ on the WIPO Development Agenda. Part IV discusses the role of emerging human rights norms as well as international law principles such as non-derogation and freedom of implementation.

These proposals are offered to restore domestic and global balance in the face of what we perceive to be the hardening IIPRC imbalance.

II. TRIPS AND PRINCIPLES OF TREATY INTERPRETATION

The balancing role of articles 7 and 8 has not received full support in the WTO case law. The WTO Appellate Body's analysis in *Canada—Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their Member States* (hereinafter *Canada—Patent Protection of Pharmaceutical Products*) is not definitive, which even the Appellate Body itself recognized at the time:

101. [W]e note that our findings in this appeal do not in any way prejudice the applicability of Article 7 or Article 8 of the *TRIPS Agreement* in possible future cases with respect to measures to promote the policy objectives of the WTO Members that are set out in those Articles. Those Articles still await appropriate interpretation.¹⁴¹

Achieving a proper balance within the IIPRC necessarily involves assessing how the pertinent adjudicatory bodies are interpreting the relevant legal texts. For all practical purposes, the most relevant bodies in this context are those established by the WTO. Therefore, we analyze the evolving nature of WTO case law and suggest applicable principles, in connection with general principles of treaty interpretation, including those developed by the Vienna Convention of the Law of Treaties (VCLT), applicable jurisprudence of the International Court of Justice (ICJ), as well as the WTO Dispute Settlement Understanding (DSU) and the Dispute

139. Graeme B. Dinwoodie & Rochell C. Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95, 96 (2004).

140. Chon, *supra* note 6; see also Margaret Chon, *Intellectual Property "from Below": Copyright and Capability for Education*, 40 U.C. DAVIS L. REV. 803 (2007) [hereinafter Chon, *Intellectual Property "from Below"*]; Chon, *supra* note 8.

141. Appellate Body Report, *Canada-Term of Patent Protection*, ¶ 101, WT/DS170/AB/R (Sept. 18, 2000).

Settlement Body (DSB) of the WTO. Furthermore, although not a dispute settlement decision, the Ministerial Conference in Singapore emphasized the importance of the preamble in the Declaration adopted on December 13, 1996: “For nearly 50 years Members have sought to fulfil, first in the GATT and now in the WTO, the objectives reflected in the preamble to the WTO Agreement of conducting our trade relations with a view to raising standards of living worldwide.”¹⁴² We also explore the general nature of interpretation of international texts, including the role of principles versus rules.

A. The Principle of *In Claris Non Fit Interpretatio* versus the Principle of Integration

Thus far, the WTO case law reveals a restrictive interpretive approach towards the TRIPS agreement. Many have been critical of this approach, which is based on an aggressively textual¹⁴³ and one-sided view of the objectives and principles of TRIPS.¹⁴⁴ For example, Robert Howse states:

The recent decision of a WTO panel, in the Canadian *Generic Medicines* case, however, ignores [Article 7’s] words about balance and mutual advantage [and may] . . . have very harmful impacts, particularly on developing countries . . . Even though it was dealing with an explicit “exceptions” provision, comprehensible only if there are legitimate, competing policy interests, the Panel was only interested in how much the rights holder might lose, not in how much society might gain, from a given exception. It never asked what scope the exception might require to achieve the social purpose at issue.¹⁴⁵

The general framework for treaty interpretation is governed by articles 31¹⁴⁶ and 32¹⁴⁷ of the VCLT. The International Court of Justice displays

142. World Trade Organization, Singapore Ministerial Declaration of 13 December 1996, ¶ 2, WT/MIN(96)/DEC, 36 I.L.M. 218 (1997). See also Petersmann, *supra* note 32 (emphasizing general principles of justice).

143. Joseph 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, 206 (2001) (observing the “almost obsessive attempts of the Appellate Body to characterize . . . interpretations of the Agreement as ‘textual’”).

144. See Edwin Cameron, *Patents And Public Health: Principle, Politics And Paradox*, 1 SCRIPT- ed: ONLINE 517 (2004), <http://www.law.ed.ac.uk/ahrc/script-ed/issue4/Cameron.pdf>; Dinwoodie & Dreyfuss, *supra* note 5.

145. Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. 493-96 (2002).

146. Vienna Convention, *supra* note 118, art. 31. Article 31 reads:
General rule of interpretation

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:

special reliance upon such interpretative principles.¹⁴⁸ Within the WTO's explicit decision-making framework, article 3.2 of the DSU refers to the "customary rules of interpretation of public international law,"¹⁴⁹ which are understood as those rules incorporated in the VCLT. For example, the WTO panel in *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products* explicitly relied on *GATT acquis*,

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- (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.

Id.

147. Vienna Convention, *supra* note 118, art. 32. Article 32 reads:

Supplementary means of interpretation

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) leaves the meaning ambiguous or obscure; or
- (b) leads to a result which is manifestly absurd or unreasonable.

Id.

148. In doing so, it seeks in the first place to determine the usual and natural meaning of the words in their context, without, however, sticking too closely to the particular rules applicable under the procedural law of any legal system, and in that regard frequently refers to article 31 of the VCLT. "[A]n international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of the interpretation." THE INTERNATIONAL COURT OF JUSTICE 92 (5th ed. 2004), *available at* <http://www.icj-cij.org/icjwww/igeneralinformation/ibleubook.pdf> (citing *Legal Consequences for States of the Continued Presence of South Africa in Namibia, Advisory Opinion*, 1971 I.C.J. 21 (June 1971)).

149. Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 3(2), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, *available at* http://www.wto.org/English/docs_e/legal_e/28_dsu.pdf. Art. 3(2) states that [t]he dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

Id.

customary rules of interpretation of public international law and, specifically, article 31 of the VCLT.¹⁵⁰

However, the WTO's Appellate Body has generally given high priority to treaty text. For example, in *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, the Appellate Body stated:

The Panel did not follow all of the steps of applying the “customary rules of interpretation of public international law” as required by Article 3.2 of the DSU. As we have emphasized numerous times, these rules call for an examination of the ordinary meaning of the words of a treaty, read in their context, and in the light of the object and purpose of the treaty involved. A treaty interpreter must begin with, and focus upon, the text of the particular provision to be interpreted. . . . Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usefully be sought.¹⁵¹

As applied in the TRIPS context, the WTO dispute settlement panel in *Canada—Patent Protection of Pharmaceutical Products* reiterated this principle of *in claris non fit interpretatio*.¹⁵²

Thus, the correct approach was to focus first on the text of the provisions to be interpreted read in its context and to discern from this the intention of the parties to

150. Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R (Aug. 24, 1998). The basic methodology is set out in Panel Report, *United States—Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan*, ¶ 7.27, WT/DS184/R (Feb. 28, 2001).

As the Appellate Body has repeatedly stated, panels are to consider the interpretation of the WTO Agreements, including the AD Agreement, in accordance with the principles set out in the Vienna Convention on the Law of Treaties (the “Vienna Convention”). Thus, we look to the ordinary meaning of the provision in question, in its context, and in light of its object and purpose. Finally, we may consider the preparatory work (the negotiating history) of the provision, should this be necessary or appropriate in light of the conclusions we reach based on the text of the provision.

Id.

151. Appellate Body Report, *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 114, WT/DS58/AB/R (Oct. 12, 1998) (citations omitted).

152. “In clarity there is no room for interpretation” (translated from Latin). In connection with this rule, it might be remarked that clarity presumes community of ground between legislator and interpreter at a very considerable level, which time and cultural elements can easily deny. For instance, authors have indicated that the clear interpretation of TRIPS article 27.1 at its inception excluded business methods as patentable matter; but soon after the WTO initial term, changes in U.S. case law brought about this matter as covered by the patent laws; the fact that other Members would not follow this understanding should not attract undue discrimination charges (perhaps the contrary should be held true, from a societal point of view). As to the scope of the non-discrimination rule of TRIPS article 27, see Denis B. Barbosa *O princípio de não-discriminação em propriedade intelectual, in Usucapião de Patentes e Outros Estudos de Propriedade Industrial*, LUMEN JURIS, 2006. Legal culture also may influence the clarity standard, as, for instance, common-law practitioners could be attracted to an historical interpretation, always politically useful when interpreting the actual bargain among the contracting parties, but not accepted as a primary means of interpretation in Continental legal systems.

an agreement. It was only if this left a doubt that it was appropriate to seek enlightenment from the object and purpose of the agreement.¹⁵³

This panel opposed the use of the object and purpose of TRIPS, as also stated in its preamble, as interpretative tools to the document.

Canada claimed to be interpreting Article 30 of the TRIPS Agreement *in context* when it invoked the first recital to the Preamble and Articles 1.1 and 7 of the TRIPS Agreement. It was clear that the whole text of an agreement, including the preamble, formed part of the context of a provision of that agreement. However, the above provisions were not in reality being invoked by Canada as *context* to discern the ordinary meaning of the terms used in Article 30, but as expressions of *object and purpose*. The arguments drawn from these provisions by Canada all related to the supposed object and purpose of the TRIPS Agreement and not to contextual guidance as to the meaning of the terms of Article 30 thereof.¹⁵⁴

The *Canada—Patent Protection of Pharmaceutical Products* panel’s interpretative method does not conform to mainstream treaty interpretation, which includes the principle of integration: The whole treaty shall be read together, rather than with a focus on a single provision, however clearly that provision may shine in isolation.¹⁵⁵ Indeed, a counter-example to the panel’s method exists within the intellectual property jurisprudence of the WTO: A different panel interpreting TRIPS, the *United States—Section 110(5) of the U.S. Copyright Act* panel, adopted this integration principle, stating “that the text of the treaty must of course be read as a whole. One cannot simply concentrate on a paragraph, an article, a section, a chapter or a part.”¹⁵⁶

The whole treaty includes, perhaps especially, the stated objects and purposes of the document. An essential part of a treaty is its preamble.¹⁵⁷ As to the relevance of external sources, the treaty segment under inspection should be read together with the whole body of relevant international law, both at the moment of the inception of the treaty and at the moment when the interpretation is performed.¹⁵⁸ This principle of integration is as

153. Panel Report, *Canada—Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their Member States*, at 51, WT/DS114/R (March 17, 2000).

154. *Id.* at 51-52.

155. IAN BROWNLIE, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW* 604 (6th ed. 2003).

156. Panel Report, *United States—Section 110(5) of the U.S. Copyright Act*, at 17 n.49, WT/DS160/R (June 15, 2000).

157. GERVAIS, *supra* note 101, at 80.

The preamble to the TRIPS Agreement is an essential part of it. Under “GATT law”, preambles are on occasion relied upon to a considerable extent by panels when the wording of a provision is not clear or where it is susceptible to divergent interpretations. . . . The preamble, together with footnotes, should be considered as an integral part of the agreement, a condensed expression of its underlying principles.

Id.

158. BROWNLIE, *supra* note 155, at 604.

important as the principle of prioritizing text, so heavily relied upon by the *Canada—Patent Protection of Pharmaceutical Products* panel. It would be proper, therefore, to classify the panel decision as an incomplete ground upon which to build a robust TRIPS reading.

This integration principle can be detected in some other WTO decisions. In construing the WTO Marrakesh Agreement, the Appellate Body report in *Brazil—Desiccated Coconut* invoked the preamble to the Agreement in the context of the integrated WTO system that replaced the old GATT in 1947.¹⁵⁹ Dispute settlement panels have made the same inclusive interpretive gesture in other circumstances (leaving aside the cases concerning environmental issues).¹⁶⁰

The integration principle provides for a supra-textual reading of the treaties, which is not extraneous to WTO case law.¹⁶¹ It considers both the treaty as a whole, including its teleological markings (like preambles),¹⁶²

159. Appellate Body Report, *Brazil – Measures Affecting Desiccated Coconut*, at 18, WT/DS22/AB/R (Feb. 21, 1997). The authors of the new WTO regime intended to put an end to the fragmentation that had characterized the previous system. This can be seen from the preamble to the *WTO Agreement* which states, in pertinent part:

Resolved, therefore, to develop an integrated, more viable and durable multilateral trading system encompassing the General Agreement on Tariffs and Trade, the results of past trade liberalization efforts, and all of the results of the Uruguay Round of Multilateral Trade Negotiations.

Id.

160. Panel Report, *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, ¶ 7.2, WT/DS90/R (Apr. 6, 1999) (“At the outset, we recall that the Preamble to the WTO Agreement recognises both (i) the desirability of expanding international trade in goods and services and (ii) the need for positive efforts designed to ensure that developing countries secure a share in international trade commensurate with the needs of their economic development. In implementing these goals, WTO rules promote trade liberalization, but recognize the need for specific exceptions from the general rules to address special concerns, including those of developing countries.”); *see also* Panel Report, *Brazil – Export Financing Programme For Aircraft – Recourse By Canada To Article 21.5 of the DSU*, ¶ 6.47 n.49, WT/DS46/RW (May 9, 2000) (“The preamble to the *WTO Agreement* recognises [sic] ‘that there is need for positive efforts designed to ensure that developing countries, and especially the least-developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development.’”).

161. *See* Appellate Body Report, *United States-Standards for Reformulated and Conventional Gasoline*, at 17, WT/DS2/AB/R (Apr. 29, 1996) [hereinafter *Gasoline*] (“[T]he *General Agreement* is not to be read in clinical isolation from public international law.”). A critical analysis of the interpretative usages of the adjudicatory bodies of OMC can be found in Evandro Menezes de Carvalho, *The Juridical Discourse of the World Trade Organization: The Method of Interpretation of the Appellate Body’s Reports*, 7 GLOBAL JURIST TOPICS, Iss. 1, Art. 4 (2007), available at <http://www.bepress.com/cgi/viewcontent.cgi?article=1211&content=gj>.

162. Panel Report, *United States—Section 110(5) of the U.S. Copyright Act*, WT/DS160/R (June 15, 2000); *see also* Appellate Body report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (Oct. 12, 1998) (“A treaty interpreter must begin with, and focus upon, the text of the particular provision to be interpreted. It is in the words constituting that provision, read in their context, that the object

and even other treaties.¹⁶³ Like the overall WTO Agreement itself, TRIPS should not be read in “clinical isolation” from public international law.¹⁶⁴

B. Constructing Legal Principles out of Articles 7 and 8 of TRIPS

One barrier to incorporating balance as a concept within TRIPS is that the WTO dispute settlement bodies so far have not fully captured the valence of articles 7 and 8.¹⁶⁵ Thus, we recommend the application of two interpretive principles to their jurisprudence: (1) an “evolutive

and purpose of the states parties to the treaty must first be sought. Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usually be sought.”) In Panel Report, *United States—Sections 301-310 of the Trade Act of 1974*, ¶ 7.22, WT/DS152/R (Dec. 22, 1999), the Panel concluded that the elements of Article 31 of the VCLT, “are to be viewed as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order.” The same was stated in Panel Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 8.46, WT/DS135/R (Sept. 18, 2000), providing that “to the extent that Article 31 of the Vienna Convention contains a single rule of interpretation and not a number of alternative rules, the various criteria in the Article should be considered as forming part of a whole.”

163. Under the standards of ICJ of what should be the context (the framework of the entire legal system prevailing at the time of the interpretation), even some particular instances of soft law would be relevant rules of international law applicable in the relations between the parties. This is not a secondary instance of interpretation (as perhaps the rulings in the *Shrimp-Turtles* and *Canada Pharmaceuticals* cases might be felt to indicate) but should be consulted *together with the context* where a primary reading is to be affected.

164. See generally Gabrielle Marceau, *A Call for Coherence in International Law: Praises for the Prohibition against “Clinical Isolation” in WTO Dispute Settlement*, 33 J. WORLD TRADE 87-152 (1999) (arguing in favor of incorporating non-WTO law in WTO DSU decisions). The integration of TRIPS in the overall WTO structure also raises an extremely important issue: the balancing of interests that, as shall be seen below, is a crucial aspect of TRIPS application and enforcement, and is a complex operation where trade interests and specific intellectual property-related interests shall be considered in some specific cases. However, to the proportion that access to technology, expressive creations and commercial image instruments are essential to a certain notion of development, a complete nullification of societal values related to intellectual property rights and obligations would seem contrary to the core TRIPS law, particularly as interpreted by the Member states in the Doha Round exercises.

165. As Ruth Okediji stated, “[a] particularly revealing aspect of these [relevant TRIPS] disputes is the way each of the Panels and the Appellate Body have ducked the thorny question of how to apply the preambular statements and the broad themes of Article 7 and 8 to evaluate the substantive obligations of the TRIPS Agreement.” Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT’L L. REV. 819, 914 (2003); see also Dinwoodie & Dreyfuss, *supra* note 5, at 220-21 (noting the need for more elaboration of articles 7 and 8 to preserve balance and a robust international public domain); Chon, *supra* note 6, at 2843 (“A key impediment, however, is that the language referencing development in TRIPS [Article 8] is not mandatory, but rather hortatory and that the language is placed within parts of the treaty that are not in the main treaty body. This issue (rather than the substantive content of development) has preoccupied the few legal scholars who have addressed these terms.”).

interpretative” approach that considers the changing context for interpretation of relevant treaty provisions; and (2) a “vectorial” approach that acknowledges and weighs competing principles that animate the agreements.

1. *From Rules to Principles: The Principle of Evolutive Interpretation*

International law jurists have articulated a principle of evolutive interpretation¹⁶⁶ consistent with the interpretative practice of the ICJ.¹⁶⁷ As stated earlier, the Vienna Convention on the Law of Treaties provides a basis for considering subsequent agreements and practices of the parties in treaty interpretation.¹⁶⁸ In the case of TRIPS, the combination of articles 7 and 8, and 71.1 of TRIPS, provided the basis for the Doha Declaration on TRIPS and Public Health as well as the General Council Decision implementing Paragraph Six of that declaration.¹⁶⁹ This so-called Paragraph Six solution subsequently evolved into a non-soft law norm—proposed article 31*bis*.¹⁷⁰ Under the evolutive interpretation principle, these “subsequent developments” arguably supersede the *Canada Patent Protection of Pharmaceutical Products* panel’s limited interpretation of articles 7 and 8.

The Doha Declaration on TRIPS and Public Health and General Council Decision are obvious applications of the balancing approach anticipated by articles 7 and 8 and the preambulatory text. These balancing exercises were undertaken by the very source holding the *jus tractuum* (the treaty power)—that is, the member states themselves—in a manner provided by the WTO and TRIPS rules. Thus, it is an authentic interpretation by authoritative law-making bodies clearly integrating development within intellectual property norm-interpretation. Furthermore,

166. MARISTELA BASSO, O DIREITO INTERNACIONAL DA PROPRIEDADE INTELECTUAL 76 (Livraria Do Advogado ed., 2000). See also Gabrielle Marceau, *The WTO Dispute Settlement and Human Rights*, in INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES 181, 200 (Frederick M. Abbott et al. eds., 2006).

167. *Kasikili/Sedudu Island (Botswana/Namibia)*, 1999 I.C.J. 1045 (Dec. 13) (Parra-Aranguren, J., dissenting). As a general rule of interpretation, Article 31, paragraph 3(b), of the 1969 Vienna Convention on the Law of Treaties provides that account shall be taken, together with the context, of “any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.” Vienna Convention, *supra* note 118, art. 31(b).

168. Vienna Convention, *supra* note 118, arts. 31(3)(a)-(b).

169. Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 6; see also Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 4 (affirming “WTO members’ right to protect public health and, in particular, to promote access to medicines for all”) (emphasis added); General Council Decision, *supra* note 122.

170. See Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/41 (Dec. 6, 2005).

these agreements directly indicate that some of the exceptions provided by the TRIPS text (especially article 31) are to be employed as tools to enforce the development and public interest values indicated by article 8. Finally, the Doha Declaration on TRIPS and Public Health and General Council Decision regarding intellectual property dispel the starkly one-sided interpretation of TRIPS in *Canada Patent Protection of Pharmaceutical Products*, according to which TRIPS was only intended to enhance protection to the intellectual property rights holder.

An evolutive interpretation principle is further guided by the Doha Declaration, which states that work in the TRIPS Council on these reviews or on any other implementation issue should also look at the relationship between the TRIPS Agreement and the UN Convention on Biodiversity; the protection of traditional knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPS Agreement.¹⁷¹ It adds that the TRIPS Agreement's objectives (article 7) and principles (article 8) should guide the TRIPS Council's work on these topics, and must take development fully into account.¹⁷² Finally, the new WIPO Development Agenda links the language of article 7 to development norms within the WIPO's intellectual property mandate. While not an agreement of the WTO member states regarding the interpretation of TRIPS, this language is nonetheless relevant as a type of "practice" of certain member states (overlapping among the WTO and the WIPO) because of the close relationship of the WTO to the WIPO within the IIPRC. It reinforces the primacy of balancing intellectual property rights with pro-development and public interest flexibilities.

2. *From Rules to Principles: The Principle of Vectorial Interpretation*

a. Defining the Vectorial Approach

The preamble, as well as articles 7 and 8 of TRIPS, are to be understood as norms of different function and character than the strictly prescriptive provisions of the same text (for instance, the rule of a minimum term for patents). The former are in the nature of principles whereas the latter are built as rules.¹⁷³ Principles serve a different function than do rules.

171. Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 19.

172. *Id.*

173. LUIS ROBERTO BARROSO, INTERPRETAÇÃO E APLICAÇÃO DA CONSTITUIÇÃO, FUNDAMENTOS DE UMA DOGMÁTICA CONSTITUCIONAL TRANSFORMADORA 232 (Editora Saraiva 5th ed., 2003). As Barroso, the most celebrated Brazilian constitutional law author, explains:

The qualitative distinction between rule and principle is one of the pillars of the modern Constitutional Law, indispensable for overcoming the legal positivism where the concept of Law was restricted to rules. The Constitution turns into an open system, comprising rules and principles, permeable to legal values beyond the

They lead away from a positivist approach towards a normative approach of treaty interpretation.¹⁷⁴

Within a treaty, principles can either be inferred (as in the antidumping case mentioned above) or explicitly read from the preamble and principle-specific clauses. This is especially the case with respect to TRIPS article 8 (labeled “Principles,” so as to dispel any doubts as to its nature). But article 7, joined by some crucial preamble text,¹⁷⁵ also has a purpose. Moncayo von Hase has emphasized the active interpretation resulting from a purpose-centered—or teleological—approach.¹⁷⁶

positivism, where the ideas of justice and of accomplishment of the basic rights play a central role. The change of paradigm in this matter must render special tribute to the systematization of Ronald Dworkin. Its elaboration concerning the different roles played by rules and principles gained universal course and now is the conventional knowledge in the field. Rules are normative proposals formulated under form of all or nothing . . . Principles contain, normally, a higher valorative load, an ethical bedding, a relevant policy decision, and indicate a certain direction to follow. It occurs that it may exist, in a pluralist sequence, other principles that shelter diverse decisions, values or fundaments, even opposed among themselves. The collision of principles, therefore, is not only possible, as it is part of the logic of the system, which has a dialectic nature. Therefore its incidence cannot be treated in terms of all or nothing, of validity or invalidity. A dimension of weight or importance must be recognized to the principles. Considering the elements of the concrete case, the interpreter will have to make biased choices, when coping with inevitable antagonisms, as the ones that exist between the freedom of speech and the right of privacy, the free initiative and the state intervention, the right of property and its social function. The application of the principles is effected predominantly by means of balancing.

Id. (citations omitted) (translated by Denis Borges Barbosa). For a comprehensive analysis of the application of the opposition between principle and rules in the context of International and Comparative Law, see Jacob Dolinger, *Evolution of Principles for Resolving Conflicts in the Field of Contracts and Torts*, in 283 RECUEIL DES COURS: COLLECTED COURSES OF THE HAGUE ACADEMY OF INTERNATIONAL LAW 187 (2000).

174. ROBERT ALEXY, *TEORÍA DE LOS DERECHOS FUNDAMENTALES* 81 (1997).

175. The first recital indicates two potentially opposing interests to be balanced: Intellectual Property vs. Trade (“*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade,” TRIPS, *supra* note 4, pmb.). The third and fourth recitals draw an opposition between *private* interests to be given due regard (“*Recognizing* that intellectual property rights are private rights,” TRIPS, *supra* note 4, pmb.) and public interests to be similarly endorsed (“*Recognizing* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives,” TRIPS, *supra* note 4, pmb.). The fifth recital is a clear and strong expression of a substantive equality mandate towards the least developed countries.

176. Andrés Moncayo von Hase, *La protección de las invenciones en América Latina durante los años 2001-2002*, INCIDENCIA DEL ADPIC EN LAS LEGISLACIONES LATINOAMERICANAS, available at <http://www.ml.ua.es/webprom/Jornadas/documentos/Moncayo-Invenciones.pdf> [hereinafter Moncayo von Hase, *La Protección*].

Another important aspect of a principle-based approach is that principles are not applied in the abstract, but rather to the facts in a specific case, upon the chosen value-grounds.¹⁷⁷ Such an approach has in fact occurred in some cases, where the equities of a particular case and the consequences of choosing one outcome over another were part of the process of adjudication. By contrast, the adjudicating body in *Canada—Patent Protection of Pharmaceutical Products* decided to ignore such interpretative mechanisms, as though they were irrelevant to the specific case under its review.¹⁷⁸ Thus, the panel decided to focus on just one of the interests to be balanced: the purpose of TRIPS as to intellectual property rights was held to be to “reinforce the protection of these rights.” Therefore, this decision is an example of an unbalanced, hypertextual, ultrapositivist ruling.¹⁷⁹

Sus artículos 7 y 8 ponen de relieve los objetivos y principios básicos que inspiran al Acuerdo y que han de guiar su interpretación. En ellos se pone énfasis en la necesidad de lograr un equilibrio entre la protección de los derechos de propiedad intelectual y la necesidad de difundir y transferir tecnología y la posibilidad de adopción por parte de los Estados parte de medidas destinadas a proteger el medio ambiente y la salud pública y prevenir el abuso de los derechos de propiedad intelectual por sus titulares.

Id. at 2. For a more specific analysis of such reading by the same author, as applied to the Canada pharmaceuticals decision, see www.eclac.cl/mexico/capacidadescomerciales/CD%20Seminario%2011%20nov%2005/DOCUMENTOS/AMoncayo%20OMPI-CEPAL.pdf [hereinafter Moncayo von Hase, *Canada Pharmaceuticals*]; von Hase, *supra* note 110, at 137.

177. James Gathii, *Fairness as Fidelity to Making the WTO Fully Responsive to All its Members*, in THE AMERICAN SOCIETY OF INTERNATIONAL LAW: PROCEEDINGS OF THE 97TH ANNUAL MEETING 163 (2003), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=594485&high=%20james%20Gathii (“WTO Appellate Body (AB) in the initial *Shrimp-Turtle* case (*Shrimp-Turtle I*) held, in interpreting the meaning of Article 3.1 of the SPS Agreement, that where there is a choice in construing a treaty provision, the principle of *in dubio mitius*—‘the less onerous meaning to the party which assumes the obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties’—is to be preferred. The AB therefore concluded: ‘We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome obligation.’” (footnotes omitted)).

178. More precisely, the panel decided to focus on just one of the interests to be balanced: the purpose of TRIPS as to intellectual property rights was held to “reinforce the protection of these rights.” Panel Report, *Canada—Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their Member States*, at 52, WT/DS114/R (March 17, 2000).

179. Robert Howse, *supra* note 145, at 502. By denying the balancing norm of Articles Seven and Eight just to enhance the interests of the rights holders, the panel was excluding the effect of a provision of the text. *Gasoline*, *supra* note 161, at 17 (“One of the corollaries of the ‘general rule of interpretation’ in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.”).

By contrast, we propose a vectorial approach. This approach would incorporate the purposes of TRIPS, as expressed in its preambular language and articles 7 and 8. It would also pay more heed to the principle of integration, as described in Section II.A, as well as to foundational treaty principles where conflicting values may be at issue in the particular facts of a dispute. Thus, the objectives and principles of TRIPS should play a central role in the interpretation of the entire agreement.

b. Towards a Vectorial Reading of TRIPS

The TRIPS principles command a vectorial reading. The norms expressed in the preamble and articles 7 and 8 indicate opposing interests that should be given due respect and reconciliation. A vectorial reading supposes that different interests receive their due. The resulting finding of law never excludes any of the interests at stake but, much to the contrary, shall strive to give to each its proper legal consideration according to the classical rule of *sui cuique tribuere*. Vectorial analysis is not satisfied by a starkly unilateral interpretation of TRIPS, or even by the overall WTO context: As the much quoted *Gasoline* case states, the General Agreement cannot be read in clinical isolation.¹⁸⁰

An effective vectorial approach assumes that all competing interests are to be given some degree of subjective fungibility. That is, any party may be held to the same rigors of the law (putting every party in Rawls's "original position,")¹⁸¹ extended to the global community.¹⁸² Whether a vectorial approach in international trade law is safe or wise is a very serious question. Developing and developed country interests are not fully fungible, at least in the short term,¹⁸³ and the long-term view is not the

180. See *Gasoline*, *supra* note 161.

181. See generally JOHN RAWLS, A THEORY OF JUSTICE (1999).

182. Gathii, *supra* note 177, at 159.

Egalitarian liberals invoke a Rawlsian framework according to which benefits and burdens in the trading regime ought to be distributed in accordance initially with an equality principle that would treat all members of the WTO similarly and without distinction. However, egalitarian liberals emphasize the importance of John Rawls's difference principle, according to which, in the distribution of benefits and burdens, concern for the most vulnerable members of the trading regime should be taken into account. One thread that runs through this approach is that fairness is regarded as a condition of moral equality and, for some of its advocates, a precondition for economic justice.

Id. (quoting JOHN RAWLS, A THEORY OF JUSTICE 4, 14-15 (1971)).

183. When some portion of the parties is probably immune from that fungibility—as TRIPS assumes that the least developed countries for the time being are—a rule of substantive equality is a requirement of Justice, or (in a rather utilitarian perspective) of long term efficiency. Chon notes:

As Carlos Correa has stated, 'When the [knowledge] products are essential for life—as with food and pharmaceuticals—allocative efficiency becomes an important objective on both economic and equity grounds.' In other words, equality tilts the

province of adjudicatory bodies. These are real problems. But the fact is that the WTO Agreements include vectorial norms, in addition to the rule of *pacta sunt servanda*.

Articles 7 and 8 are, beyond any doubt, interpretative tools with respect to the meaning of the TRIPS agreement.¹⁸⁴ Crucial for many developing countries in the TRIPS negotiations was the perceived vectorial role of articles 7 and 8. A stated target for developing countries during TRIPS negotiations was to achieve a balancing of interests.¹⁸⁵ Written submissions of a more general nature presenting views on these questions were circulated by Thailand,¹⁸⁶ Mexico,¹⁸⁷ and Brazil.¹⁸⁸

The Brazilian position was relevant in this context. Brazil emphasized the need to keep in mind both the trade-related and developmental aspects of intellectual property rights. It distinguished the discussion in the developing countries' working group from more legal discussions being held by the developed countries, including:

balance towards static efficiency and away from dynamic efficiency arguments, at least for resource-poor areas of the world. A failure to understand that will lead to policy impasses.

Chon, *supra* note 6, at 2891.

184. Moncayo von Hase, *La Proteccion*, *supra* note 176.

185. See TRIPS Negotiating Document, MTN.GNG/NG11/W/32/Rev.1 (Sept. 29, 1989).

186. Statement by Thailand at the Meeting of 12-14 September 1988, MTN.GNG/NG11/W/27 (Sept. 12, 1988).

The Thai statement . . . emphasi[zed] that the two fundamental goals pursued by governments when granting intellectual property protection are the stimulation or encouragement of intellectual property creation and the accord of proper and legitimate protection of the public interest; *the former must not put an undue burden on or adversely affect the latter*.

TRIPS Negotiating Document, ¶ 5, MTN.GNG/NG11/W/32/Rev.1 (Sept. 29, 1989).

187. GATT Secretariat, *Statement Made by the Delegation of Mexico at the Meeting of 17, 18 and 21 October 1988*, MTN.GNG/NG11/W/28 (Oct. 19, 1988).

The statement by Mexico . . . [stated] that the negotiating objective regarding the improvement of intellectual property rights should not become a barrier to access by developing countries to technologies produced in developed countries. Any results obtained in the Group would therefore necessarily have to include more flexible elements for the use of such technology by developing countries, since countries with different levels of development cannot respond in the same way to each of the trade and intellectual property aspects. Mexico also advocates examination of Articles IX, XX and XXIII of the General Agreement and says that the provisions of the General Agreement should not be used to modify legal regimes governing intellectual property rights, but should aim, in the best of cases, at recommendations to reduce distortions in international trade and barriers to that trade which may derive from the application and protection of intellectual property rights.

GATT Secretariat, *Synoptic Tables Setting Out Existing International Standard and Proposed Standards and Principles*, ¶ 5, MTN.GNG/NG11/W/32/Rev.1 (Sept. 29, 1989).

188. Submission from Brazil, MTN.GNG/NG11/W/30 (Oct. 30, 1988).

- i) The extent to which rigid and excessive protection of intellectual property rights impedes access to the latest technological developments, restricting therefore the participation of developing countries in international trade. In this context, it emphasizes the importance of specific exclusions from the protection of intellectual property rights.
- ii) The extent to which abusive use of intellectual property rights gives rise to restrictions and distortions in international trade. Practices which have this effect should be subject to adequate multilateral discipline.
- iii) The risks that a rigid system of protection of intellectual property rights implies for international trade. Attentive consideration should be given to cases where the protection and enforcement of intellectual property rights become a barrier or harassment to legitimate trade, including where it is used as an excuse to implement protectionist and discriminatory measures.¹⁸⁹

The language of article 7 does not limit itself to exclusive rights, as the final clause indicates: “The protection and enforcement of intellectual property rights should contribute . . . to a *balance of rights and obligations*.”¹⁹⁰ The idea of balancing is obviously a vectorial device. Balancing, as is developed in the legal discourse in many countries, appears explicitly in TRIPS article 7. It prevents the protection of the interests of the intellectual property rights holders to the exclusion of other “rights and obligations.”

Article 8 of TRIPS foresees that each country can legislate, within the scope of TRIPS, “to protect the public health and nutrition and to promote the public interest in sectors of vital importance [for its] socioeconomic and technological development.”¹⁹¹ The retention of state sovereignty or traditional “police powers” in these areas relative to other measures in the TRIPS Agreement, combined with the procedural rule that the alleging party has the burden of proof, point to an implicit article 8 default procedural presumption in a vectorial analysis.

Article 8 also has substantive as well as procedural dimensions. “[P]ublic health and . . . interest in sectors of vital importance”¹⁹² are obviously interest categories of high value in any legal system. Once the content of such measures are not *prima facie* a means of arbitrary or unjustifiable discrimination between countries where the same conditions

189. TRIPS negotiating document, ¶ 5, MTN.GNG/NG11/W/32/Rev.1 (Sept. 29, 1989).

190. TRIPS, *supra* note 4, art. 7 (emphasis added).

191. TRIPS, *supra* note 4, art. 8.1 (“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”). Incidentally, the provision is, by allowing the national law to *promote the public interest in sectors of vital importance to their socio-economic and technological development*, almost a *littera ad litteram* reproduction of the wording of art. 5. XXIX of the Brazilian Constitution of 1988.

192. TRIPS, *supra* note 4, art. 8.1.

prevail, or are not a disguised restriction on international trade, a vectorial interpretative approach should give great weight to the built-in flexibilities of TRIPS to address domestic development concerns.¹⁹³

c. Re-Interpreting Caselaw Through the Vectorial Approach

In the first few years after the adoption of TRIPS, the WTO Dispute Settlement Body (DSB) considered two complaints regarding domestic standards of patent protection alleged to have violated international trade law obligations. Despite the explicit language of articles 7 and 8, as well as the negotiating history of those articles, both decisions proceed from the assumption that TRIPS is primarily concerned with protecting intellectual property, even though TRIPS plainly indicates a vectorial approach.

In *India Patent Protection for Pharmaceutical and Agricultural Chemical Products*, the WTO Appellate Body considered whether India had complied with its obligations under TRIPS with respect to its mailbox process for filing patent applications for pharmaceutical, agricultural, and chemical products. India's obligations to provide minimum standards of patent protection would become effective only ten years after the adoption of TRIPS (i.e., in 2005). India unsuccessfully defended the original complaint lodged by the United States (and largely supported by the European Union) before a DSB panel. It was largely unsuccessful in its attempt to overturn the panel decision on appeal. The Appellate Body decision tempered some of the more disagreeable aspects of the panel's

193. The conclusion of article 8 is an important consideration: "[P]rovided that they are consistent with the provisions of this Agreement." *Id.* art. 8.2. A similar provision can be found at the 1947 GATT art. XX (b). General Agreement on Tariffs and Trade, art. XX(b), Oct. 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 194. GATT 1947 allows for such measures as non-violative, provided that they "are not applied in a manner [that] constitute[s] a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade." *Id.* Article 8.1 simply "provides that necessary measures must be 'consistent with' the Agreement." UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 126 (2005). As the UNCTAD Resource book notes:

Since language of a treaty is presumed not to be surplus, it would appear that Article 8.1 is to be read as a statement of TRIPS interpretative principle: it advises that Members were expected to have the discretion to adopt internal measures they consider 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. The constraint is that the measures they adopt should not violate the terms of the agreement. This suggests that measures adopted by Members to address public health, nutrition and matters of vital socio-economic importance should be presumed to be consistent with TRIPS, and that any Member seeking to challenge the exercise of discretion should bear the burden of proving inconsistency. Discretion to adopt measures is built into the agreement. Challengers should bear the burden of establishing that discretion has been abused.

Id. at 126-27.

findings, but its reasoning viewed the main object and purpose of TRIPS as the need to promote effective and adequate protection of intellectual property rights. In the Appellate Body's view, TRIPS is simply about the protection of intellectual property.¹⁹⁴

As discussed above, balance suffered a similar fate in *Canada Patent Protection of Pharmaceutical Products*, where the panel adopted the European Communities' argument that three conditions of TRIPS article 30 should not be construed against the objectives and purposes stated in TRIPS articles 7 and 8. In doing so, the panel rejected Canada's position that "these purposes call for a liberal interpretation of the three conditions . . . so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies."¹⁹⁵ The panel ultimately stated that doing so would constitute "a renegotiation of the basic balance of the Agreement."¹⁹⁶

By contrast, under a vectorial interpretation, the application of each provision of TRIPS by the member states would be analyzed by reference to the principles identified in the preamble and articles 7 and 8. Rather than assuming that the balance has already been struck with respect to each separate part of the treaty, an adjudicative body would recalibrate the balance of principles with respect to each treaty provision as applied to the specific legal issue in dispute.

Moreover, any particular dispute would be considered under the principle of evolutive interpretation, discussed earlier in Subsection II.B.1. That is, interpretation of treaty text should be considered in light of subsequent agreements and practices regarding its interpretation. As discussed, the overall interpretative context for development provisions within TRIPS has changed dramatically with the advent of the Doha Declaration on TRIPS and Public Health and its subsequent developments.

We now turn to our second proposal. Unlike the first, we apply it primarily to the activities of the WIPO as the second integral strand of the IIPRC, which are explicitly linked to human development.

194. Report of the Panel, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/6 (Oct. 16, 1997); Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).

195. Report of the Panel, *Canada—Patent Protection of Pharmaceutical Products, Complaint by the European Communities and their member States*, ¶ 7.24, WT/DS114/R (March 17, 2000).

196. *Id.* ¶ 7.26.

III. A SUBSTANTIVE EQUALITY PRINCIPLE WITHIN THE IIPRC

A. Defining Substantive Equality

As recently observed,

[p]olicy choices of international social redistribution and economic intervention, can rest only with difficulty on a legal mechanism of formal non-discrimination; quite the contrary, they necessitate degrees of “positive discrimination” or “affirmative action”, not only between the rich and the poor, the developed and the developing, but between different sorts and categories of developing economies.¹⁹⁷

Formal equality within the IIPRC is shaped at the level of applicable legal principles, as well as practices within dispute resolution mechanisms. MFN, a bedrock principle of the multilateral trading system of GATT, was recently imported into IIPRC through TRIPS article 4.¹⁹⁸ Combined with the principle of national treatment,¹⁹⁹ already a long-standing provision of the Berne and Paris Conventions,²⁰⁰ the TRIPS Agreement embodies two powerful principles of non-discrimination. MFN is a principle of non-discrimination among foreign nationals; national treatment is a principle of non-discrimination barring internal discrimination in favor of domestic actors over non-nationals. The “floor” of acceptable conduct is set “voluntarily” by each member state: in the case of MFN, by “any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country;”²⁰¹ in the case of national treatment, by any “treatment . . . accord[ed]”²⁰² to the Member’s own nationals. These two non-discrimination principles within TRIPS are entrenched within GATT/WTO generally, although MFN was quite often recognized in the breach.²⁰³ This may continue to be the case under TRIPS.²⁰⁴ These non-discrimination principles have historically impeded efforts to infuse trade

197. Broude, *supra* note 3, at 35-36.

198. TRIPS, *supra* note 4, art 4; *supra* note 187.

199. TRIPS, *supra* note 4, art 3.

200. Paris Convention for the Protection of Industrial Property, art. 2, 828 U.N.T.S. 305 (Mar. 20, 1883); Berne Convention for the Protection of Literary and Artistic Works, art. 5, 828 U.N.T.S. 221 (Sept. 9, 1886).

201. TRIPS, *supra* note 4, art. 4.

202. *Id.* art. 3(1).

203. Broude, *supra* note 3, at 11-12.

The non-discriminatory nature of the GATT/WTO should therefore be taken as a relative matter rather than an absolute one. The question has (of course) never been whether non-discrimination should be abolished as a guiding or organizing principle, but rather, under which circumstances should discrimination be condemned and under which should it be absolved. In the main, this has been regarded as a question of trade economics: in blunt lay terms, when does discrimination create more trade than it diverts?

Id. at 12.

204. UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, *supra* note 193, at 79-81.

with nuanced development efforts because the principles are relatively hostile to differentiation among states, including by development status. They are the two pillars of “formal equality” within international intellectual property.²⁰⁵

A third aspect of formal equality expresses itself through the minimum standards of TRIPS, which are imposed on all member states regardless of their actual levels of development. For example, TRIPS modified the global minimum patent standards substantially with its rule that “patent rights [be] enjoyable without discrimination as to place of invention, the field of technology and whether products are imported or locally produced.”²⁰⁶ This patent-specific non-discrimination principle revised the domestic policy space for all member states, which previously had been allowed, for example, to withhold the granting of patents for pharmaceutical products or to encourage patent holders to work the patent locally.²⁰⁷ Article 27(1), in the guise of non-discrimination, raised the global minimum standards of protection in the patent domain to a higher level than had existed previously. This represents a type of “aggregation” or technology-neutrality that is increasingly criticized as a matter of domestic policy.²⁰⁸

At the level of dispute resolution, the WTO relies on highly formalistic decision-making processes, which has caused two leading international intellectual property observers to characterize the dispute settlement system as one of formal equality in the context of industrialized countries’ innovation policies.²⁰⁹ This observation of formalism in norm-interpretation, a fourth pillar of formal equality, has parallels in the general trade literature, where the DSB has been criticized for the same reasons.²¹⁰ Moreover, a relatively small percentage of the complaints filed with the WTO have been filed by developing countries, and developed countries like the United States have refused to implement WTO rulings adverse to their domestic interests. These facts suggest that, “after a decade of operation the

205. *Id.* at 89.

206. TRIPS, *supra* note 4, art 27.1. The least-developed countries have been given until January 1, 2016 to meet this obligation with respect to pharmaceutical products. Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 7.

207. UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, *supra* note 193, at 368-72.

208. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1626 (2003).

209. Dinwoodie & Dreyfuss, *supra* note 139, at 96.

210. Broude, *supra* note 3, at 16.

The other side of this coin, a growth defect in its own right, is the formalistic and legalized nature of the WTO’s dispute settlement system. Lashed to an almost static political norm-making system, the judicial branch of the WTO is extremely careful not to stray from the boundaries of political consensus, for fear of damaging its own legitimacy, when faced with sensitive issues.

Id.

WTO remains a rich man's club beyond the reach of most developing nations.²¹¹

Like the WTO, the WIPO is also permeated with formal equality. This is most evident in the WIPO's norm-setting activities. As an intergovernmental organization, the WIPO treats its member states formally as equal players: It is a shibboleth that the WIPO is or should be a member-driven organization. Yet, as discussed in Part I, structural asymmetry prevents various member states from engaging in fully informed decision-making at both national and international levels.²¹² Recognition of and dissatisfaction with formal equality at the WIPO gave rise to the original proposal called the "Establishment of a Development Agenda for WIPO."²¹³

Since the WIPO General Assembly considered the initial proposal in the fall of 2004, various member states made further formal submissions in seven subsequent meetings.²¹⁴ These documents elaborated upon difficulties with the WIPO's treatment of member states as formally equal, and suggested both substantive and procedural reforms to inject pro-

211. Drache, *supra* note 47, at 6.

212. See text accompanying notes 94-100.

213. *Proposal by Argentina and Brazil*, *supra* note 73.

214. These submissions include proposals submitted to the Intersessional Intergovernmental Meeting (IIM) First Session Apr. 11-13, 2005 by the so-called "Friends of Development." See WIPO, *Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document Wo/GA/31/11*, IIM/1/4 (Apr. 6, 2005); WIPO, *Proposal by the United States of America for the Establishment of a Partnership Program in WIPO*, IIM/1/2 (Mar. 18, 2005); WIPO, *Proposal by Mexico on Intellectual Property and Development*, IIM/1/3 (Apr. 1, 2005); WIPO, *Proposal by the United Kingdom*, IIM/1/5 (Apr. 7, 2005). Submissions also include proposals submitted to the IIM Second Session June 20-22, 2005. See WIPO, *Proposal by the Kingdom of Bahrain on the Importance of Intellectual Property in Social and Economic Development and National Development Programs*, IIM/2/2 (June 14, 2005); WIPO, *Proposal by the United Kingdom*, IIM/2/3 (June 14, 2005). Submissions also include a proposal submitted to the IIM Third Session. See WIPO, *Proposal by Morocco on Behalf of the African Group Entitled "The African Proposal for the Establishment of a Development Agenda for WIPO"*, IIM/3/2 (July 18, 2005). Submissions also include proposals submitted to the Provisional Committee on the Development Agenda (PCDA) First Session. See WIPO, *Proposal by Chile*, PCDA/1/2 (Jan. 12, 2006); WIPO, *Proposal by Columbia*, PCDA/1/3 (Feb. 14, 2006); WIPO, *Proposal by the United States of America to Establish a Partnership Program in WIPO: An Elaboration of Issues Raised in Document IIM/1/2*, PCDA/1/4 (Feb. 17, 2006); WIPO, *Proposal for the Establishment of a Development Agenda for WIPO: A Framework for Achieving Concrete and Practical Results in the Near and Longer Terms*, PCDA/1/5 (Feb. 17, 2006). Submissions also include proposals submitted to the PCDA Second Session. See WIPO, *Proposal on the Decision of the PCDA on the Establishment of a WIPO Development Agenda*, PCDA/2/2 (June 23, 2006); WIPO, *Proposal on Recommendation to the General Assembly of WIPO*, PCDA/2/3 (June 30, 2006). In addition, an official document was prepared by Ambassador Enrique A. Manalo, Chair of the General Assembly, for the Third Session of the PCDA held in February 2007. See WIPO, *Working Document for the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA)*, PCDA/3/2 (Feb. 20, 2007).

development concerns into the WIPO's mandate.²¹⁵ A clash of perspectives, if not civilizations, has been evident over the meaning of the term "development." For example, the United States has equated development to growth, emphasizing the benefits of intellectual property and the dangers of piracy.²¹⁶ On the other hand, a Chilean proposal urged the WIPO to study:

[T]he costs [of intellectual property systems] and, in turn, the most . . . appropriate levels of protection of intellectual property rights, taking into account the degree of development and particular social and cultural situation in a country, based on the minimum standard[s] established by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).²¹⁷

Gathering these multiple perspectives under one big tent at the conclusion of the February 2006 meeting of the Provisional Committee for the Development Agenda (PCDA), the WIPO Secretariat organized the over one hundred separate proposals into six clusters.²¹⁸ These include:

- (A) Technical Assistance and Capacity Building;
- (B) Norm-setting, Flexibilities, Public Policy and Public Domain;
- (C) Technology Transfer, Information and Communication Technology (ICT) and Access to Knowledge;
- (D) Assessments, Evaluation and Impact Studies;
- (E) Institutional Matters Including Mandate and Governance; and
- (F) Other Issues.

The General Assembly, at its September 2007 meeting, adopted the forty-five recommendations that the WIPO member states agreed upon and forwarded for consideration.

To counter the formal equality that pervades the IIPRC, Professor Chon has previously proposed a "substantive equality" principle. This proposal is based upon a development as freedom-oriented approach to intellectual property norm-setting and norm-interpretation. Under this approach, the lawmaker would exercise more skepticism towards the validity of a regulation where it conflicts with a development-sensitive human need, as defined in part by the Millennium Development Goals. A regulation in this context is defined as a grant of an exclusive right over a knowledge good or, conversely, the withholding or narrowing of an exception or limitation to that exclusive right. This substantive equality

215. WIPO, *Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document WO/GA/31/11*, ¶¶ 42, 40-52, IIM/1/4 (Apr. 6, 2005).

216. WIPO, *Proposal by the United States of America to Establish a Partnership Program in WIPO: An Elaboration of Issues Raised in Document IIM/1/2*, PCDA/1/4 (Feb. 17, 2006).

217. WIPO, *Proposal by Chile*, at 4, PCDA/1/2 (Jan. 12, 2006).

218. WIPO, *PCDA, Report*, at Annex I, PCDA/1/6 (July 3, 2006).

principle would be applied both domestically and in international decision-making venues.²¹⁹

A substantive equality principle should shift the balance between static and dynamic efficiencies, so that short-term access and affordability may take priority over long-term innovation policy goals where necessary.²²⁰ The principle will allow lawmakers to achieve a different balance of minimum standards with flexibilities, and possibly even to distinguish among different technologies, despite the mandate of non-discrimination in article 27(1).²²¹ It may allow lawmakers to distinguish among different industries, countries, and levels of development, if necessary.

This substantive equality principle can be employed both at the international level and at the national level; both in public law and in private ordering. It can be multiple and decentralized, in order to address the multiple sites of international intellectual property norm-setting and norm-interpretation. Here, we turn to a different aspect of the regime complex than was analyzed in Part II, namely, the WIPO. We speculate on how the substantive equality principle might impact the norm-setting mandates approved as part of the WIPO Development Agenda.

B. Applying Substantive Equality to Intellectual Property Norm-Setting: The WIPO Development Agenda

Some development agencies and developing countries approach intellectual property from a development as freedom model.²²² Moreover,

219. Chon, *supra* note 6, at 2885; *see also* Chon, *Intellectual Property “from Below”*, *supra* note 140; Chon, *supra* note 8.

220. Joseph E. Stiglitz, *Knowledge as a Global Public Good*, in *GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY* 308 (Inge Kaul et al. eds., 1999). “The gain in *dynamic* efficiency from the greater innovative activity [from intellectual property protection] is intended to balance out the losses from *static inefficiency* from the underutilization of the knowledge or from the underproduction of the good protected by the patent.” *Id.* at 311 (emphasis in original). Argentinean economist Carlos M. Correa states that “[t]he static-dynamic efficiency rationale applicable to an industrial country does not necessarily hold where inequality is high. Strong protection for intellectual property rights may have significant negative allocative consequences in developing countries without contributing to—and even impeding—their technological development.” Carlos M. Correa, *Managing the Provision of Knowledge: The Design of Intellectual Property Laws*, in *PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION* 414 (Inge Kaul et al. eds., 2003).

221. Chamas CI, SM Paulino de Carvalho & S Salles-Filho, *Current Issues of IP Management in Health and Agriculture in Brazil* 12, in *INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES* (Anatole Krattiger, et al. eds., 2007).

222. *Innovation, Essential Health Research and IPRs: The WHO Working Group*, INTELL. PROP. Q. UPDATE, Third Quarter 2006, at 1-7, available at http://www.ciel.org/Publications/IP_Update_3Q06.pdf (describing WHO’s Working Group

human rights norms are beginning to intersect with human development norms within the IIPRC:

[T]he implementation of article 27 of the UDHR and article 15 of the ICESCR [suggest that b]y striking the right balance in these articles, states may be able to increase the resources that can be used to realize other human rights. After all, a reduction of intellectual property protection that exceeds the core minimum obligations under human rights instruments would provide more access for the public to exercise their rights to cultural participation and development and to the benefits of scientific progress. Such reduction may also further the protection of the right to food (in terms of patented seeds, agrochemicals, and foodstuffs), the right to health (in terms of patented pharmaceuticals), the right to education (in terms of copyrighted textbooks and software), and the right to freedom of expression (in terms of copyrighted works in general).²²³

These views are beginning to impact the view of how intellectual property law should operate in a global policy-making space where the production of multiple public goods must be encouraged.²²⁴ Furthermore, the IIPRC is encountering the development as freedom concerns adopted widely in United Nations Millennium Development Goals (UNMDG).²²⁵

Within intellectual property, these development as freedom approaches must contend with the formal equality rules of intellectual property, which have been forged largely within a model of development as growth. Universal access to primary education, for example, is a goal set by the United Nations as one of the UNMDG. Under the development as freedom approach, education is arguably a core constituent component of development, which builds capacity for innovation. Under a development as growth model, education has no special claim on intellectual property but is rather simply an instrumental aspect of human capital formation used to further economic growth. The absence of a development as freedom approach in the WIPO comes through sharply in the WIPO's discussion of its development role vis-à-vis education. The lament is about the lack of education about intellectual property rights rather than the lack of access to basic education.²²⁶

that is to draw up a global strategy and plan of action for promoting medical research and development (R&D) for diseases that disproportionately affect developing countries, pursuant to WHA 59.24).

223. Yu, *supra* note 127; Helfer, *supra* note 127 (analyzing General Comment 17, which interprets ICESCR Article 15(1)(c)); Dreyfuss, *supra* note 127; *see also* Alston, *supra* note 14.

224. *See* GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308 (Inge Kaul et al. eds., 1999); *see also* PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION 414 (Inge Kaul et al. eds., 2003).

225. G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 18, 2000), *available at* <http://www.un.org/millenniumgoals/index.html>. Philip Alston claims that these have arguably attained the status of customary international law. Alston, *supra* note 14, at 771-74.

226. KAMIL IDRIS & HISAMITSU ARAI, WIPO, PUBL'N No. 988(E), THE INTELLECTUAL PROPERTY-CONSCIOUS NATION: MAPPING THE PATH FROM DEVELOPING TO DEVELOPED 56-57 (2006).

UN agencies other than the WIPO, such as the World Health Organization, the Food and Agriculture Organization, or the UN High Commission on Human Rights, are more sympathetic to the human development approach and may view their mandates broadly as intersecting with the intellectual property norm-setting mandates of the WIPO.²²⁷ Nonetheless, these other organizations are still ancillary to the intellectual property norm-setting regime, which is currently dominated by the WTO and the WIPO. Any fundamental change to the way these two organizations approach intellectual property and development must come from within these organizations themselves. A substantive equality principle would operate within a norm-setting environment, such as the WIPO, to include social welfare goals other than innovation.

The WIPO Development Agenda discussion has highlighted the significance of the WIPO's inclusion as a member of the UN system. Among other things, the original proposal called for the WIPO to implement its functions in the context of various initiatives of the United Nations, of which it is an agency. Because of its long and somewhat complex history—initially as BIRPI, an administrative bureau for the Paris and Berne Conventions in 1893; then as the WIPO, an international intellectual property organization not affiliated with the UN; and in its current incarnation since 1974 as a specialized agency of the UN²²⁸—the WIPO perhaps has multiple and fractured identities. On the one hand, it is an intellectual property maximalist organization, reflecting its origins as a bureau for two treaties that were drafted by and for the rights holders of developed countries. This history of promoting intellectual property worldwide on behalf of developed countries is reflected in its 1967 WIPO Convention, which states that the organization's purpose is to “*promote the protection of intellectual property throughout the world . . .*”²²⁹ On the other hand, since 1974, the WIPO has another mandate as a UN agency. The 1974 Agreement between the United Nations and the WIPO refers to the latter as being:

[A] specialized agency [within the UN] and as being responsible for taking appropriate action in accordance with its basic instrument, treaties and agreements administered by it, inter *alia*, for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate *economic, social and cultural development*.²³⁰

227. Musungu, *supra* note 39; Helfer, *supra* note 55.

228. Musungu & Dutfield, *supra* note 56, at 4.

229. Convention Establishing the World Intellectual Property Organization, art. 3, 848 U.N.T.S. 3 (July 14, 1967), available at http://www.wipo.int/treaties/en/convention/pdf/trtdocs_wo029.pdf (emphasis added).

230. Agreement Between the U.N. and the WIPO, art. 1, Dec. 17, 1974, available at <http://www.wipo.int/treaties/en/agreement/index.html> (emphasis added); see also James

The initial WIPO Development Agenda proposal reiterated the instrumental purpose of intellectual property and called for a contextualized assessment of the impact of intellectual property on development. It alluded several times to the WIPO's role as a UN agency.²³¹ For example, the proposal stated:

As a United Nations specialized agency, WIPO has an obligation to ensure that its technical cooperation activities are geared towards implementing all relevant UN development objectives, which are not limited to economic development alone. These activities should also be fully consistent with the requirements of UN operational activities in this field - they must be, in particular, neutral, impartial and demand-driven.²³²

The WIPO Development Agenda debate points to potential constraints upon the WIPO to reflect upon the WIPO's own changing identity and role vis-à-vis development. This is in part due to its historical embeddedness as a rights-holders organization, and to disagreement among member states about what development means. It is also in part due to the WIPO's unreflective alignment with a model of development as growth, apparent in the kinds of member-state proposals that the WIPO chooses to prioritize in its standing committees. For example, since 1998 and especially in its recent sessions, the Standing Committee on Copyright and Related Rights (SCCR) has focused energy on the protection of broadcasting organizations.²³³ This is viewed as a natural extension of the digital agenda, which began in 1996 with the negotiations over the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.²³⁴ On the other hand, a Chilean proposal to study international minimum exceptions and limitations, which was proposed to the SCCR's twelfth session and discussed at some length during its thirteen session,²³⁵ has languished.

Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9.

231. *Proposal by Argentina and Brazil*, *supra* note 73.

232. *Id.* at VII. This particular recommendation (with slightly different wording) is one of the forty-five to be forwarded to the General Assembly in September 2007. *PCDA Final Recommendations*, *supra* note 2 ("1. WIPO technical assistance shall be, inter alia, development oriented, demand driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States and activities should include time frames for completion. In this regard, design, delivery mechanisms and evaluation processes of technical assistance programs should be country specific.").

233. WIPO, SCCR, *Revised Draft Basic Proposal for the WIPO Treaty on the Protection of Broadcasting Organizations*, SCCR/15/2 (July 31, 2006).

234. WIPO, Copyright Treaty, Geneva, Dec. 20, 1996, 36 I.L.M. 65; WIPO, Performances and Phonograms Treaty, Geneva, Dec. 20, 1996, 36 I.L.M. 76.

235. WIPO, SCCR, *Proposal by Chile on the Analysis of Exceptions and Limitations*, SCCR/13/5 (Nov 22, 2005); WIPO, SCCR, *Proposal by Chile on the Subject "Exceptions and Limitations to Copyright and Related Rights"*, SCCR/12/3 (Nov. 2, 2004).

Included in the forty-five recommendations proposed by the WIPO member states and later adopted by the General Assembly, was the establishment of a Committee on Development and IP.²³⁶ With respect to Cluster B, which bears most directly on the question of global intellectual property balance and development, these recommendations are as follows:

15. Norm setting activities shall:

- be inclusive and member driven;
- take into account different levels of development;
- take into consideration a balance between costs and benefits;
- be a participatory process, which takes into consideration the interests and priorities of all WIPO Member States and the viewpoints of other stakeholders, including accredited intergovernmental organizations and non governmental organizations; and
- be in line with the principle of neutrality of the WIPO Secretariat.

16. Consider the preservation of the public domain within the WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain.

17. In its activities, including norm setting, WIPO should take into account the flexibilities in international IP agreements, especially those which are of interest to developing countries and LDCs.

18. To urge the IGC to accelerate the process on the protection of genetic resources, traditional knowledge and folklore, without prejudice to any outcome, including the possible development of an international instrument or instruments.

19. To initiate discussions on how, within the WIPO's mandate, to further facilitate access to knowledge and technology for developing countries and LDCs to foster creativity and innovation and to strengthen such existing activities within WIPO.

20. To promote norm-setting activities related to IP that support a robust public domain in WIPO's Member States, including the possibility of preparing guidelines which could assist interested Member States in identifying subject matters that have fallen into the public domain within their respective jurisdictions.

21. WIPO shall conduct informal, open and balanced consultations, as appropriate, prior to any new norm setting activities, through a member-driven process, promoting the participation of experts from Member States, particularly developing countries and LDCs.

22. WIPO's norm setting activities should be supportive of the development goals agreed within the UN system, including those contained in the Millennium Declaration.

The WIPO Secretariat, without prejudice to the outcome of Member States considerations, should address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: a) safeguarding national implementation of intellectual property rules b) links between IP and competition c) IP-related transfer of technology d) potential flexibilities, exceptions and limitations for Member States and e) the possibility of additional special provisions for developing countries and LDCs.

236. *PCDA Final Recommendations*, *supra* note 2.

23. To consider how to better promote pro-competitive IP licensing practices, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries, in particular developing countries and LDCs.²³⁷

The numerous references in Cluster B to the public domain, as well as to flexibilities and access to knowledge, indicate that these are considered a legitimate part of a pro-development global intellectual property balance. A substantive equality principle, if implemented within the new norm-setting context to be created by the WIPO Development Agenda, would make a difference in the way the WIPO Secretariat exercises its considerable discretion to prioritize and implement its member-driven activities. Such a principle would cause the various decision-making processes within the institution to embrace the consideration of various social welfare goals in addition to innovation.

A human development-driven approach to intellectual property, for example, would be guided by the need to facilitate and prioritize access to basic education. There are many ways in which this goal might be facilitated, by broader exceptions and limitations to copyright,²³⁸ or by innovative activity premised on content within a robust public domain.²³⁹ If the WIPO eventually adopts a development as freedom approach to its norm-setting activities, it might, for example, prioritize the Chilean proposal within the SCCR. In addition to the general study the WIPO already commissioned on exceptions and limitations in the digital environment,²⁴⁰ it would further investigate the use of flexibilities, specifically in the area of development. Combined with a substantive equality principle, the WIPO would focus on intellectual property rights and exceptions as policy tools for enhancing access to knowledge generally and access to basic education and advanced research specifically for development purposes—perhaps even suggesting users' rights or substantive maxima that might override national standards.²⁴¹

We now turn to our third and final proposal, which addresses global intellectual property balance in the face of proliferating bilateral trade instruments.

237. *PCDA Final Recommendations*, *supra* note 2, at annex ¶¶ 15-22. *See also supra* Section I.C.

238. *See Chon, supra* note 8.

239. Pamela Samuelson, *Enriching Discourse on Public Domains*, 55 *DUKE L.J.* 783 (2006).

240. WIPO, SCCR, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment*, SCCR/9/7 (Apr. 5, 2003).

241. *See, e.g., Dinwoodie & Dreyfuss, supra* note 5, at 220-21 (advocating the use of “substantive maxima” to preserve an international public domain of knowledge).

IV. A DYNAMIC INTERPRETATIVE FRAMEWORK FOR INTELLECTUAL PROPERTY BILATERAL TREATIES

A. Intellectual Property and Human Rights: the Emergence of Rules of Customary International Law

After an initial reluctance to link international trade to intellectual property protection within the WTO system, developing countries regarded TRIPS as a safeguard against unilateral trade sanctions or bilateralism. More than ten years after entering into the TRIPS Agreement, however, this picture looks substantially different.²⁴²

TRIPS induced developing countries to engage in substantial reforms of their intellectual property regimes.²⁴³ But no serious initiatives were adopted at an international level—whether bilateral or multilateral—to implement the goals and principles set forth in articles 7 and 8 of TRIPS. In addition, developing countries' expectations were not met as to the increasing transfer of technology and investment flows that would result from the reinforcement of intellectual property protection.²⁴⁴ Moreover, just

242. See experts conclusions of the European and Latin American Seminar organized at the Law School of UBA (Universidad de Buenos Aires) Seminar held in Buenos Aires and organized by L'Association Internationale de Droit Economique and CEIDIE-UBA: "El acuerdo ADPIC 10 años después: visiones cruzadas Europa y Latinoamérica, October 31-November 2, 2005 (only available in Spanish, Editorial La Ley, 2007; English translations forthcoming).

243. After the TRIPS Agreement came into force on January 1, 1995, the United States continued to make use of Section 301 of the U.S. Trade and Tariff Act (inclusion of countries in watch lists or trade sanctions) and monitor the performance of all countries on an annual basis under its 301 process. United States bilateralism did not cease after that date. It continued to negotiate intellectual property agreements with developing nations, bundling intellectual property standards into agreements establishing free trade areas. See Peter Drahos, *Negotiating Intellectual Property Rights: Between Coercion and Dialogue*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT XXX, 173 (Peter Drahos & Ruth Mayne eds., 2002). Since the conclusion of the Uruguay Round in 1994 and the adoption of TRIPS, many developing countries, including most Latin American and Caribbean countries, introduced substantial changes in their intellectual property regimes and domestic laws, thus beginning to reduce the pre-Uruguay Round heterogeneity in intellectual property systems. Thus, recent modifications of national and regional regimes implied the spreading out in Latin America and the Caribbean of stronger intellectual property rights and their extension into new fields. See Mario Cimoli, Joao Carlos Ferraz & Annalisa Primi, *Science and Technology Policies in Open Economies: The case of Latin America and the Caribbean*, Santiago, Chile, United Nations Economic Commission for Latin America and the Caribbean (ECLAC), Serie Desarrollo Productivo, No.165, October 2005, p. 28.

244. As stressed in ECLAC's study, above and beyond the evolution towards more homogeneous systems of intellectual property management, Latin American and Caribbean countries recently saw the coming out of disadvantages related with current running patterns of IP rights and systems, mostly due to deep asymmetries between the region and more advanced countries in terms of mastering IP related aspects. Actually, price

before the end of the transitional period under article 65.2 of TRIPS, which entitled developing countries to delay the application of the provisions of TRIPS, the United States, and to a lesser extent the European Union, sought to reinforce intellectual property rights beyond TRIPS via bilateral agreements.²⁴⁵

A new wave of bilateral free trade agreements (FTAs) reinforcing the protection of intellectual property well beyond TRIPS standards has emerged in the last seven years. The United States and the European Union have concluded numerous FTAs with developing countries containing specific provisions providing for the reinforcement of intellectual property protection.²⁴⁶ These bilateral agreements build upon the international

of patented products and processes are augmenting, inducing vicious effects in the region; furthermore, the increasing barriers posed to reverse engineering and imitative practices, which had been a key pillar of South East Asian technological catch up, limit and hinder domestic learning processes.

Cimoli, Ferraz & Primi *supra* note 243, at 28. In Southeast Asia, the number of residents' patents is growing at a higher rate than those of non-residents, while in Latin America and the Caribbean non-resident patenting leads the scene. In such a context, commercialization of foreign products or processes is facilitated, while, very often, local technological capabilities may be hindered. Divergence in the patent patterns and the asymmetry of industrial specialization patterns and structure among countries has been regarded, among other factors, as reasons to believe that a policy advocating for strong intellectual property rights needs to be implemented in a cautious manner. Throughout history, stronger intellectual property systems have tended to be the result of technological development and the creation of firms capable of taking advantage of these systems, at least as much as they have been the cause of development. See BRONWYN H. HALL, GOVERNMENT POLICY FOR INNOVATION IN LATIN AMERICA, 30 (2005), http://iris37.worldbank.org/domdoc/PRD/Other/PRDDContainer.nsf/WB_ViewAttachments?ReadForm&ID=85256D2400766CC785257184005C2B2B&.

245. The United States is exporting its high level of intellectual property rights protection by means of a new generation of free trade agreements (FTAs) concluded largely with developing countries. As Professor Abbot emphasizes, "these levels of protection exceed those required by the TRIPS Agreement which establishes minimum substantive standards of protection and enforcement for all WTO Members." Frederick Abbot, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law* (ICTSD Issue Paper No. 12, 2006), available at http://www.unctad.org/en/docs/iteipc20064_en.pdf.

246. Thus, for instance, most FTAs require an extension of patent terms for pharmaceutical products (or other regulated products) to "compensate" for unreasonable curtailment of the patent term based on regulatory review procedures. See Agreement Between the Government of the United States of America and the Government of the Kingdom of Bahrain on the Establishment of a Free Trade Area, U.S.-Bahr., art. 14; United States – Chile Free Trade Agreement, U.S.-Chile, art. 17.9.6 (requiring the term extension of patents, beyond Article 33 of TRIPS that requires protection for at least 20 years from filing date, upon request for delays, which must include five years from filing and three years from examination request). Some FTAs require the Parties to allow patent holders to block parallel imports of patents products and to "provide to authors, performers, and producers of phonograms the right to . . . prohibit the importation into that Party's territory of copies of the work, performance, or phonogram that are made . . . outside that Party's territory with the authorization of the author, performer, or producer of the phonogram." See United States –

architecture of intellectual property rights, and establish as a major principle that nothing in the agreements derogates from the obligations and rights of the parties by virtue of TRIPS or other multilateral intellectual property agreements administered by the WIPO (hereinafter, referred to as the “non-derogation clause” or “principle”).²⁴⁷ They also encompass the national treatment principle of non-discrimination between nationals of the countries that are parties to the FTAs.²⁴⁸ As a consequence of the most-favored nation principle in TRIPS, the advantages, benefits, and privileges granted by the FTAs to nationals of another WTO Member are typically accorded to the nationals of all other members of the WTO, with exceptions such as customs unions and free trade areas pursuant to GATT XXIV.²⁴⁹

The FTAs focus on specific issues not fully dealt with to the satisfaction of the United States or the European Union in TRIPS. In other words, the major trading powers enlarged and intensified the intellectual property agenda through the last generation of FTAs. These contain detailed provisions on domain names on the Internet, related rights of performers and producers of phonograms, remedies against the circumvention of effective technological measures, effective legal remedies

Morocco Free Trade Agreement, U.S.-Morocco, arts. 15.9.4, 15.5. Some FTAs extended patentable subject matters to areas where TRIPS provided for some degree of flexibility or freedom to WTO Member States. *See id.* art.15.9.2 (requiring Morocco to make patents available to plants and animals); Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, art 4.18, authorizing exclusions from patentability only on grounds of *ordre public* or for treatment of humans or animals); Memorandum of Understanding on Issues Related to the Protection of Intellectual Property Rights Under the Agreement Between the United States and Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, ¶ 5, Oct. 24, 2000, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Jordan/Annexes/asset_upload_file120_8462.pdf (accompanying the U.S.-Jordan FTA and requiring Jordan not to exclude “business methods or computer-related inventions” from patent protection). Similarly, in the field of trademarks, the scope of protection of the so-called “well-known trademarks” has been increased in several FTAs which require Parties to give effect to WIPO’s Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks. *See* WIPO, *General Report*, A/34/16 (Sept. 29, 1999). WIPO’s Joint Recommendation sets forth higher standards of protection of well known trademarks and is treated in some FTAs as if it were a Treaty and not merely a declaration or soft law. *See* Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, *supra*, art. 4; Christine Haight Farley, “The Scope of Trademark Protection in Free Trade Agreements”, Briefing Paper, Workshop on “Negotiating Intellectual Property Provisions in Free Trade Agreements”, Miami, November 19, 2003, (The Program on IP and the Public Interest Washington College of Law, Washington, The Consumer Project on Technology, Washington and CEIDIE, Buenos Aires, Argentina).

247. *See* United States – Chile Free Trade Agreement, *supra* note 246, art. 17.1.5; *infra* Section IV.B.

248. *See* United States – Chile Free Trade Agreement, *supra* note 246, art. 17.1.6.

249. TREBILCOCK & HOWSE, *supra* note 5, at 55.

to protect rights management information, and protection of encrypted program-carrying satellite signals.²⁵⁰

In areas already encompassed by TRIPS, FTAs expand the coverage of trademarks and the protection of pharmaceutical products.²⁵¹ For example, the Central American Free Trade Agreement (CAFTA) expands protection by different means, namely the establishment of a new category of rights by providing exclusive protection with respect to information or data previously used to obtain marketing or sanitary approvals. This category of exclusive rights, unknown for many developing countries counterparts previous to the signature of the last generation of FTAs, entails the prohibition of the use of undisclosed test or other data, that is, undisclosed information about the safety and efficacy of pharmaceutical products for five years from the date of its marketing or sanitary approval.²⁵²

As stated recently, “[t]his relatively new form of IP protects investment in clinical trials for the marketing approval of pharmaceuticals and agrochemicals, rather than in a particular form of innovation o[r] creation. Therefore, it pushes the limits of traditional intellectual property to the pure protection of commercial assets.²⁵³ In turn, this has a major impact on generic competition and public health.²⁵⁴

Clearly, these FTAs contain so-called TRIPS-plus provisions, either by establishing higher standards of protection going beyond those required by the TRIPS Agreement or by eroding or eliminating the existing flexibilities under TRIPS, or even by wiping out what was considered an

250. See United States – Chile Free Trade Agreement, *supra* note 246, arts. 17.3, 17.7.5(d), 17.7.6(b), 17.8; United States – Morocco Free Trade Agreement, *supra* note 246, arts. 15.3, 15.8.

251. See Pedro Roffe, David Vivas & Gina Vea, *Maintaining Policy Space for Development: A Case Study on IP Technical Assistance in FTAs* tpls. 1 & 2 (ICTSD Issue Paper No. 19, 2007), available at <http://www.iprsonline.org/resources/docs/Roffe-Vivas-Vea%20Blue19.pdf>; see, e.g., United States – Morocco Free Trade Agreement, *supra* note 246, arts. 15.2, 15.10.

252. See Carlos Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT’L L. 79, 85-88 (2004).

253. Roffe, Vivas & Vea, *supra* note 251 at 5; see, e.g., United States – Singapore Free Trade Agreement, U.S.-Sing., art. 16.8.1; United States – Chile Free Trade Agreement, *supra* note 246, arts. 17.9, 17.10; Pedro Roffe, *Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement* 24-26 (Quaker Int’l Affairs Programme TRIPS Issue Paper No. 4, 2004), available at <http://www.quno.org/geneva/pdf/economic/Issues/Bilateral-Agreements-and-TRIPS-plus-English.pdf>.

254. In recognition of this, the U.S. Congress recently reached an agreement with the Office of the U.S. Trade Representative, softening some of the provisions in the FTAs pertaining to test data, and reiterating local flexibilities in setting patent terms and remedies for infringement. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, BIPARTISAN AGREEMENT ON TRADE POLICY: INTELLECTUAL PROPERTY PROVISIONS (2007), http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file312_11283.pdf.

option of WTO Members.²⁵⁵ At first glance, FTAs entail, in general terms, a departure from the basic principles and objectives of articles 7 or 8 of TRIPS.

However, there is still room to implement the principles of articles 7 and 8 by seeking an appropriate interaction between human rights and intellectual property rights.²⁵⁶ In such a context, general principles and rules of public international law may be of great help. According to the WTO DSU, WTO panels are required to apply such principles and rules.²⁵⁷ They may also help to establish some limits from outside the FTAs to the ever-expanding intellectual property protection under such agreements, which go far beyond TRIPS.

The declared objectives of FTAs are vast. They seek to avoid distortions in the reciprocal trade relations between parties. In the case of the U.S.-Peru FTA, mention is made to the goal of enhancing the standard

255. A case in point is the option under article 27.3(b) to protect plant varieties, either by patents, an effective *sui generis* system, or by any combination thereof. This provision had to be reviewed after four years of the date of entry into the WTO Agreement. Discussions as to the scope, objective, and extent of such review has led to very interesting debates within the TRIPS Council, and its revision or modification is still pending. In addition, under paragraph 3(a) of article 27 of TRIPS, Members may also exclude diagnostic, therapeutic, and surgical methods for the treatment of humans or animals from patentability. Under paragraph 2 of article 27 of TRIPS, Members of the WTO “may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which [within their territory] 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” TRIPS, *supra* note 4, art. 27.2. Some FTAs recently concluded by the United States with developing countries only repeat and stress paragraph 1 of article 27, which only foresees the obligation to provide patent protection, whether products or processes, in all fields of technology. See TRIPS, *supra* note 4, art. 27.1. By doing so, some commentators have concluded that flexibilities and options under paragraph 2 and 3 of article 27 of TRIPS have been given away and, therefore, by means of the most favored nation principle of article 4 of TRIPS, rights or concessions granted by one WTO Member State to nationals of another Member State in the framework of an FTA shall extend to all other nationals of the other WTO Member States. See Josef Drexler, *The Evolution of TRIPS: Towards Flexible Multilateralism*, Seminar, *El acuerdo ADPIC 10 años después: visiones cruzadas Europa y Latinoamérica*, held at the University of Buenos Aires Law School by L’Association Internationale de Droit Economique and CEIDIE-UBA, Oct. 31-Nov. 2, 2005. With respect to the TRIPS-plus aspects of FTAs in the field of patents, see J-F. Morin, “*La brevetabilité dans les récents traités de libre-échange américains*”, (2004) RIDE 4, 483-501.

256. See generally INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES (Abbott, et al. eds., 2006).

257. The general rule of interpretation of treaties enunciates that not only the context shall be taken into account but also any relevant rules of international law applicable in the relations between the parties. See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, art. 3.2, 33 I.L.M. 1125, (1994); Vienna Convention *supra* note 118, art. 31, ¶ 3(c); see also ÉRIC CANAL-FORGUES, LE RÉGLEMENT DES DIFFÉRENDS À L’OMC 102-121 (2d ed. 2003).

of living and reducing poverty.²⁵⁸ The U.S.-Chile agreement has a special preamble to the Intellectual Property Chapter, where the importance of the Doha Declaration on the TRIPS Agreement on Public Health is recognized.²⁵⁹ In other cases, like in the Central American Free Trade Agreement, the Doha Declaration is omitted, but a side letter or understanding executed by the parties recognizes its importance and emphasizes that nothing in the chapter on intellectual property of the CAFTA Agreement hampers the ability of the parties to adopt measures necessary to promote access to medicines for all, in particular with regards to cases of HIV/AIDS, tuberculosis, malaria, and other epidemics or diseases.²⁶⁰ Furthermore, in different FTAs, recognition of the importance of access to medicines is further evidenced either in the text or in the form of side letters or understandings: intellectual property provisions in FTAs shall not impede parties from making use of and implementing the so-called Paragraph Six Solution of the Doha Declaration with regard to countries facing a public health emergency and lacking manufacturing abilities to produce the needed medicines.²⁶¹ Recently, the U.S. Congress reiterated

258. See United States – Peru Trade Promotion Agreement, U.S.-Peru, pmbi., Apr. 12, 2006.

259. See United States – Chile Free Trade Agreement, *supra* note 246, at ch. 17 pmbi. (“Recognizing the principles set out in the Declaration on the TRIPS Agreement on Public Health, adopted on November 14, 2001, by the WTO at the Fourth WTO Ministerial Conference, held in Doha.”).

260. See Understanding Regarding Certain Public Health Measures, Aug. 5, 2004, available at http://www.ustr.gov/assets/Trade_Agreements/Regional/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf?ht= (all the Parties to the Agreement agreed that the obligations of Chapter Fifteen (Intellectual Property Rights) “do not affect a Party’s ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”). See also OFFICE OF THE U.S. TRADE REPRESENTATIVE, FREE TRADE WITH COLUMBIA: SUMMARY OF THE UNITED STATES – COLUMBIA TRADE PROMOTION AGREEMENT 5 (2007), http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file820_13073.pdf?ht=.

261. See General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003); General Council, General Council Chairperson’s Statement, WT/GC/M/82 (Nov. 13, 2003). This decision has been conceived to enable the WTO member countries lacking capacity in pharmaceuticals to make effective use of compulsory licensing. See Understanding Regarding Certain Public Health Measures, *supra* note 260, (noting that all the Parties to the CAFTA Agreement agreed that: “In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman’s statement accompanying the Decision (JOB (03)/177, WT/GC/M/82) (collectively the TRIPS/health solution”), Chapter Fifteen (Intellectual Property) does not prevent the effective utilization of the TRIPS/health solution”); see also OFFICE OF THE U.S. TRADE REPRESENTATIVE, *supra* note 260.

that in the U.S.-Peru and U.S.-Panama FTAs, the side letters “should be made part of the text of the FTA.”²⁶²

Article 1.1 of the TRIPS Agreement entitles any WTO Member country to enhance intellectual property protection, provided that such reinforcement of protection is not inconsistent with the Agreement itself.²⁶³ This means that TRIPS-plus provisions are in principle a valid manifestation of WTO Member sovereign powers, further confirmed by the *pacta sunt servanda* rule embodied in all of the recent FTAs. Thus, article 15.1 of the CAFTA Agreement requires parties at “a minimum” to give effect to Chapter Fifteen (Intellectual Property Rights) of the Agreement and further entitles parties “to grant more extensive protection and enforcement of intellectual property rights” in their domestic laws than is required under that Chapter, provided that such protection is not inconsistent with the FTAs.²⁶⁴

However, when it comes to interpreting TRIPS-plus provisions of FTAs (and domestic implementing legislation thereof), one important question arises: should TRIPS-plus provisions be interpreted in light of the text of the TRIPS Agreement by itself, or should they be analyzed in light of the Doha Declarations as well? One should bear in mind that Paragraph 17 of the Doha Declaration of November 14, 2001, stresses the importance of interpreting and applying TRIPS in a manner that supports the goal of promoting public health through both access to existing medicines and through research and development (R&D) in new medicines.²⁶⁵ The

262. See Letter from Charles B. Rangel & Sander M. Levin, Ways & Means Committee Chairman & Trade Subcommittee Chairman, United States House of Representatives, to Susan C. Schwab, United States Representative (May 10, 2007), available at <http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf>; William New, *US to Loosen Drug Patent Provisions in Some Trade Deals*, INTELL. PROP. WATCH, May 17, 2007, <http://www.ip-watch.org/weblog/index.php?p=622>.

263. See TRIPS, *supra* note 4, art. 1.1. (“Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”).

264. See The Dominican Republic – Central America – United States Free Trade Agreement, art. 15.1, Aug. 5, 2004, [hereinafter CAFTA] (“Each Party shall, at a minimum, give effect to this Chapter. A Party may, but shall not be obliged to, implement in its domestic law more extensive protection and enforcement of intellectual property rights than is required under this Chapter, provided that such protection and enforcement does not contravene this Chapter.”); see also United States – Chile Free Trade Agreement, *supra* note 246, art. 17.1.

265. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, ¶ 17, 41 I.L.M. 746, (“We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration.”).

importance of access to medicines is further emphasized in Paragraph Four of the Doha Declaration on TRIPS and Public Health, adopted on the same day,²⁶⁶ as well as in the subsequent General Council Decision. Taking into account the clear objectives of these subsequent agreements under an evolutive interpretive principle, may a FTA derogate from access to medicines or create substantial barriers therein for the purpose of reinforcing patent rights beyond TRIPS?

The Doha Declarations, both of which were unanimously adopted by WTO Members after entering into the TRIPS Agreement, may be regarded as a normative framework that may establish certain limits to the free will of the parties to a subsequent treaty. They express universal acknowledgment of a fundamental human right that may not be automatically discarded by intellectual property rights—that is, the right to life, which subsumes within it the right to health, and its more evident expression, access to medicines. In the context of TRIPS, Frederick Abbott has stated that

If a peremptory human rights norm is engaged then, as prescribed by Article 53 of the Vienna Convention of the Law of Treaties (VCLT), the AB would be required to void any conflicting rule (or the entire offending agreement). Thus, if the right to life is a peremptory norm, and if the mandatory patenting of pharmaceuticals directly conflicted with the right to life (hypothetically), the AB would be required to void the applicable rule of the TRIPS Agreement.”²⁶⁷

The Doha Declarations thus might establish one bridge between intellectual property protection and human rights. The former are not absolute and may not be conceived without certain limits. In fact, such equilibrium or interaction between intellectual property rights and human rights already exists under domestic law.²⁶⁸ The Doha Declarations also enable this interaction to take place in international law. In this context, the

266. “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 for this purpose.” Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 4.

267. Frederick M. Abbott, *TRIPS and Human Rights: Preliminary Reflections*, in INTERNATIONAL TRADE AND HUMAN RIGHTS, *supra* note 256, at 145, 158; accord Simon Walker, *A Human Rights Approach to the WTO’s TRIPS Agreement*, in INTERNATIONAL TRADE AND HUMAN RIGHTS, *supra* note 256, at 171, 176 (“The right to health . . . includes a right to affordable, essential drugs, as set out in the WHO’s essential drug list.”); see also Frederick M. Abbott, *The ‘Rule of Reason’ and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS*, in HUMAN RIGHTS AND INTERNATIONAL TRADE 279, 279-283 (Thomas Cottier, Joost Pauwelyn & Elisabeth Bürgi Bonanomi, eds., 2005) (detailing the various treaty provisions that form a basis for a right to health).

268. Cf. Christophe Geiger, *Fundamental Rights, a Safeguard for the Coherence of Intellectual Property Law?*, 35 INT’L REV. INTELL. PROP. & COMPETITION L., 268-80 (2004).

entire TRIPS machinery, together with its Declarations and the General Council Decision, could be considered an *integral framework* that enshrines the rights to life and health, and the consequent ability of states to adopt measures to protect these rights in cases of emergencies or epidemics. If *opinio juris* exists at a universal level, as evidenced in international declarations and human rights conventions and coupled with a coherent state practice, we could be witnessing the emergence of an imperative rule of international law that may be balanced against—or even preempt—intellectual property protection.

Key to this approach is understanding that the relationship of human rights to intellectual property is dynamic. WTO Member states are moving decisively in the direction of the incorporation of the rights to life and health (and therefore access to medicines) within the TRIPS integral framework, subject at a very minimum to a balance with intellectual property rights.²⁶⁹ A more generous view would accord these human rights precedence over intellectual property rights. For example, one interpretative approach towards the FTAs could consider the rights to life and health as possible core human rights, as evidenced by the integral framework provided by the Doha Declarations and the General Council Decision. Again in the context of TRIPS, Abbott has stated,

The identification of core rights may be important in applying human rights in the interpretation and application of the TRIPS Agreement. If a human right is considered “core,” inviolable and non-relative, then such right may not be subject to “balancing” as against non-core or relative interests. If the concept of core rights has currency, the “right to life” would certainly be among them.²⁷⁰

As expressed through the TRIPS integral framework, the right to life may even be evolving towards a peremptory norm of general international law, the so-called *jus cogens*, which is defined by the VCLT as “a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the

269. Abbott, *supra* note 267, at 146-47 (“Meetings in the TRIPS Council on access to medicines that ultimately resulted in the Doha Declaration on the TRIPS Agreement and Public Health flowed largely from efforts by developing WTO Members to deal with public health problems affecting their people. The TRIPS Council did not begin taking access to medicines issues seriously because the OECD governments became more enlightened about the consequences of TRIPS and patents. Rather, this took place because the worldwide public did not accept that the rights of pharmaceutical industry patent holders should take precedence over the rights to life and health of millions of individuals. The human rights dimension will play a substantial role in the response of the WTO and other multilateral organizations to public health issues. It is precisely because fundamental human rights are at stake, and that these rights are paramount in public consciousness, that the legal situation will adapt.”).

270. *Id.* at 147-48 (“Non-core rights are relative in differing degrees. Non-core human rights may be the subject of progressive realization. Important examples are the right to education and the right to health.”).

same character.²⁷¹ The main feature of such rules is their indelibility.²⁷² The least controversial examples of *jus cogens* are the prohibition of the use of force, the law of genocide, the principle of racial discrimination, crimes against humanity, and the rules prohibiting slaves and piracy. The principle of permanent sovereignty over the natural resources and the principle of self-determination also have this special status.²⁷³ The TRIPS integral framework suggests that the right to life (subsuming the right to health and therefore access to medicines) is moving towards incorporation within such a *corpus* of law. The eventual outcome would be a right not disposable by the parties to a treaty and superseding the legal framework that states may establish through such a treaty.²⁷⁴

In sum, TRIPS-plus provisions in the FTAs could be valid only to the extent that they do not derogate, substantially reduce the scope, or neutralize the right to life (or another fundamental human right).

B. The Relationship of States' Obligations to States' Rights: The Non-Derogation Principle

Non-derogation of rights and obligations arising out of TRIPS and other multilateral conventions on intellectual property protection as embodied in certain FTAs could determine the scope of the commitments undertaken by the parties to such trade agreements. The non-derogation principle is also an important interpretative tool that might bridge intellectual property and human rights.

The TRIPS Agreement contains a non-derogation principle but it is limited to *obligations* under existing intellectual property conventions. TRIPS article 2.2 states:

Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.²⁷⁵

The purpose of this clause is to prevent parties from using TRIPS as an excuse for not complying with pre-existing commitments between WTO

271. Vienna Convention, *supra* note 118, art. 53.

272. IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 488-89 (6th ed. 2003) (“They are rules of customary law which cannot be set aside by treaty or acquiescence but only by the formation of a subsequent customary rule of a contrary effect.”).

273. *Id.*

274. As Jean Combacau and Serge Sur contend, *Ius cogens* rules are to be distinguished from ordinary mandatory rules in the sense that a breach of an ordinary obligatory rule entails the international responsibility of the defaulting State while a violation of a *ius cogens* rule leads to the absolute nullity of the treaty which is contrary to such imperative rule. See JEAN COMBACAU & SERGE SUR, DROIT INTERNATIONAL PUBLIC 155 (3d ed. 1997).

275. TRIPS, *supra* note 4, art. 2.2.

Member countries.²⁷⁶ TRIPS article 2.2 is confined to obligations of Member states under specified multilateral conventions that existed prior to TRIPS.

The non-derogation clauses in FTAs have a broader scope in certain cases. Thus, the U.S.-Chile Free Trade Agreement article 17.1.5 establishes that:

Nothing in this Chapter concerning intellectual property rights shall derogate from the *obligations and rights* of one Party with respect to the other by virtue of the TRIPS Agreement or *multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO)*.²⁷⁷

A non-derogation provision is also contained in article 1.3 of the CAFTA Agreement, which links the United States to all the Central American States, in the form of a confirmation by the parties of the rights and obligations arising from “the WTO and other agreements” to which they are parties. Furthermore, in article 15.7 of CAFTA, “*the Parties affirm their existing rights and obligations under the TRIPS Agreement and intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO) and to which they are party.*”²⁷⁸ Therefore, non-derogation clauses in FTAs are in some cases not only concerned with *obligations*, but also with *rights* under preexisting multilateral treaties on intellectual property

Thus, the non-derogation clauses, as included in some of the above-mentioned FTAs, are wider than the one included in TRIPS. They are not only aimed at preventing the FTAs from working to the detriment of the obligations previously undertaken by the states under intellectual property multilateral agreements within the scope of the WIPO, but they also ensure

276. See RESOURCE BOOK ON TRIPS AND DEVELOPMENT, *supra* note 193, at 50; Roffe, *supra* note 253, at 15. In this sense, in the *EC-Bananas arbitration* under the WTO dispute settlement machinery which involved, *inter alia*, a discussion as to the level of suspension of concessions applied to the EC, arbitrators referred to article 2.2 stressing that:

This provision can be understood to refer to the obligations that the contracting parties of the Paris, Berne and Rome Conventions and the IPIC Treaty, who are also WTO Members, have between themselves under these four treaties. This would mean that, by virtue of the conclusion of the WTO Agreement, e.g. Berne Union members cannot derogate from existing obligations between each other under the Berne Convention. For example, the fact that Article 9.1 of the TRIPS Agreement incorporates into that Agreement Articles 1-21 of the Berne Convention with the exception of Article 6bis [sic] does not mean that Berne Union members would henceforth be exonerated from this obligation to guarantee moral rights under the Berne Convention.

Decision by the Arbitrators, *European Communities - Regime for the Importation, Sale and Distribution of Bananas - Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU*, ¶ 149, WT/DS27/ARB/ECU (Mar. 24, 2000).

277. United States – Chile Free Trade Agreement, *supra* note 246, art. 17.5 (emphasis added).

278. CAFTA, *supra* note 264, art. 15.7.

that the rights of those states under these agreements, including the TRIPS Agreement, are not derogated by the FTAs. In fact, the non-derogation clause in those FTAs encompasses not only all agreements administered by the WIPO but also all the provisions of TRIPS.

What is meant by the “rights and obligations” of the parties under these multilateral agreements? The notion of “obligations” under the agreements administered or sponsored by the WIPO or under TRIPS seems to be clear. By signing FTAs, states cannot free themselves from the obligations they have undertaken as regards the protection of the IPR under the agreements administered or sponsored by the WIPO or under TRIPS. They must always acknowledge the rights and privileges recognized therein to IPRs holders.

However, what are the states’ “rights” under said agreements and under TRIPS? The answer to this question is more complex. For instance, a right according to TRIPS would mean that a party may make use of the flexibilities and exceptions allowed by the TRIPS Agreement, including the “right to protect public health” reiterated by the Doha Declaration on TRIPS and Public Health.²⁷⁹ Nevertheless, if a state waives a right by virtue of an FTA, what is the effect of the non-derogation clause?

Arguably, the non-derogation clause will not be effective in the presence of an express waiver given by a party to an FTA to apply an exception or to make use of a flexibility acknowledged in TRIPS. If, for instance, a party to an FTA explicitly waived certain freedoms arising under the TRIPS Agreement, such as the freedom to choose the system of exhaustion of rights under its domestic laws based on the existing permission under article 6 of TRIPS, then the non-derogation clause would have no effect in view of the fact that under article 1.1 of TRIPS, members of the WTO may grant a greater degree of intellectual property protection than that acknowledged in TRIPS on the sole condition that its provisions are not violated. In such a case, the obligation of a state under a FTA to adopt territorial exhaustion would thus entail a strengthening of the patent’s holder exclusive right to import and would be *prima facie* lawful.

By contrast, the non-derogation clause would have full effect as regards those provisions included in TRIPS that had not been the subject of an explicit waiver by the party to an FTA. Thus, taking into account that the waiver of sovereign powers should be interpreted restrictively,²⁸⁰ any flexibility or restriction to the IPRs allowed under the TRIPS Agreement

279. Doha Declaration on TRIPS and Public Health, *supra* note 120, ¶ 4 (affirming “WTO Members’ *right* to protect public health and, in particular, to promote *access to medicines* for all.”) (emphasis added).

280. This conclusion derives from the very concept of sovereignty, the so-called reserved domain of the States and the principle of sovereign equality of States under public international law. See U.N. Charter art. 2, para. 1; Nguyen Quoc Dinh, Patrick Daillier & Alain Pellet, *Droit International Public* 404-16, 411 (4th ed. 1993).

that has not been expressly abdicated would fall within the umbrella of the non-derogation clause and would, therefore, survive.

In that sense, the mere presence of a non-derogation clause such as the one included in some of the FTAs described above would be significant enough to put a curb on the non-violation complaints that a party to an FTA may file against another. At present, these kinds of claims cannot be filed under the TRIPS Agreement due to the existence of a *de facto* moratorium in this regard as a result of a disagreement between WTO Member states.²⁸¹ However, non-violation complaints are expressly contemplated in the CAFTA Agreement and in the FTA between the United States and Morocco, among others.²⁸² Non-violation complaints can be filed by a party when a domestic measure of another party, although not unlawful under the FTA, may frustrate or make it difficult for the former to benefit from certain advantages arising under the treaty.²⁸³ In such context, the existence of a non-derogation clause in an FTA may play a significant role by pointing out

281. Article 64.1 of the TRIPS Agreement established initially that “Subparagraphs 1 (b) and (c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.” TRIPS, *supra* note 4, art. 64.1. Procedural rules on Subparagraphs 1 (b) and (c) of Article XXIII of GATT 1994 relating to “non-violation” complaints are incorporated as article 26.1 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (the “DSU”). Non-violation complaints are possible for goods and services (under GATT for goods and market-opening commitments in services). However, for the time being, members have agreed not to use them under the TRIPS Agreement. Under article 64.2 this “moratorium” (i.e., the agreement not to use TRIPS non-violation cases) was to last for the first five years of the WTO (i.e., 1995–99). It has been extended since then. The TRIPS Council has discussed whether non-violation complaints should be allowed in intellectual property, and if so, to what extent and how (“scope and modalities”) they could be brought to the WTO’s dispute settlement procedures. At least two countries (the U.S. and Switzerland) say non-violation cases should be allowed in order to discourage members from engaging in “creative legislative activity” that would allow them to get around their TRIPS commitments. Most would like to see the moratorium continued or made permanent. Some have suggested additional safeguards. However, no consensus has been reached. The August 1, 2004 General Council (of WTO) decision (the “July 2004 package”) extended the moratorium. See TRIPS, *supra* note 4, art. 64.2; WTO Secretariat, Background and the Current Situation, available at: http://www.wto.int/english/tratop_e/trips_e/nonviolation_background_e.htm.

282. United States – Morocco Free Trade Agreement, *supra* note 246, art. 20.2(c); CAFTA, *supra* note 264, annex 20.2.1(e). As stated in a report of the South Centre, “Bilateral Agreements such as the recently concluded US-Chile, Central American Free Trade Agreement (CAFTA), and US-Australia, for instance, irrevocably place intellectual property within the scope of non-violation complaints. . . . The effects of these complaints in relation to the rights of the Parties to regulate intellectual property in the public interest could be significant . . . [and may make developing countries] more vulnerable to pressure to refrain from using flexibilities offered by intellectual property standards.” *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, INTELL. PROP. Q. UPDATE, First Quarter 2004, available at <http://www.southcentre.org/info/scielipquarterly/ipdev2004q1.pdf>.

283. TREBILCOCK & HOWSE, *supra* note 5, at 513-14.

that any sovereign power or right of a state existing under a multilateral treaty on intellectual property protection (e.g., the right to make use of certain exceptions or flexibilities, or the right to adopt domestic measures to protect the environment or public health) that has not been expressly waived under an FTA continues to survive. Consequently, any lawful government measure taken under a multilateral treaty on intellectual property protection could not be questioned by means of a non-violation complaint under an FTA.

Another issue that emerges with respect to the scope of the non-derogation clause is to determine which are the treaties “sponsored” by the WIPO and therefore reached by such clause. Is the UPOV agreement administered by a governmental body other than the WIPO a “WIPO-sponsored agreement?”²⁸⁴ If this is so, the exceptions that would correspond under either the 1978 or the 1991 UPOV Convention (the experimental use, the plant breeder, and the farmer exceptions provided therein) would be a right of the states that are parties thereto and would be considered valid and surviving if said states are, in turn, parties to an FTA that contains a non-derogation clause as the ones previously analyzed. To the extent that the FTA does not state or reflect clearly an express waiver of the states of any of the exceptions established in treaties like the UPOV agreement (i.e., the 1991 Convention and in particular the 1978 one, which contains wider exceptions to the plant breeder’s exclusive rights), these exceptions, again, would survive. When there is a doubt about whether a domestic measure of a state based on the exceptions established in any of the UPOV Conventions is consistent with the FTA, the non-derogation clause could be a helpful guideline to maintain the national measure. Thus, the non-derogation clause is undoubtedly a significant interpretative criterion in the disputes arising from FTAs containing this kind of safeguard.²⁸⁵

C. The Relationship of the Non-Derogation Principle to the Freedom of Implementation Principle

After stressing the obligation of WTO Members to give effect to the provisions of the TRIPS Agreement, TRIPS article 1.1 establishes that “*Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*” In that sense, TRIPS confirms a general customary rule of

284. The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization with headquarters in Geneva (Switzerland). UPOV was established by the International Convention for the Protection of New Varieties of Plants. The UPOV Convention was adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991. The objective of the Convention is the protection of new varieties of plants by an intellectual property right. Text of the conventions available at: <http://www.upov.int/>.

285. In a similar sense but with a more cautious optimism in this regard, see Roffe, *supra* note 253, at 16.

international law that methods employed by states to apply and implement their international obligations within their territories are left to the domestic law of each state.²⁸⁶ This fundamental principle has allowed the United States and the European Union to deny the self-executing character and direct effect of the provisions of the TRIPS Agreement itself.²⁸⁷ FTAs do not reproduce expressly this principle. They only emphasize the states' obligation to apply their provisions, which is the repetition of the rule that compels the states to fulfil their international obligations in good faith (*pacta sunt servanda*).

The absence of an analogous principle of freedom of implementation within the FTAs is bearing asymmetric results. Thus, the United States continues to follow its legal tradition of denying: (1) the self-executing character and direct effect of the treaties related to economic and commercial matters in its territory; (2) the right of individuals to invoke or enforce the FTAs' provisions before domestic courts on the basis of an alleged inconsistency between domestic implementing laws and the text of the treaty itself; or (3) the supremacy of international law over domestic law, as is usual in a large number of developing countries.²⁸⁸ By contrast,

286. This means that, in principle, public international law is not concerned with the means but with the results: the lack of adaptation of domestic law to international obligations leads to the international responsibility of the defaulting State. See MONCAYO, ET AL., DERECHO INTERNACIONAL PÚBLICO 56, Tomo 1, (Zavalia, ed., 4a. reimpression, 1994).

287. With regard to such practice in the United States and in the European Union, see Moncayo von Hase, Andrés, *The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE 108-18 (1998). See also European Court of Justice decisions in ECJ-Portugal/Council, C-149/96 –European Court Reports (EPR) 1999, I-8395 and Dior and Layher, joint cases C-300/98 and C-392-ECR 2000, I-11307 (all the decisions are also available on the Court's website at <http://curia.eu.int>); Walter Kälin, *Implementing Treaties in Domestic Law: from Pacta Sunt Servanda to Anything Goes*, in 47 MULTILATERAL TREATY-MAKING 111-128 (Vera Gowlland-Debbas, ed., 2000). With respect to the denial of the direct effect and self-executing character of FTAs' provisions under US practice, see Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, UNCTAD-ICTSD Project on IPRs and Sustainable Development, February 2006. The U.S. and European Union practice puts countries acknowledging direct effects to self-executing provisions of treaties under their domestic law, as it is the case in many developing countries, at disadvantage *vis-à-vis* countries like the United States which do not allow individuals to invoke treaty provisions or rights before domestic courts.

288. Section 102 of the *Dominican Republic-Central American-United States Free Trade Agreement Implementation Act* is a typical provision denying self-executing effect to treaty rules no matter how clear and complete the rules may be:

Sec. 102. RELATIONSHIP OF THE AGREEMENT TO UNITED STATES AND STATE LAW

(a) RELATIONSHIP OF AGREEMENT TO UNITED STATES LAW.

(1) UNITED STATES LAW TO PREVAIL IN CONFLICT.—No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect.

the lack of any reference to this principle of freedom of implementation within the FTAs is clearly felt in the implementation process of the obligations arising from FTAs by the Central American countries and the Dominican Republic. This process is being monitored by the United States, which makes the effective application of the CAFTA conditional on the introduction of the TRIPS-plus standards of FTAs into the domestic legislations of the parties. Thus, the implementing legislation itself has become the subject matter of on-going negotiations with the United States. These run the risk of eliminating the flexibilities that may still be found in the FTAs themselves or of preventing the parties from interpreting and applying their international commitments in the way most suitable to their domestic interests. The ability of the CAFTA countries to resort to the implementing legislation as a method to establish a balance between the TRIPS-plus provisions of FTAs and the social needs of their population as technology users has been reduced.²⁸⁹

Taking into account the said asymmetry in the processes of implementation of the FTAs and their legal and political effects, the non-derogation principle may play a significant role at the time of assessing the validity of the additional TRIPS- or FTA-plus concessions that states may be forced to introduce in their domestic implementing legislation. International law prevails over domestic law, pursuant to article 27 of the

(2) CONSTRUCTION.—Nothing in this Act shall be construed—

(A) to amend or modify any law of the United States; or

(B) to limit any authority conferred under any law of the United States, unless provided for in this Act.

(b) RELATIONSHIP OF AGREEMENT TO STATE LAW.—

(1) LEGAL CHALLENGE.—No State law, or the application thereof, may be declared invalid as to any person or circumstance on the ground that the provision or application is inconsistent with the Agreement, except in an action brought by the United States for the purpose of declaring such law or application invalid. . . .

(c) EFFECT OF AGREEMENT WITH RESPECT TO PRIVATE REMEDIES.—

No person other than the United States—

(1) shall have any cause of action or defense under the Agreement or by virtue of congressional approval thereof; or

(2) may challenge, in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, or any political subdivision of a State, on the ground that such action or inaction is inconsistent with the Agreement

Section 102 of the Dominican Republic-Central American-United States Free Trade Agreement Implementation Act, Pub. L. No. 109-53, 109th Cong., 1st Sess. (2005).

289. Officials of developing countries who took part or were involved in the negotiations with the United States on the implementing legislation of the FTAs have publicly acknowledged in several academic seminars and international cooperation forums that this process has degenerated into the introduction of additional TRIPS-plus demands by the United States not provided for in the FTAs. *See, e.g.*, WIPO Regional Meeting of the Heads of Intellectual Property Offices, June 2006; WIPO-ECLAC Courses and Expert Meeting Groups on Intellectual Property, 2004-2007.

Vienna Convention on the Law of Treaties.²⁹⁰ In some states, the constitutional systems acknowledge the supremacy of international law over the domestic law. In such cases especially, a domestic rule arising from an FTA's implementation legislation that eliminates a flexibility or public policy space provided in the TRIPS Agreement or a WIPO treaty that had not been subject to an express derogation in an FTA may be invalidated on the grounds that it is contrary to the non-derogation obligation established in the FTA.

The United States practice of denying the self-executing character of FTA provisions which is consistent with previous and past practice in the same direction towards bilateral or multilateral economic or trade agreements shows that the freedom of implementation principle remains a general customary rule of international law. Therefore, said principle, as well as the non-derogation clause, will be extremely useful at the time of evaluating the effects and legal value that should be conferred to simplified agreements, "understandings," or "side letters" that the parties to the FTAs have signed in the form of a separate document with the United States in areas sensitive to their interests. Thus, for instance, the Central American countries and Peru have signed an understanding on public health with the United States.²⁹¹ In addition, Peru has signed a side letter with the United States in which both countries acknowledge the importance of the protection of biodiversity.²⁹² To the extent that these side letters or understandings are not part of the FTAs' texts, they would, in principle, be excluded from the dispute resolution system set forth in those treaties. This would entail a difficulty for the states interested in claiming or enforcing the fulfilment of these treaty provisions.

However, nothing prevents the states from granting the side letters or understanding the status of an agreement or autonomous international treaty, which can be invoked within their territories by individuals before domestic courts on the basis of the principle of freedom of implementation

290. See Vienna Convention, *supra* note 118, art. 27 (codifying preexisting customary rules on the matter by stating: "*Internal law and observance of treaties*: A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty.").

291. Understanding Regarding Certain Public Health Measures, *supra* note 260,

292. The governments of Peru and the United States, for instance, have signed two "side letters." See Understanding Regarding Certain Public Health Measures, *supra* note 260; Understanding Regarding Biodiversity and Traditional Knowledge, U.S.-Peru, Apr. 12, 2006, available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TP-A/Final_Texts/asset_upload_file719_9535.pdf?ht=. As stated earlier, the U.S. Congress has directed the USTR to accord the side letter on public health the status of treaty text. In the Understanding regarding Biodiversity and Traditional Knowledge "the parties recognize the importance of the following: (1) obtaining consent from the appropriate authority prior to accessing genetic resources under the control of such authority; (2) equitable sharing the benefits arising from the use of traditional knowledge and generic resources; and (3) promoting quality patent examination to ensure the conditions of patentability are satisfied."

and the non-derogation clause. This means that the implementation and incorporation of a side letter or an understanding into the domestic law based on said principles will enable states to justify or defend the conservation, execution or implementation of their public and legislative policies aimed at preserving the public health, protecting biodiversity, and regulating access to genetic resources in accordance with the principles of the Doha Declarations or the Convention on Biodiversity,²⁹³ as the case may be.

CONCLUSION

Arguably, all member states, whether developed or developing, are affected negatively by the failure of the IIPRC to embrace a broader development mandate. All states benefit from global communicable disease control and other global public goods, such as universal primary education and food security. All global institutions must coordinate around these areas, if for no other reason than the positive spillover effects on all countries.

Our proposals seek to inject development into international intellectual property, along the framework of a development as freedom model. In this model, the innovation mandate of intellectual property is balanced and weighed with “different, equally legitimate and democratically defined . . . policy goals . . . to promote liberty and welfare in a broad sense.”²⁹⁴ As we have attempted to demonstrate, this balancing framework must occur simultaneously within and among all aspects of the IIPRC, in order to ensure that the most vulnerable populations benefit from and, at the very least, are not harmed by, intellectual property.

293. The objectives of the Convention on Biodiversity, “are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.” Convention on Biological Diversity, Convention Text art. 1, *available at* <http://www.cbd.int/convention/articles.shtml?a=cbd-01>.

294. Cottier, *supra* note 34.