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THREE WAYS OF LOOKING AT A BLACKBIRD

POLITICAL, LEGAL, AND INSTITUTIONAL PERSPECTIVES ON PHARMACEUTICAL PATENTS AND ACCESS TO MEDICINES

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Since the negotiations leading to the adoption of the TRIPS Agreement and throughout the recent proliferation of TRIPS-Plus provisions, scholars, policymakers, and activists alike have been sharply divided between those who saw pharmaceutical patents as a tool for promoting of technological progress and those who denounced their adverse impact on access to affordable medicines worldwide. This article seeks to reconstruct that debate by focusing on three of its interlocking dimensions and the narratives built around them. First, the opposition between intellectual property and public health may be seen as part of a political and diplomatic struggle between developed and developing countries. Second, it may be construed as a normative conflict between two policy objectives equally recognized and protected under international law (in particular under trade rules and human rights rules, respectively). Third, it may reflect a clash between the discourses and the deeply ingrained rationalities of different international institutions, such as the WTO, the WHO, and the UN human rights bodies. Focusing on any of these three dimensions frames our understanding of a crucial global issue and shapes our vocabulary to address it. However, each narrative also has its own blind spots and obscures as much as it reveals.

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I. INTRODUCTION

I was of three minds,
Like a tree
In which there are three blackbirds.[1]

On January 23, 2017, the Director-General of the World Trade Organization (WTO) proudly announced that the amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights[2] (TRIPS Agreement) had entered into force upon receiving the required ratification by two thirds of the WTO member states.[3] The amendment, originally adopted in December 2005, is the last of a series of WTO legal instruments aimed at relaxing certain patent protection obligations set out in the TRIPS Agreement in order to facilitate access to medicines at an affordable cost. One would expect the announcement to make big news: after all, this is the first substantive modification to the text of a WTO agreement since the organisation's inception in 1995. More importantly, however, the entry into force of the TRIPS amendment offers a welcome opportunity to look back, with some perspective, at one of the most heated global policy debates at the turn of the century.

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[1] Wallace Stevens, *Thirteen Ways of Looking at a Blackbird*, *in* HARMONIUM (1923).

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

[3] 2017 News Items, WORLD TRADE ORG., https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm (last visited Apr. 9, 2017).

For many scholars exploring the relationship between pharmaceutical patents and access to affordable medicines has been quite a revelation. Those who dared venturing into this field discovered a wealth of compelling materials spanning across multiple disciplines–from policy proposals to legal articles, from economic papers to activist manifestos. The last two decades "have seen nothing less than an explosion of interest" in the issue,[4] which has been the subject of discussion in myriad venues including national and international government bodies, think tanks, academic conferences, and the like. Many hailed the progressive strengthening of global intellectual property (IP) standards as an indispensable incentive to research and development (R&D) and technological innovation. Many others retorted that the availability of low-priced generic medicines is indispensable for access to affordable healthcare and therefore constitutes a fundamental socio-economic entitlement that trumps market-driven logics. This opposition did not merely reflect divergent policy stances but engaged competing worldviews, stirred ardent passions, and prompted "inflammatory words" that divided commentators "into two opposite camps, with the campers talking past, rather than to, each other".[5] Besides the extreme degree of polarization perhaps the most intriguing aspect of the debate was the sheer variety of narratives and perspectives built around it. In fact, one can think of at least three directions that scholarly discussions have taken throughout the years.

First, many observers have considered the ongoing regulatory struggle as part of a political and diplomatic conflict between developed and developing countries. Accordingly, this narrative focuses on the negotiating strategies that a handful of wealthy nations deployed to pursue a "global intellectual property ratchet"[6]allegedly at the expense of the rest of the world. Equally relevant is the question of why developing countries have agreed to such a bargain and how they have organised their resistance.

A second approach breaks from the North-South divide and instead conceives of pharmaceutical patents and access to medicines as two policy objectives equally recognized and protected under international law (in particular under trade rules and human rights rules respectively). As many states are bound by simultaneous international obligations in respect of both goals, this narrative addresses the question of how to reconcile the pursuit of such objectives when a normative conflict occurs.

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[4] Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and the New Dynamic of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 6 (2004).

[5] Peter K. Yu, *The Global Intellectual Property Order and its Undetermined Future,* 1 WORLD INTELL. PROP. ORG. J. 1, 7 (2009).

[6] The expression is borrowed from Peter Drahos, *BITs and BIPs: Bilateralism in Intellectual Property*, 4(6) J.OF WORLD INTELL. PROP. 791, 798 (2001).

Finally, some authors have stressed that the opposing claims in favour of pharmaceutical patents and access to affordable medicines reflect a struggle for institutional hegemony between the WTO and other international agencies such as the World Health Organization (WHO), the United Nations (UN) human rights bodies, and the World Intellectual Property Organization (WIPO). As each institution caters to the needs of a specific transnational constituency and develops its own agenda, preoccupations, and priorities, this third approach explores ways to improve the interface among these overlapping institutional regimes.

Hence, one may tell the story of the relationship between pharmaceutical patents and access to medicines as a conflict of sovereign nations, a conflict of norms or a conflict of institutions. The purpose of this article is to disentangle these interlocking and overlapping narratives and to assess how each shaped scholarly perception of the issue at hand. As Wallace Stevens wrote a century ago–there are many ways to look at a blackbird, and each glance offers a fresh and different insight into the ineffable essence of the animal. Likewise, focusing on any dimension of the global debate around IP and public health frames our understanding of the issue and shapes our vocabulary to address it. Each approach differs in its identification of the salient facts, its mobilization of specific actors, and its definition of the appropriate space for action and agency. At the same time each narrative has its own biases and blind spots and obscures as much as it reveals. Indeed, one might say that the conflict between pharmaceutical patents and access to medicines constitutes an ideal case study for the current mushrooming of theoretical approaches to global law and politics.[7]

The article consists of three sections, each exploring a different narrative of the issue at hand. As will be seen, these accounts are not meant to be mutually exclusive. Instead, each of them captures certain dimensions of the conflict while neglecting others. By its nature, this tripartite analysis makes no pretense of exhaustiveness with regard to the economic and distributive rationales affecting pharmaceutical production and access, both of which have been explored at length elsewhere. Nor does it seek to have the last say as to the normative outcomes of the debate. Much more modestly, the following analysis aims to sketch three pictures that, once superimposed, will hopefully reveal the multifaceted theoretical underpinnings of a most fascinating global issue.

[7] *See* Andrea Bianchi, *Looking Ahead: International Law's Main Challenges*, *in* ROUTLEDGE HANDBOOK OF INTERNATIONAL LAW 392, 406-07 (David Armstrong ed., 2009).

II. THE POLITICAL NARRATIVE: GRAND BARGAINS, THE NEW IMPERIALISM, AND THE NORTH-SOUTH DEVELOPMENT DIVIDE

Like any other conflict, armed or otherwise, the conflict between pharmaceutical patents and access to medicines calls for the identification of its fault lines. The first narrative sees it as yet another incarnation of the political struggle between developed and developing countries–the former being 'patent makers' imposing high levels of IP protection and the latter 'patent takers' striving for greater access to medicines and other technological advances. This view is not only the most common among early commentators, it also provides an excellent introduction to the debate for it helps map the recent evolution of international patent rules and the underlying policy arguments.

We are all familiar with the common claim that IP protection provides an essential stimulus to research and technological innovation and serves as an incentive for the disclosure and dissemination of inventions.[8] This is all the more so in the research-intensive field of pharmaceutics[9]: R&D expenditures account, on average, for roughly 80% of the overall investment required to develop a new molecular entity.[10] The average development process lasts approximately 14 years and costs over USD 1 billion per new drug.[11] Moreover, pharmaceuticals are often subject to

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[8] This premise does not go uncontested. *See, e.g.,* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Sandy Campart & Étienne Pfister, *Les conflits juridiques liés à la propriété intellectuelle: le cas de l'industrie pharmaceutique et biotechnologique*, 99 REVUE D'ÉCONOMIE INDUSTRIELLE 87, 103-04 (2002); Valentina Vadi, *Balancing the Human Right to Health and Intellectual Property Rights after Doha*, 14 ITALIAN Y.B. INT'L L. 195, 197-99 (B. Conforti et al. eds., 2004); Joseph Stiglitz, *Economic Foundations of Intellectual Property Rights,* 57(6) DUKE L. J. 1693 (2008); Daniele Archibugi & Andrea Filippetti, *The Globalisation of Intellectual Property Rights: Four Learned Lessons and Four Theses*, 1(2) GLOBAL POLICY 137 (2010).

[9] Recent figures show that the total worldwide R&D spending of pharmaceutical companies increased from USD 108 billion in 2006 to USD 141 billion in 2015. *See* Alexander Schuhmacher, Oliver Gassmann & Markus Hinder, *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14(105) J. OF TRANSLATIONAL MED. 1 (2016) [hereinafter Schumacher et al.].

[10] *See* Silvia Salazar, *Intellectual Property and the Right to Health*, *in* INTELLECTUAL PROPERTY AND HUMAN RIGHTS: A PANEL DISCUSSION TO COMMEMORATE THE 50TH ANNIVERSARY OF THE UNIVERSAL DECLARATION ON HUMAN RIGHTS 65, 71 (William C. Holmes & World Intellectual Prop. Org. eds., 1998); ANDREA ONORI, INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 29, 42 (2006); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3(1) CHI. J. INT'L L. 47, 60-61 (2002).

[11] *See, e.g.*, Schumacher et al., *supra* note9, at 3-4; Claude Mfuka, *Accords ADPIC et Brevets Pharmaceutiques: Le Difficile Accès des Pays en Développement aux Médicaments Antisida*, 99 REVUE D'ÉCONOMIE INDUSTRIELLE 191, 196 (2002); Joseph A. DiMasi, Ronald W. Hansen &

administrative or legislative regulations that require long periods of testing in order to assess their safety and/or efficacy prior to commercialization.[12] Once on the market new molecular entities are generally easy to copy through so-called reverse engineering, thus making their commercial value particularly volatile and dependent on IP protection.[13] These factors help explain why pharmaceutical companies tend to direct their investments towards those jurisdictions that provide robust patent protection and avoid those that do not:[14] as of 2013, pharmaceutical supply in the United States, Western Europe and Japan accounted for about two thirds of the global market.[15]

At the same time, affordable drugs remain largely out of reach in many parts of the world. The WHO estimated that in 2011 one third of the planet's population lacked access to essential medicines.[16] For instance, in 2014 lifesaving antiretroviral therapy for HIV was available to less than 14 million affected people against 34 million in need of treatment.[17] The price of patented drugs plays a significant role in the equation. Experts differ onto the exact impact of IP protection on the sales

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Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151 (2003).

[12] S*ee, e.g.*, Carlos M. Correa, *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3(1) CHI. J. INT'L L. 69 (2002).

[13] Harvey E. Bale, Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J. OF INT'L ECON. L. 637 (1998); Philippe Cullet, *Patents and Medicines: the Relationship between TRIPS and the Human Right to Health*, 79(1) INT'L AFF.139, 141 (2003).

[14]*See* Ida M. Azmi & Rokiah Alavi, *TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia*, 4(6) J. OF WORLD INTELL. PROP. 947, 948 (2000).

[15] *See* Sudip Chaudhuri, *Can Foreign Firms Promote Local Production of Pharmaceuticals in Africa?*, *in* MAKING MEDICINES IN AFRICA: THE POLITICAL ECONOMY OF INDUSTRIALIZING FOR LOCAL HEALTH 103, 104 (Maureen Mackintosh et al. eds., 2016). Data were similar in the early 2000s, when 38.6% of global pharmaceutical production was concentrated in North America, 29.2% in Europe, and 14.2% in Japan. *See* ONORI, *supra* note 10, at 29-30.

[16] HANS V. HOGERZEIL & ZAFAR MIRZA, THE WORLD MEDICINES SITUATION 2011: ACCESS TO ESSENTIAL MEDICINES AS PART OF THE RIGHT TO HEALTH 1 (2011). *See also* Mohammed K. El-Said, *TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries*, 31(3) AM. U. INT'L L. REV. 373, 378 (2016). Essential medicines are defined by the WHO as "those that satisfy the priority health care needs of the population", having regard to "disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness". *Essential Medicines and Health Products*, WORLD HEALTH ORG., http://www.who.int/medicines/services/essmedicines_def/en/ (last visited Apr. 10, 2017).

[17] JOINT U.N. PROGRAMME ON HIV/AIDS (UNAIDS), FACT SHEET 2015 (2015), *available at*
http://www.unaids.org/en/resources/campaigns/HowAIDSchangedeverything/factsheet.

price of pharmaceuticals in different markets as well as on the incidence of pricing on access to cures.[18] However, there is substantial agreement that patented pharmaceuticals come at significantly higher retail prices than generics.[19] Suffice it to say that in the early 2000s the average annual cost of a generic HIV antiretroviral cocktail treatment in India was estimated at less than USD 200, while the same treatment based on patented drugs would cost over USD 12,000 in the United States.[20] In turn, healthcare in most low-income countries largely relies on out-of-the-pocket expenditures from households, as governments do not have the financial resources and infrastructure necessary to provide for an effective public health system.[21] In light of the above many have argued that the higher sales prices of drugs stemming from the adoption of rigid patent protection may result in decreased access to affordable healthcare for the poor.[22]

Moreover, some consider that the economic rationale behind pharmaceutical patents simply does not hold when it comes to diseases that typically affect the least developed countries (LDCs). Given the modest or negligible size of those markets there is relatively little incentive for pharmaceutical companies to engage in long and costly R&D investments targeting such diseases.[23] In the early 2000s research

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[18] *See, e.g.*, Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?*, 23(3) HEALTH AFF. 155 (2004); Laurens M. Niëns et al., *Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World*, 7(8) PLOS MED. 1 (2010); Zinatul A. Zainol, *Pharmaceutical Patents and Access to Essential Medicines in Sub-Saharan Africa*, 10(58) AFR. J. BIOTECHNOLOGY 12376, 12378-82 (2011); Patricia M. Danzon, Andrew W. Mulcahy & Adrian K. Towse, *Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition, and Procurement*, 24(2) HEALTH ECON. 238 (2013).

[19] *See, e.g.*, Frederic M. Scherer & Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, 5(4) J. OF INT'L ECON. L. 913 (2002); Cullet, *supra* note 3, at 141; Marcelo D. Varella, *L'Organisation mondiale du commerce, les brevets, les médicaments et le rapport Nord-Sud: un point de vue du Sud*, (18)1 REVUE DE DROIT INTERNATIONAL ÉCONOMIQUE 79, 82 (2004); Eyal Benvenisti & George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE WESTERN RESERVE J. OF INT'L L. 21, 25 (2004); ONORI, *supra* note 10, at 41-42.

[20] *See, e.g.*, Editorial, *India's Choice*, N.Y. TIMES, Jan. 18, 2005, at A2; Mfuka, *supra* note 11, at 192.

[21] *See* ANDREW CREESE, NADINE GASMAN, MAMADOU MARIKO ET AL., THE WORLD MEDICINES SITUATION 42 (2004); Bjorn Ley, *Patent Rights and Access to Medicines: Are Patents Really the Only Barrier for Good Health Care in Developing Countries?*, *in* HUMAN RIGHTS AND INTELLECTUAL PROPERTY RIGHTS: TENSIONS AND CONVERGENCES 101, 113-14 (Mpazi Sinjela ed., 2007).

[22] Sykes, *supra* note 10, at 59.

[23] *See, e.g.*, Mattias Ganslandt, Keith E. Maskus & Eina V. Wong, *Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal*, 24(6) THE WORLD ECON. 779, 779 (2001) [hereinafter Ganslandt et al.]; ONORI, *supra* note 10, at 42; Cécile Le Gal, *Droit à*

towards the specific health needs of least developed countries "ha[d] almost come to a standstill".[24] In 2002 less than 5% of total pharmaceutical R&D was concerned with pandemics such as HIV/AIDS, tuberculosis, and malaria. Two of the sector leaders, Pfitzer and Glaxo-Smithklein-Beecham, devoted less than 1% of their R&D expenditure to this end.[25] As for so-called neglected tropical diseases[26], pharmaceutical R&D investments were virtually nil.[27] The situation has somewhat improved in recent years, as product development partnerships between pharmaceutical companies, academic centres, and public interest organisations redressed some of these R&D inequities.[28] Still, according to 2012 sources, only 10 per cent of global pharmaceutical research is applied to diseases that affect the poorest 90 per cent of the world's population.[29] On this basis, it has been argued that

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la santé et droit de propriété intellectuelle: l'accès aux médicaments dans les pays en voie de développement, 3 REVUE DE DROIT SANITAIRE ET SOCIAL 456, 457 (2005); Joshua Cohen, Maria Staroselsky Dibner & Andrew Wilson, *Development of and Access to Products for Neglected Diseases*, 5(5) PLOS ONE (2010); Ernst R. Berndt et al., *Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations*, 34(2) HEALTH AFF.245 (2015); El-Said, *supra* note 16, at 380-83.

[24] Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3(1) CHI. J. INT'L L. 27, 27 (2002).

[25] ONORI, *supra* note 10, at 28. *See also* Ganslandt et al., *supra* note 23, at 207. However, GlaxoSmithKline was later responsible for developing the first malaria vaccine, which is currently at the rollout stage in three Sub-Saharan countries. *See, Questions and Answers on RTS,S/AS01 Malaria Vaccine*, WORLD HEALTH ORG., http://www.who.int/immunization/research/development/malaria_vaccine_qa/en/ (last visited Apr. 10, 2017).

[26] This term designates certain diseases circumscribed to tropical and subtropical conditions, and includes rabies, leishmaniosis, and leprosy. A full list of neglected tropical diseases is available on the WHO website at *Neglected Tropical Diseases*, WORLD HEALTH ORG., http://www.who.int/neglected_diseases/diseases/en/ (last visited Apr. 10, 2017).

[27] *See* 't Hoen, *supra* note 24, at 42; Cullet, *supra* note 13, at 142; Véronique Lorelle, *Les maladies négligées du tiers-monde*, LE MONDE, May 26, 2003, at A2; Brian Till, *How Drug Companies Keep Medicine Out of Reach*, THE ATLANTIC, May 15, 2013, *available at* http://www.theatlantic.com/health/archive/2013/05/how-drugcompanies-keep-medicine-out-of-reach/275853/.

[28] *See, e.g.*, Richard T. Mahoney, *Product Development Partnerships: Case studies of a New Mechanism for Health Technology Innovation*, 9(33) HEALTH RES. POL'Y & SYS. (2011), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3175464/pdf/1478-4505-9-33.pdf (last visited May 16, 2017); WORLD HEALTH ORG., FOURTH WHO REPORT ON NEGLECTED TROPICAL DISEASES: INTEGRATING NEGLECTED TROPICAL DISEASES INTO GLOBAL HEALTH AND DEVELOPMENT 49 (2017), *available at* http://apps.who.int/iris/bitstream/10665/255011/1/9789241565448-eng.pdf?ua=1 (last visited May 15, 2017).

[29] DEUTSCHE STIFTUNG WELTBEVOELKERUNG, INNOVATIONS IN GLOBAL HEALTH RESEARCH AND DEVELOPMENT (R&D): AN AGENDA FOR THE SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS (SRHR) COMMUNITY 7 (2012), *available at*

a wholesale import of patent regulations from the global North would fail to provide an efficient stimulus to medical innovation targeting the specific health needs of the global South.[30]

Against this backdrop the last thirty years have witnessed a rapid evolution of international legal rules governing pharmaceutical patents. Prior to the establishment of the WTO a handful of multilateral and regional conventions existed which regulated discrete aspects of IP protection.[31] The WIPO, created in the late 1960s, was in charge of administering those treaties in order to "promote the protection of intellectual property throughout the world".[32] Few of these instruments, however, set substantive standards as to the subject matter or the duration of protection, and virtually none contemplated strict enforcement mechanisms.[33] Therefore, states were largely free to choose the level of IP protection that best suited their policy preferences, taking into account factors such as their development stage, the relative weight of IP-related imports and exports, the degree of technological innovation, and the socio-economic stakes in the areas of health and education.[34] For a long time governments viewed the pharmaceutical sector as a particularly sensitive industry operating in permanent equilibrium between profit-maximization and social-benefit logics, and many domestic legislations provided for weak, if any, patent protection on pharmaceuticals.[35]A

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https://www.dsw.org/uploads/tx_aedswpublication/2012_10_Innovations_in_Global_Health_R_D_-_An_Agenda_for_the_SRHR_Community.pdf (last visited May 16, 2017).

[30] John H. Barton, *Intellectual Property Rights and Innovation*, *in* CAPITAL OF OUR TIME: THE ECONOMIC, LEGAL, AND MANAGEMENT CHALLENGES OF INTELLECTUAL CAPITAL 123 (Nicholas Imparato ed., 1999).

[31] *See, e.g.*, Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305.

[32] Convention Establishing the World Intellectual Property Organization art. 3(i), July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3.

[33] *See, e.g.*, CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 7 (2009).

[34] *Id.* at 15. *See also* MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 549-52 (3d ed. 2005); Brent B. Allred & Walter G. Park, *Patent Rights and Innovative Activity: Evidence from National and Firm-Level Data*, 38(6) J. OF INT'L BUS. STUD. 878, 896 (2007).

[35] *See* Ana María Pacón, *What Will TRIPS Do for Developing Countries?*, *in* FROM GATT TO TRIPS: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 356 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996); Vadi, *supra* note 8, at 198; Cullet, *supra* note 13, at 141. For instance, the United Kingdom, the first European state to protect pharmaceutical patents, has adopted the relevant legislation in 1949, *Patents Act, 1949*, Act No. 89/1949; France in 1959, *Loi fédérale sur les brevets d'invention*, RS. 232.14, Rec. 1955, at 893; Germany in 1968, *see* PATENTGESETZ UND GEBRAUCHSMUSTERGESETZ

number of large emerging economies such as India, Brazil, and Argentina were home to thriving generic drug industries which ensured a steady supply of cheap medicines to the rest of the developing world.[36]

The situation started changing in the 1980s when a number of private stakeholders, including large pharmaceutical multinationals in developed countries, started a campaign for stronger protection of their IP rights at the national and international level.[37] An early result of this lobbying, the Omnibus Trade and Competitiveness Act, was adopted by the US Congress in 1988 with the aim of bolstering the United States' leverage in trade negotiations. The statute, which amended Section 301 of the 1974 Trade Act (Section 301), enabled the US Trade Representative (USTR) to identify foreign countries lacking adequate IP protection and to impose unilateral trade sanctions against them.[38] Internationally, the United States joined forces with other industrialized countries to include IP-related issues in the agenda of the Uruguay Round of negotiations which eventually led to the establishment of the WTO.[39] This attempt to merge IP and trade concerns met with resistance from a group of large developing countries, in particular India and Brazil, which worked to stall the negotiations and to defend their policy autonomy.[40] In the end,

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IN DER FASSUNG V. 2.1.1968 (Rudolf Busse ed., 1972); Switzerland in 1976, *Loi fédérale sur les brevets d'invention*, RS. 232.14, Rec. 1955, at 893, as amended, Rec. 1976, at 1997.

[36] *See, e.g.*, Scherer & Watal, *supra* note 19, at 914; ONORI, *supra* note 10, at 69; John H. Barton, *TRIPS and the Global Pharmaceutical Market*, 23(3)HEALTH AFF. 146, 147 (2004).

[37] *See* DUNCAN MATTHEWS, GLOBALIZING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 12 (2002); James Thuo Gathii, *The Structural Power of Strong Pharmaceutical Power Protection in the US Foreign Policy*, 7 J. GENDER RACE & JUST. 267 (2003); DEERE, *supra* note 33, at 8; Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, *in* TRANSNATIONAL LEGAL ORDERS 311, 315 (Terence C. Halliday & Gregory Shaffer eds., 2015).

[38] *See* Alan O. Sykes, *Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301*, 23 L. & POL'Y INT'L BUS. 263 (1992); Taylor C. O'Neal, *The Limits of Economic Power: Section 301 and the World Trade Organization Dispute Settlement System*, 30 VAND. J. TRANSNAT'L L. 209 (1997); Peter K. Yu, *TRIPS and its Discontents*, 10(2) MARQ. INTELL. PROP. L. REV. 369, 372 (2006).

[39] For instance, in an early communication to its negotiating partners, the United States called for the recognition of the "trade distortions and impediments" deriving from the lack of enforcement of IP rights in areas such as chemicals, transport equipment parts, books, and motion pictures. *See*, Preparatory Committee, Trade and Intellectual Property Rights, PREP.COM (86)W/46, at 2 (July 8, 1986).

[40] *See, e.g.*, B.S. Chimni, *Political Economy of the Uruguay Round of Negotiations: A Perspective*, 29(2) INT'L STUD. 135, 140-41 (1992); DEERE, *supra* note 33, at 8; A.V. Ganesan, *Negotiating for India*, *in* THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 211, 213 (Jayashree Watal & Antony Taubman eds., 2015). According to those states, IP protection had "no direct or significant relationship to international trade", Group of Negotiations on Goods (GATT), Applicability of the Basic

however, the TRIPS Agreement made its way to the final package of WTO covered agreements.[41]

Commentators have offered differing views as to why the recalcitrant states capitulated. For some, developing countries and LDCs were coerced into the deal through economic and diplomatic pressure–especially by the threat of trade retaliation under Section 301.[42] For others, most such states lacked the capacity and expertise necessary to appraise fully the consequences of the adoption of stringent IP protection and to build solid counterclaims.[43] The most credited explanation is that developing countries simply acquiesced to the adoption of the TRIPS Agreement as part of a grand (albeit unequal) bargain which included

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Principles of the GATT and of Relevant International Intellectual Property Agreements or Conventions- Communication From India, MTN.GNG/NG11/W/39, at 2 (Sept. 5, 1989), and should remain "completely outside the GATT jurisdiction", Preparatory Committee, Draft Ministerial Declaration, PREP.COM(86)W/41/Rev.1/Add.1 (Jul. 22, 1986).

[41] For a detailed account of the final stages of the negotiations, see, for example, Daniel J. Gervais, *Intellectual Property, Trade and Development: The State of Play*, 74(2) FORDHAM L. REV. 505, 505-08 (2005).

[42] *See, e.g.*, Benvenisti & Downs, *supra* note 19, at 27; Ley, *supra* note 21, at 132; Mfuka, *supra* note 11, at 203; Vadi, *supra* note 8, at 202; Drahos, *supra* note 6, at 792; Benjamin Coriat, *Du 'Super 301' aux TRIPS: La 'Vocation Impériale' du Nouveau Droit Américain de la Propriété Intellectuelle*, 99 REVUE D'ÉCONOMIE INDUSTRIELLE 179, 183-85 (2002); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36(1) CASE W. R. J. INT'L L. 79 (2004); Justin Malbon, *TRIPS-Plus Treaty Terms: Dealing with Coercion*, *in* INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR? 159, 167 (Justin Malbon & Charles Lawson eds., 2008). For instance, an Indian and a Brazilian top-level negotiators recently recalled how, during the Uruguay Round, their delegations keenly felt the pressure exerted by the United States through Section 301. In their recollection, both India and Brazil chose to be tactical and bargain for better IP rules, rather than fighting a battle already lost. *See* Ganesan, *supra* note 40, at 219-20; Piragibe dos Santos Tarragô, *Negotiating for Brazil*, *in* THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 239, at 242, 254 (Jayashree Watal & Antony Taubman eds., 2015).

[43] *See, e.g.*, SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 9 (2003); Matthew Turk, *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of TRIPS but not TRIPS-Plus*, 42(3) N.Y.U. J. INT'L L. & POL. 981, 994 (2010); Hanns Ullrich, *The Political Foundations of TRIPS Revisited*, *in* TRIPS PLUS 20: FROM TRADE RULES TO MARKET PRINCIPLES 85, 94 (Hanns Ullrich et al. eds., 2016). However, the secretariat of the UN Conference on Trade and Development provided expertise to some developing country delegations during the Uruguay Round, thereby helping rebalance the expertise equation. *See* Antonio G. Trombetta, *Negotiating for Argentina*, *in* THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 257, 271 (Jayashree Watal & Antony Taubman eds., 2015).

concessions for increased market access in the textile and agricultural sectors.[44]A final account rejects the notion of capitulation altogether. Rather, the reinforcement of IP standards at the global level may well have been in the self-interest of states such as Brazil or India based on the expectation that they would soon join the club of technology innovators and IP-exporters.[45]

Be it as it may, the entry into force of the TRIPS Agreement on January 1, 1995, marked a significant milestone in the history of global IP regulations.[46] As sought by its developed-country proponents, the Agreement establishes minimum standards of legal protection that all WTO member states are required to implement in their domestic legislations in areas such as trademarks, patents, copyrights, geographical indications, and industrial designs. In particular, the TRIPS Agreement stipulates that "patents shall be available for any inventions, whether products or processes, in all fields of technology", thus covering pharmaceutical products.[47] The term of patent protection must not be less than "a period of twenty years counted from the filing date".[48] In light of these provisions WTO member states are no longer entitled to exclude pharmaceutical products from the range of patentable inventions, but rather they are required to implement stringent and prolonged patent protection for such products.[49] Furthermore, the standards contained in the TRIPS Agreement provide a minimum baseline of IP protection in domestic jurisdictions and do not prevent WTO member states from implementing "more extensive protection" consistent with the provisions of the Agreement.[50] Finally, WTO member states are required to provide IP protection

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[44] *See* Yu, *supra* note 38, at 371; Daniel J. Gervais, *TRIPS and Development*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 3, 7-11 (Daniel J. Gervais ed., 1st ed. 2007); DEERE, *supra* note 33, at 8; Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT'L L.& FOREIGN AFF. 311, 314 (2011).

[45] Yu, *supra* note 5, at 13; Yu, *supra* note 38, at 376-79; Gervais, *supra* note 44, at 11-12. *See generally* Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13(1) UCLA PAC. BASIN L.J. 166, at 167, 169-71 (1994).

[46] Cullet, *supra* note 13, at 144; Yu, *supra* note 5, at 3.

[47] TRIPS Agreement, *supra* note 2, art. 27.1.

[48] TRIPS Agreement, *supra* note 2, art. 33.

[49] On the twenty-year duration of patents, some have argued that a similar term is usually found in the domestic legislations of most developed countries and "is thought to strike a sensible balance" between the reward to the inventor and the dissemination of the invention. Sykes, *supra* note 10, at 58. Others retort that, far from being grounded in solid economic evidence, this lengthy term results in the "over-protection of important domestic industries" and directly reflects their concerted lobbying efforts. Benvenisti & Downs *supra* note 19, at 24.

[50] TRIPS Agreement, *supra* note 2, art. 1.1.

on a most favoured nation (MFN) basis.[51] The fact that the TRIPS Agreement comes under the WTO umbrella means that the disputes arising from its interpretation and application are enforceable through the pervasive and effective WTO dispute settlement mechanism.[52]

Together with these standards and procedures the TRIPS Agreement sets out certain flexibilities aimed at according WTO member states sufficient leeway to achieve socio-economic goals including the protection of public health.[53] These 'escape valves' include, among other things, varying transitional periods for implementation in favour of developing and least-developed countries (the longest of which were initially set to elapse in 2005)[54], the possibility of parallel imports, i.e., the importation, with or without the consent of the patent holder, of a product legally marketed in another country by the patent holder[55], and the granting of compulsory licenses, i.e., non-exclusive licenses granted to third parties by an act of government, irrespective of the will of the patent owner.[56]

The diplomatic tensions surrounding the TRIPS Agreement did not cease with the entry into force of the treaty. Throughout the first years of its application, the Agreement "became a symbol of the vulnerability of developing countries (…) and galvanized critics regarding the influence of multinational corporations on global economic rules".[57] In particular, scholars from developing countries maintained that the imposition of global IP rules as a pre-requisite to participation in international trade[58] was a tool for developed states to assert their supremacy, pull up the ladder of access to technology, and extort undeserved "rents on behalf of multinational corporations".[59] Meanwhile, an increasingly tight network of NGOs,

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[51] TRIPS Agreement, *supra* note 2, art. 4.

[52] *See* Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, 40 U.C. DAVIS L. REV. 971, 984 (2007).

[53] For a comprehensive analysis of each of these flexibilities, see CARLOS M. CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (2000); SISULE F. MUSUNGU & CECILIA OH, WORLD HEALTH ORG., THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 68 (2005); Ley, *supra* note 21.

[54] TRIPS Agreement, *supra* note 2, art. 65, 66.

[55] Article 6 of the TRIPS Agreement leaves the rules governing the geographical exhaustion of IP rights to the discretion of WTO member states.

[56] TRIPS Agreement, *supra* note 2, art. 31.

[57] DEERE, *supra* note 33, at 2.

[58] Ullrich, *supra* note 43, at 98.

[59] Jagdish Bhagwati, *What It Will Take to Get Developing Countries into a New Round of Multilateral Trade Negotiations*, *in* TRADE POLICY RESEARCH 2001 19, 21 (John M. Curtis ed., 2001). *See also* Brian F. Fitzgerald, *Trade-Based Constitutionalisms: The Framework for Universalizing Substantive International Law?*, 5 U. MIAMI INT'L & COMP. L.REV.111, 153

academics, and political figures helped raise public awareness of the impact of IP protection on issues such as public health and policy autonomy and organized the resistance. For instance, some commentators blasted a WTO panel ruling providing a restrictive interpretation of the TRIPS flexibilities[60] as failing to preserve the delicate balance of social and economic interests reflected in the stated purposes of the Agreement and unduly curbing the regulatory autonomy of WTO member states.[61] Another panel decision, which limited the United States' indiscriminate use of Section 301[62], was hailed as reducing diplomatic tensions by removing the credibility of threats of unilateral sanctions against non-TRIPS-compliant states.[63] More famously, a 1998 lawsuit initiated by a coalition of large multinational companies against the government of South Africa over a compulsory licensing system for HIV/AIDS medicines[64] incurred such a public backlash that the complainants eventually dropped the action.[65]

Thanks to this transnational mobilization by 2001 most WTO member states were conscious of the potential impact of the TRIPS Agreement on access to affordable medicines. In November 2001, under pressure from a group of developing countries, the Fourth WTO Ministerial Conference adopted the Doha Declaration

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(1997); WORLD BANK, GLOBAL ECONOMIC PROSPECTS AND THE DEVELOPING COUNTRIES 2002, xvii (2001), *available at* http://documents.worldbank.org/curated/en/285571468337817024/310436360_20050012014722/additional/multi0page.pdf; Jagdish Bhagwati, *Afterword: The Question of Linkage*, 96(1) AM. J. INT'L L. 126, 127 (2002).

[60] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

[61] Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3(4)J. OF WORLD INTELL. PROP. 493, 506 (2000). *See also* Helfer, *supra* note 4, at 77-79.

[62] Panel Report, *United States – Sections 301-310 of the Trade Act 1974*, WT/DS152/R (Dec. 22, 1999).

[63] *See, e.g.*, MATTHEW KENNEDY, WTO DISPUTE SETTLEMENT AND THE TRIPS AGREEMENT: APPLYING INTELLECTUAL PROPERTY STANDARDS IN A TRADE LAW FRAMEWORK 84-86 (2016).

[64] *Pharmaceutical Manufacturers' Association of South Africa v. President of the Republic of South Africa* 4183/98 (HC) (Feb. 18, 1998), *available at* http://www.cptech.org/ip/health/sa/pharmasuit.html.

[65] *See* DEERE, *supra* note 33, at 163; Vadi, *supra* note 8, at 203; 't Hoen, *supra* note 24, at 30; Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians*, 29(4) INT'L J. OF HEALTH SERVICES 765 (1999); Tshimanga Kongolo, *Public Interest Versus the Pharmaceutical Industry's Monopoly in South Africa*, 4(5) J. OF WORLD INTELL. PROP. 609, 613 (2001); Sandra Bartelt, *Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6(2) WORLD J. OF INTELL. PROP. 283, 294 (2004).

on the TRIPS Agreement and Public Health (Doha Declaration),[66] unanimously considered as a "significant milestone" in the legal and diplomatic relations within the WTO.[67] The Declaration stipulated, among other things, 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". To this end, the Declaration reaffirmed the importance of the TRIPS flexibilities and, in some cases, broadened their scope. For instance, it extended the transitional period for the implementation of TRIPS-compliant patent regimes by least developed countries to 2016 and gave WTO members substantial leeway to define the circumstances for granting compulsory licenses.[68] In August 2003, the Declaration was complemented by the so-called 'Paragraph 6 Solution',[69] a decision of the WTO General Council that temporarily permitted the export of generic drugs produced through compulsory licenses to countries lacking adequate manufacturing capacity.[70] Finally, in December 2005 the General Council adopted a formal amendment to the TRIPS Agreement which made the Paragraph 6 Solution a permanent feature of the treaty. As mentioned in the introduction, the amendment entered into force in January 2017. Despite attracting some criticism for doing too little[71] or too much[72], these instruments were saluted as an important victory for needs of the global South in the WTO[73] as they allowed at least the largest developing countries to effectively promote affordable healthcare policies.[74]

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[66] World Trade Organisation, Ministerial Declaration of 14 November 2001, WT/MIN(01)DEC/2, 41 ILM 746 (2002), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

[67] Haochen Sun, *Reshaping the TRIPs Agreement Concerning Public Health: Two Critical Issues*, 37(1) J. WORLDS TRADE 163, 168 (2003).

[68] *See* Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28(1) LIVERPOOL L. REV. 41, 49 (2007); 't Hoen, *supra* note 24, at 41-42; Cullet, *supra* note 13, at 153.

[69] World Trade Organisation, General Council Decision of Aug. 30 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1 (2003), *available at* https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[70] *See* Vadi, *supra* note 8, at 211; MUSUNGU & OH, *supra* note 53, at 68; Yu, *supra* note 44, at 319-21.

[71] *See generally* Wenwei Guan, *IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment*, 29(2) LEIDEN J. OF INT'L L. 411 (2016).

[72] *See* Sykes, *supra* note 10, at 49, 66.

[73] German Velásquez, *Bilateral Trade Agreements and Access to Essential Drugs*, *in* INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 63 (Jorge A. Bermudez & Maria A. Oliveira eds., 2004); Vadi, *supra* note 8, at 208.

[74] *See* Yu, *supra* note 44, at 323-25.

Yet, the struggle was far from over. Around the same time as the adoption of the Doha Declaration, some developed nations, spearheaded by the United States and the European Union, started including IP-related clauses in their bilateral and regional FTAs with developing countries. These clauses, commonly referred to as 'TRIPS-plus provisions', require signatories to implement higher standards of IP protection than those set out in the TRIPS Agreement.[75] These provisions may mandate the inclusion of new areas of IP rights, for instance by protecting inventors' exclusive rights to the pharmaceutical test data, strengthen the protection or extend the duration of such rights, and/or restrict the use of the flexibilities available under the TRIPS Agreement, for example by prohibiting parallel imports or limiting recourse to compulsory licenses.[76] While they apply solely among the contracting states, these additional obligations have the potential to become the new global IP standard as the MFN clause contained in the TRIPS Agreement will require a WTO member making TRIPS-plus commitments to accord the same treatment to all other members.[77] In recent years, the United States has bilaterally negotiated TRIPS-plus clauses in its international agreements with, among others, Australia,[78] Bahrain,[79] Jordan,[80] Chile,[81] Colombia,[82] Peru,[83] Morocco,[84] and Singapore,[85] and has included similar provisions in the regional FTA with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the

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[75] Mohammed K. El-Said, *From TRIPS-Minus to TRIPS to TRIPS-Plus: Implications of IPRs for the Arab World*, 8(1) J. OF WORLD INTELL. PROP. 53 (2005); Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, *in* REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 215 (Lorand Bartels & Federico Ortino eds., 2006).

[76] S*ee* INT'L INTELLECTUAL PROP. INST., PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 30 (2000); MUSUNGU & OH, *supra* note 53, at 47; Sell, *supra* note 68, at 60-63; Correa, *supra* note 12; Correa, *supra* note 42, at 83-91; Mercurio, *supra* note 75, at 224-34.

[77] *See* Susy Frankel, *Challenging TRIPS-Plus Agreements: The Potential Utility of Non-violation Complaint*, 12(4) J. OF INT'L ECON. L. 1023, 1033 (2009); Drahos, *supra* note 6, at 802; Mercurio, *supra* note 75, at 223.

[78] Australia-United States Free Trade Agreement, U.S.-Austl., May 18, 2004, T.I.A.S. No. 6422.

[79] United States-Bahrain Free Trade Agreement, U.S.-Bahr., Sept. 14, 2004, 44 I.L.M. 544.

[80] United States-Jordan Free Trade Agreement, U.S.-Jordan, Oct. 24, 2000, 41 I.L.M. 63.

[81] United States-Chile Free Trade Agreement, U.S.-Chile, June 6, 2003, 42 I.L.M 1026.

[82] United States-Colombia Trade Promotion Agreement, U.S.-Colom., Nov. 22, 2006, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text.

[83] United States-Peru Free Trade Agreement, U.S.-Peru, Apr. 12, 2006, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text.

[84] United States-Morocco Free Trade Agreement, U.S.-Morocco, June 15, 2004, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text.

[85] United States-Singapore Free Trade Agreement, U.S.-Sing., May 6, 2003, 42 I.L.M. 1026.

Dominican Republic[86]. High standards of IP protection also appear in the (now defunct) Trans-Pacific Partnership as well as in the Transatlantic Trade and Investment Partnership, and the EU-Canada Comprehensive Economic and Trade Agreement.[87]

Predictably, most development-oriented scholars have condemned the proliferation of TRIPS-plus provisions. According to many, the global IP ratchet, astutely pursued by developed countries in alternating cycles of "bilateralism, regionalism and multilateralism",[88] aims to continuously "shift the standard-setting agenda from fora in which they are encountering difficulties to those fora where they are likely to succeed".[89] This process threatens to tilt the delicate balance between the conflicting policy goals of patent protection and access to affordable medicines struck with the adoption of the Doha Declaration and the subsequent instruments, therefore bypassing the WTO arena and further threatening public health in developing countries.[90] It may also undermine the legal predictability of WTO multilateral dispute settlement in favour of a "maze" of *ad hoc* adjudicatory regimes where developed-country litigants have greater political clout.[91] For some commentators this forum-shifting strategy amounts to nothing short of imperialism in disguise as it allows powerful states to "break the coordinated resistance of the weaker parties" and curtail their ability to engage in the "logrolling" necessary for them to bargain more effectively.[92] In the same vein, some see the new turn to IP-bilateralism as an act of bad faith on the part of

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[86] Dominican Republic-Central America Free trade Agreement,May 28, 2004, 43 I.L.M. 514.

[87] For a comprehensive overview, *see* Charles T. Collins-Chase, *The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29(3) U. OF PA. J. OF INT'L L. 763, 779 (2008); DEERE, *supra* note 33, at 152; Anselm Kamperman Sanders & Dalindyebo Shabalala, *Intellectual Property Treaties and Development*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 41, 67-69 (Daniel J. Gervais ed., 2d ed. 2014).

[88] Mercurio, *supra* note 75, at 216-24.

[89] Drahos, *supra* note 6, at 798-99. *See also* Joost Pauwelyn, *Legal Avenues to "Multilateralising Regionalism": Beyond Article XXIV*, *in* MULTILATERALIZING REGIONALISM: CHALLENGES FOR THE GLOBAL TRADING SYSTEM 368, 386 (Richard Baldwin & Patrick Low eds., 2009); Yu, *supra* note 38, at 409; Correa, *supra* note 42, at 81; Mercurio, *supra* note 75, at 222; Collins-Chase, *supra* note 87, at 780; JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 564-577 (2000); Helfer, *supra* note 44, at 42.

[90] *See, e.g.*, Correa, *supra* note 42.

[91] Pauwelyn, *supra* note 89, at 386. *See also* Yu, *supra* note 38, at 409.

[92] Eyal Benvenisti & George Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60(2) STAN. L. REV. 595, at 610, 615 (2007). *See also* Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 347 (2008).

developed states. In particular, at the time they accepted the TRIPS Agreement, developing countries expected that the upward spiraling of IP standards would stop there.[93] Therefore, it is said that the subsequent regulatory developments stripped them of their freedom from excessive IP protection[94] and put them in perpetual "negotiating fatigue".[95]

Quoi faire? For all their poignant critiques, these authors acknowledge that, from a diplomatic standpoint, governments from the global South can do quite little to shield themselves from the global IP ratchet.[96] A common reflex is to recommend that developing countries resist economic and diplomatic pressure when negotiating new trade deals with their developed counterparts.[97] For instance, in a typical pro-Third World move, some have advocated the creation of a "veto coalition" of states, possibly guided by like-minded NGOs, against the further ratcheting up of IP standards.[98] Others have gone as far as to revisit the doctrine of coercion under international treaty law to include economic and diplomatic pressure in the types of conduct that fit that label.[99]

What these proposals share, in one way or another, is the conviction that a structural rebalancing of global IP regulations depends on the political empowerment of the "net losers of globalization"[100] and on a more fruitful use of

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[93] *See* Drahos, *supra* note 6, at 791-92.

[94] *See* Frankel, *supra* note 77, at 1028.

[95] Drahos, *supra* note 6, at 804.

[96] *Id.* at 800.

[97] Collins-Chase, *supra* note 87, at 801; Sell, *supra* note 68, at 64-65. S*ee also* South Centre, *Intellectual Property In Investment Agreements: The TRIPS-Plus Implications For Developing Countries*, at 21, SC/TADP/AN/INV/2 (May 2005); Lisa Forman, *Trade Rules, Intellectual Property, and the Right to Health*, 21(3) ETHICS & INT'L AFF. 337, 345 (2007).

[98] Drahos, *supra* note 6, at 806. *See also* PETER DRAHOS WITH JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 207-09 (2002); John S. Odell & Susan K. Sell, *Reframing the Issue: The Coalition on Intellectual Property and Public Health in the WTO, 2001*, *in* NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85 (John S. Odell ed., 2006). This solution resonates with the "global coalition of the poor countries" advocated in B.S. Chimni, *Third World Approaches to International Law: A Manifesto*, 8(3) INT'L COMMUNITY L. REV. 3, 7 (2006).

[99] For example, Eyal Benvenisti and George Downs place particular emphasis on Article 2.7 of the UN Charter, which prohibits member States from intervening "in matters which are essentially within the domestic jurisdiction of any [other] State." Benvenisti &Downs, *supra* note 19, at 31. Similarly, Justin Malbon envisages redress through Article 52 of the Vienna Convention on the Law of Treaties of 1969, according to which a treaty is void if its conclusion has been procured "by the threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations". Malbon, *supra* note 42, at 167.

[100] The expression is borrowed from Sykes, *supra* note 10, at 59.

the bargaining tools at their disposal. International institutions such as the WIPO, the WTO, and bilateral treaty commissions are seen as little more than battlegrounds for a perpetual struggle between the dominant and the oppressed. This 'antagonistic' posture certainly has some merit: for one thing, it reaffirms that the form and content of international lawmaking are hardly neutral but rather stem from highly contested processes and rest on carefully designed negotiating strategies. As such, the political narrative serves as a forceful reminder that the 'universalist' aspirations of international law are often used as a discursive technique to obscure the underlying struggles and to naturalize the position of the winners.[101]

However, this narrative also has its limitations. First, focusing on the 'North vs. South' dichotomy neglects the sharp differences in bargaining power that exist within each of the two camps. For instance, recent literature has shown that while large and robust developing countries such as India, Brazil and Argentina have been largely able to resist the lure of TRIPS-plus and to implement affordable healthcare policies, smaller and lower-income states quickly abdicated the fight and adopted TRIPS-plus levels of patent protection without hesitation.[102] Second, insisting on a continued pro-North bias in the current negotiating processes is an easy target for rebuttal. For instance, some 'orthodox' international relations scholars have pointed out that developing countries are in a better bargaining position today than they were at the time of the Uruguay Round. For one thing, some coercive tools that powerful countries used during the TRIPS Agreement negotiations, such as Section 301, have lost their threat as a result of WTO adjudication. Moreover, the transnational mobilization of the late 1990s and the early 2000s has raised awareness of the impact of patent protection on public health such that today few governments may legitimately invoke their ignorance on this matter.[103] Absent these justifications the decision by many developing and least-developed countries to enter TRIPS-plus agreements would be an expression of their contractual freedom as sovereign states and "critics have the burden of explaining how these countries are not thereby made better off".[104]

This sheds light on the third and perhaps most salient blind spot of the political narrative based on a North vs. South divide: namely, its tendency to cast the issue in simplistic binary terms. As it appears from the account provided thus far, this narrative hinges on a quite traditional conception of national interest. Treating negotiating countries as free, informed, and rational actors implies that each state is

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[101] *See, e.g.*, Emmanuelle Jouannet, *Universalism and Imperialism: The True-False Paradox of International Law?*, 18(3) EUR. J. OF INT'L L. 379, 388-92 (2007).
[102] DEERE, *supra* note 33, at 2, 163-65.
[103] Turk, *supra* note 43, at 1007-09.
[104] Turk, *supra* note 43, at 1028-29.

able to bring to the table an unambiguous and pre-determined position, "to aggregate collective wishes", and "to translate them into acts."[105] This unitary state actor model has long been questioned in international relations and international law theories and proves of limited value when it comes to analyzing IP regime complexity. As some constructivist and critical scholars have pointed out, interests "are not just 'out there' waiting to be discovered; they are constructed through social interaction".[106] Moreover, and crucially, the state "is not a unified self" but rather "encompasses a variety of groups and performs a variety of functions", whose outcomes do not necessarily serve everyone's interests.[107] Applying this line of inquiry to the issue at hand one may well expect that the strengthening of pharmaceutical patents through successive waves of bilateral and multilateral treaties would make *some* sectors of society better off and *some other* sectors worse off in developed and developing countries alike. For instance, besides providing an immediate gain to pharmaceutical patent holders in industrialized economies, entering into such agreements may enhance the position of the ruling élites in low-income states by bolstering their international standing. Conversely, the rise in the sales of medicines may adversely affect impoverished healthcare-seekers in both the North and the South albeit to different degrees.[108]

Disentangling the concept of state interest enables us to see that national governments are pluralistic entities that comprise a wide array of institutions, each pursuing a specific agenda and drawing legitimacy from a specific domestic constituency.[109] Non-governmental actors such as private interest and civil society

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[105] Robert Malley, Jean Manas & Crystal Nix, *Constructing the State Extra-Territorially: Jurisdictional Discourse, the National Interest, and Transnational Norms*, 103(6) HARV. L. REV. 1273, 1285 (1990) [hereinafter Malley et al.].

[106] MARTHA FINNEMORE, NATIONAL INTERESTS IN INTERNATIONAL SOCIETY 2 (1996). *See also* Alexander Wendt, *Collective Identity Formation and the International State*, 88(2) AM. POL. SCI. REV.384, 385 (1994).

[107] Karen Knop, *Feminism and State Sovereignty in International Law*, 3(2) TRANSNAT'L LAW & CONTEMP. PROBS. 293, 333 (1993).

[108] Far from being a purely academic hypothesis, a solid case can be made that the price of essential medicines in the United States has become unsustainable for most consumers. For instance, the average price of cancer drugs exceeded USD 120,000 per patient per year in 2014, and the cost of other pharmaceutical treatments was as high as USD 300,000. *See, e.g.*, Carlos M. Correa, *Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements*, 74 S. CENTRE 5-6 (2017).

[109] Helfer, *supra* note 4, at19. *See also* Thomas Cottier, Joost Pauwelyn & Elisabeth Bürgi, *Linking Trade Regulation and Human Rights in International Law: An Overview*, *in* HUMAN RIGHTS AND INTERNATIONAL TRADE 1, 10 (Thomas Cottier, Joost Pauwelyn & Elisabeth Bürgi eds., 2005). *See also* Jonathan Liberman & Andrew Mitchell, *In Search of Coherence Between Trade and Health: Inter-Institutional Opportunities*, 25(1) MD. J. OF INT'L L. 143, 153 (2010).

groups play a pivotal role in channeling social preferences and expressing competing policy claims to influence the behavior of government agencies.[110] According to traditional public choice analysis the relative weight of the positions on the table will depend on the size, concentration, level of expertise, and economic power of each faction[111]: well-organized groups with high economic stakes and specialized knowledge will usually have greater impact on legislative outcomes than dispersed, loosely coordinated masses.[112] Thus, some have pointed out that purely state-centric accounts of recent IP negotiations "are at best incomplete and at worst misleading" as they obscure how private actors pursue their interests in a wide variety of fora, "at all possible levels and in multiple venues", in order to translate complex IP issues into political and diplomatic discourse.[113] On the other side of the fence, those discontent with pharmaceutical patents, such as NGOs and advocacy groups, have also engaged in a complex game of principled lobbying in order to empower developing states in future negotiations and foster the creation of "counter-regime norms".[114]

As will be seen, the competing constituencies at play do not operate solely within the boundaries of the national political space but also tend to create transnational solidarities and networks beyond national borders.[115] Global law and governance today seem to stem as much from inter-state lawmaking as from the activities of a host of non-territorial networks.[116] Each networked constituency seeks to assert its

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[110] Helfer, *supra* note 4, at 19. Malley et al., *supra* note 105, at 1284.

[111] *See* MANCUR L. OLSON JR., THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 5-43 (1965); Gathii, *supra* note 37.

[112] *See* Kelley Lee, Devi Sridhar & Mayur Patel, *Bridging the Divide: Global Governance of Trade and Health*, 373 THE LANCET 416, 418 (2009); Andrew T. Guzman, *Choice of Law: New Foundations*, 90 GEO. L.J. 883, 903 (2002). *See also generally* Paul C.B. Liu, *US Industry's Influence on Intellectual Property Negotiations and Special 301 Actions*, 13 UCLA PAC. BASIN L.J. 87 (1994); Mfuka, *supra* note 11, at 200.

[113] SELL, *supra* note 43at 8. While pharmaceutical companies helped shape the United States' stance in respect of patents, other domestic industries contributed to the United States' negotiating position in respect of other IP fields. For instance, before the inception of the Uruguay Round, the Levi Strauss Corporation, together with other firms such as the International Anti-Counterfeiting Coalition, requested and obtained the USTR's backing for an international anti-counterfeiting code. The code constituted the initial core of what would eventually become the TRIPS Agreement. *Id.* at 40. *See also* MATTHEWS, *supra* note 37, at 8-9.

[114] Helfer, *supra* note 4, at 58-61.

[115] *See* Paul Schiff Berman, *The Globalization of Jurisdiction*, 151(2) U. PA. L. REV. 311 (2002); Katharina Pistor, *Contesting Property Rights: Towards an Integrated Theory of Institutional and System Change,* 11(2) GLOBAL JURIST: FRONTIERS, 7 (2011).

[116] *See, e.g.*, Gunther Teubner, *The Two Faces of Janus: Rethinking Legal Pluralism*, 13 CARDOZO L. REV. 1443 (1992); Martti Koskenniemi, *Global Governance and Public International Law*, 37(3) KRITISCHE JUSTIZ 241, 243 (2004); Malley et al., *supra* note 105, at 1290.

influence at the global level and resorts to a whole host of strategies and techniques to this end. The most obvious result of this activity has been the progressive emergence over the last decades of informal bodies of rules, standards, principles, and practices to govern certain areas of global affairs more or less independently from state enforcement.[117] However, even the establishment of formal intergovernmental organisations embodies, to some degree, the coordinated efforts of specific transnational constituencies and 'crystalizes' their interests into an institutionalized regime. In fact, the traditional functionalist view, which sees international organisations simply as agents tasked by their member states to carry out functions of common interest[118], is giving way to new conceptions whereby institutional regimes are a means to transpose political differentiation from the domestic sphere onto the international plane.[119]

Inevitably, this shift in focus from national sovereigns to transnational political constituencies changes our perception of the fault lines in the conflict between pharmaceutical patents and access to medicines. The two narratives explored in the following sections partake in this 'remapping' of the debate along social sectors rather than territorial lines. As we will see, however, the proponents of the two approaches differ on one major point: namely, the possibility to reconcile or otherwise resolve the conflict at issue through recourse to rules and principles currently available under international law. Far from being a mere variance between optimists and pessimists, this difference lies at the core of the worldviews of the two camps and reflects deeply ingrained, if seldom expressed, instincts about the deep architecture of the global order.

III. THE INTERNATIONAL LAW NARRATIVE: NORMATIVE CONFLICTS, THE TURN TO INTERPRETATION, AND THE LURE OF CONSTITUTIONALISM

As anticipated in the previous Part, the second and third narratives of the conflict between pharmaceutical patents and access to medicines break from the idea of a North vs. South diplomatic standoff and instead redraw the issue along transnational lines. The second perspective, on which I focus here, emphasizes that the policy goals of IP protection and access to affordable healthcare are *both*

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[117] One such example is the *lex mercatoria* developed to settle transnational commercial disputes. *See, e.g.*, Hans-Joachim Mertens, *Lex Mercatoria: A Self-applying System Beyond National Law?*, *in* GLOBAL LAW WITHOUT A STATE 31 (Gunther Teubner ed., 1997).

[118] *See, e.g.*, Jan Klabbers, *The EJIL Foreword: The Transformation of International Organizations Law*, 26(1) EUR. J. OF INT'L L. 1, 10 (2015).

[119] *See* Martti Koskenniemi, *The Fate of Public International Law: Between Technique and Politics*, 70 (1) MOD. L. REV. 1, 4 (2007); Martti Koskenniemi, *The Politics of International Law – 20 Years Later*, 20(1) EUR. J. OF INTE'L L. 7, 9-12 (2009).

recognized under international law and explores ways to reconcile normative conflicts when they arise. As such, this narrative abandons the vernacular of imperialism, domination, and resistance and instead embraces the traditional concepts of 'fragmentation' and 'coherence' in international law.[120] In scholarly parlance, fragmentation designates the phenomenon whereby the same conduct by an international law actor is simultaneously regulated by a plurality of specialized bodies of rules (such as trade law, human rights law, environmental law, law of the sea, and so forth), enforced and promoted by sectoral courts and institutions with discrete mandates and limited spheres of jurisdiction.[121] Some see fragmentation as a natural by-product of the growing density and complexity of the international legal order. At the same time, many fear that the emergence of specialized and autonomous rules, legal institutions and areas of legal practice could threaten the coherence and harmonious development of public international law.[122] Referring to fragmentation as a 'traditional' concept may sound unorthodox as the preoccupations stemming from this phenomenon are relatively recent. Yet, this issue has occupied such vast swathes of scholarly reflection that it has come to constitute a field of study in and of itself.

For those who decry the perils of fragmentation, the relationship between pharmaceutical patents and access to medicines is a good case in point. In fact, the set of international rules on IP protection discussed in the previous section may occasionally clash with other overlapping sets of specialized rules. Most notably, access to affordable drugs is regulated as part of the human right to health protected under a number of regional and universal treaties. The early roots of this right can be traced back to the Universal Declaration of Human Rights of 1948, which stipulates, albeit in non-binding terms, that everyone has "the right to a standard of living adequate for the health and well-being of himself and his family, including … medical care".[123] Building on this premise numerous global and regional treaties as well as many domestic constitutions progressively recognized

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[120] *See, e.g.*, Klaus D. Beiter, *Establishing Conformity Between TRIPS and Human Rights: Hierarchy in International Law, Human Rights Obligations of the WTO and Extraterritorial State Obligations Under the International Covenant on Economic, Social and Cultural Rights*, *in* TRIPS PLUS 20: FROM TRADE RULES TO MARKET PRINCIPLES 445, 447 (Hanns Ullrich et al. eds., 2016).

[121] *See, e.g.*, Thomas Buergenthal, *Proliferation of International Courts and Tribunals: Is It Good or Bad?*, 14(2) LEIDEN J. OF INT'L L. 267, 272 (2001); Jansen Calamita, *Countermeasures and Jurisdiction: Between Effectiveness and Fragmentation*, 42(2) GEO. J. INT'L L. 233 (2010); Brooks E. Allen & Tommaso Soave, *Jurisdictional Overlap in WTO Dispute Settlement and Investment Arbitration*, 30(1) ARB. INT'L 1, 6 (2014).

[122] *See, e.g.*, Buergenthal, *supra* note 121, at 272; Calamita, *supra* note 121, at 237-39.

[123] Universal Declaration of Human Rights, G.A. Res 217 (III) A art. 25, U.N. Doc. A/RES/217(III)(Dec. 10, 1948)

healthcare as a fundamental human entitlement.[124] At the international level the most accomplished effort was the adoption the UN International Covenant on Economic, Social and Cultural Rights (ICESCR)[125], Article 12 of which recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", including the "prevention, treatment and control of epidemic, endemic, occupational and other diseases".[126] Like other international treaties protecting socio-economic rights, the ICESCR was inspired by socialist ideals born in the years of the industrial revolution.[127] As such, it was designed to garner the support of communist and Third-World countries (occasional allies in the international arena) while it encountered some skepticism from Western liberal democracies (traditionally more focused on civil and political rights).[128] In order to attract ratifications, the rights enshrined in the Covenant, including the right to health, were drafted in rather vague and programmatic terms. In particular, pursuant to Article 2 of the ICESCR, a member state is not required to ensure the immediate and unconditional fulfillment of such rights[129] but rather to "take steps, (...) to the maximum of its available resources, with a view to achieving progressively the[ir] full realization (...) by all appropriate means, including particularly the adoption of legislative measures".[130]

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[124] *See, e.g.*, Constitution of the World Health Organization, preambular recital 2, 14 U.N.T.S. 185 (July 22, 1946) (stating that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition"). For a comprehensive overview, see Holger P. Hestermeyer, *Access to Medication as a Human Right*, 8 MAX PLANCK Y.B. U.N. L.101 (2004).

[125] United Nations International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. No. 16, U.N. Doc. A/6316,at 49 (Dec. 16, 1966) [hereinafter ICESCR].

[126] *Id.* art. 12.

[127] Hestermeyer, *supra* note 124, at 109.

[128] Concerning the debate on the ideological roots of the different categories of human rights, see, for example, Marc Bossuyt, *La Distinction Entre les Droits Civils et Politiques et les Droits Économiques, Sociaux et Culturels*, 8(4) REVUE DES DROITS DE L'HOMME 780 (1975); Michael Bothe, *Les Concepts Fondamentaux du Droit à la Sante: Le Point de Vue Juridique*, *in* LE DROIT A LA SANTE EN TANT QUE DROIT DE L'HOMME 14, 16-17 (René-Jean Dupuy ed., 1978); Asbjørn Eide & Allan Rosas, *Economic, Social and Cultural Rights: A Universal Challenge*, *in* ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A TEXTBOOK 3 (Asbjørn Eide, Catarina Krause & Allan Rosas eds., 2d ed. 2001); Hestermeyer, *supra* note 124, at 109; Helfer, *supra* note 37, at 317.

[129] In this regard, see Hestermeyer, *supra* note 124, at 132.

[130] ICESCR, *supra* note 125, art. 2.1.

Unlike the WTO agreements, the ICESCR lacks robust adjudicatory and enforcement mechanisms.[131] Yet, over time, the Committee on Economic, Social and Cultural Rights (ESCR Committee), a group of experts tasked with reviewing state compliance with the Covenant, has issued a series of 'general comments' to interpret, clarify and, occasionally, expand the scope of the protected rights.[132] Among other things, the Committee has developed the doctrine of "core obligations" for each protected right, i.e., minimum essential levels that ICESCR member states are required to fulfill irrespective of any limitations on the resources available.[133] In 2001, the Committee held that member states' duties to respect, protect, and fulfill the right to health hinge in no negligible part on the economic availability of medicines[134] and identified the provision of essential drugs, as defined by the WHO, as one of the "core obligations" in respect of such a right.[135] Further, the Committee took the view that states may violate Article 12 of the ICESCR through the adoption of "any retrogressive measures incompatible with the core obligations under the right to health", including "the formal repeal or suspension" of the necessary legislation or "the adoption of legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health".[136] Similarly, a breach may stem from a state's failure to "take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements".[137] Through its quasi-judicial activity, the ESCR Committee has acquired considerable influence as a "focal point" in the normative development in the field of socioeconomic human rights.[138] As a result, the current position of the UN human rights bodies is that

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[131] However, the Optional Protocol to the ICESCR, which entered into force in 2013, has established a complaint and inquiry system for social, economic and cultural rights, similar to the preexisting system in place for civil and political rights. *See generally* OPTIONAL PROTOCOL TO THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A COMMENTARY (Malcolm Langford et al. eds., 2016).

[132] *See, e.g.*, Alicia E. Yamin, *Not Just a Tragedy: Access to Medication as a Right under International Law*, 21(2) B.U. INT'L L.J. 325 (2003); Helfer, *supra* note 52, at 988; Helfer, *supra* note 37, at 330.

[133] U.N. Committee on Economic, Social & Cultural Rights, *General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)*, ¶ 10, U.N. Doc. E/1991/23 (Dec. 14, 1990) [hereinafter General Comment No. 3]. Helfer, *supra* note 37, at 318.

[134] General Comment No. 3, *supra* note 133, ¶¶ 33-38. *See also* Helfer, *supra* note 37, at 327.

[135] U.N. Committee on Economic, Social & Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)*, ¶ 43(d), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

[136] *Id.* ¶ 48.

[137] *Id.* ¶ 50.

[138] Helfer, *supra* note 37, at 318.

access to affordable medicines constitutes "one of the fundamental elements" of the right to health.[139]

For the numerous states that are parties to both IP and human rights treaties[140] it might at times prove difficult to comply with both sets of obligations simultaneously. As discussed in the previous section, the adoption of the stringent patent protection standards mandated by TRIPS and TRIPS-plus provisions is likely to result in higher retail prices of drugs in domestic markets. Therefore, according to some, implementing such patent standards may create a situation less favourable to the enjoyment of the right to health than there would be otherwise, thereby constituting a "retrogressive measure" inconsistent with Articles 2 and12 of the ICESCR.[141]

Faced with the threat of a normative conflict between specialized bodies of rules, many international law scholars adopted a defensive posture and invoked a return to the unity and coherence of the international legal order. While the proposed solutions vary considerably, they all share one essential element: namely, the belief that the solution to legal fragmentation is to be found *in international law itself*. In particular, according to this narrative, adjudicators can resort to several interpretive techniques to reduce or eliminate the tensions between conflicting obligations. The most exhaustive exploration of such techniques is contained in the International Law Commission's 2006 Report on the Fragmentation of International Law (ILC Report)[142], which had been issued with the intent to address the "postmodern

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[139] U.N.H.R.C. Res. 32/15, ¶¶ 1-2, U.N. Doc. A/HRC/RES/32/15 (July 18, 2016).

[140] As of 2012, 121 state parties to the ICESCR were also members of the WTO, thus being subject to the disciplines of the TRIPS Agreement. PING XIONG, AN INTERNATIONAL LAW PERSPECTIVE ON THE PROTECTION OF HUMAN RIGHTS IN THE TRIPS AGREEMENT 255 (2012).

[141] *See, e.g.*, Cullet, *supra* note 13, at 157; Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The 'Fourth Wave' of Corporate Human Rights Scrutiny*, 25(2) HUM. RTS. Q. 425, 438-39 (2003); Yamin, *supra* note 132, at 129; Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, the Right to Health and AIDS Drugs*, 6 UCLA J. INT'L L.& FOREIGN AFF. 463, 466 (2002); Hestermeyer, *supra* note 124, at 136. *See also* Audrey R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5 J. OF INT'L ECON. L. 861 (2002); Caroline Dommen, *Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies*, 24 HUM. RTS. Q. 1 (2002); Eleanor M. Fox, *Globalization and Human Rights: Looking out for the Welfare of the Worst Off*, 35 N.Y.U. J. INT'L L.& POL. 201 (2002); Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23(3) BERKELEY J. INT'L L. 524 (2005).

[142] Rep. of the Study Grp. of the Int'l Law Comm'n, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, 58th Sess., May 1-June 9, July 3-Aug. 11, 2006, UN Doc. A/CN.4/L.682 (Apr. 13, 2006) [hereinafter ILC Report 2006].

anxieties" of international law professionals.[143] The Report did not seek to dictate a definitive solution to the issue of fragmentation. Rather, it provided resources for courts to use on a case-by-case basis thereby according "considerable flexibility in how to approach each repair job".[144]

One major avenue for harmonization explored in the ILC Report is the so-called principle of systemic interpretation which stems from a "strong presumption against normative conflict" in international law.[145] According to this principle a treaty must be interpreted taking into account the normative environment that surrounds it, that is, with due cognizance of other rules and principles that might have bearing upon the case. This approach finds confirmation in Article 31.3(c) of the Vienna Convention on the Law of Treaties (VCLT) which stipulates that the interpreter must take into account, together with the context of the treaty, "[a]ny relevant rules of international law applicable in the relations between the parties".[146] The underlying assumption is that states will make efforts to the maximum extent possible to reconcile their various international obligations and to comply with all of them.[147]As applied to the case of IP and human rights obligations, it has been suggested, for instance, that TRIPS and TRIPS-plus signatories adopt non IP-related measures to ensure access to affordable healthcare. Such measures include the imposition of price caps on essential drugs, government purchase and subsequent distribution of patented pharmaceuticals at affordable costs, the adoption of public health insurance plans, etc.[148] Some authors have expressed confidence in the potential of the principle of systemic integration thanks to which courts will be able to "interpret away" most conflicts.[149]

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[143] The expression is borrowed from Martti Koskenniemi & Päivi Leino, *Fragmentation of International Law? Postmodern Anxieties*, 15(3) LEIDEN J. OF INT.L L. 553 (2002).

[144] Sean D. Murphy, *Deconstructing Fragmentation: Koskenniemi's 2006 ILC Project*, 27(2) TEMP. INT'L & COMP. L.J. 293, 297 (2013).

[145] ILC Report 2006, *supra* note 142, ¶ 37. In turn, this presumption rests on the International Court of Justice's statement that a treaty must be interpreted "as producing and intended to produce effects in accordance with existing law and not in violation of it". Case Concerning the Right of Passage over Indian Territory (Port. v. India), Preliminary Objection, 1957 I.C.J. 125, at 142 (Nov. 26, 1957). *See also* Marko Milanović, *Norm Conflict in International Law: Whither Human Rights?*, 20(1) DUKE J. COMP. & INT'L L. 69, 73 (2009).

[146] Vienna Convention on the Law of Treaties art. 31.3(c), May 23, 1969, 1155 U.N.T.S. 331.

[147] *See, e.g.*, Cullet, *supra* note 13, at 157; Helfer, *supra* note 52, at 997; Pauwelyn, *supra* note 89, at 375.

[148] *See, e.g.*, Joseph, *supra* note 141, at 439; Ley, *supra* note 21, at132; Hestermeyer, *supra* note 124, at 136; Mercurio, *supra* note 75, at 236.

[149] Joost Pauwelyn, *The Role of Public International Law in the WTO: How Far Can We Go?*, 95(3) AM. J. INT'L L. 535, 550 (2001). *See generally* Gerrit Betlem & André Nollkaemper,

Yet, one may think of situations where a state *cannot* simultaneously comply with its TRIPS and TRIPS-plus obligations on the one hand and its obligations under human rights law on the other. For example, LDCs suffering from severe budget constraints may not be able to adopt adequate corrective measures to soften the impact of pharmaceutical patents on access to affordable drugs for the poor.[150] In such situations "genuine" normative conflicts may arise[151] that do not lend themselves to simple harmonization. What to do, then? Once again, international law provides a wide array of interpretive techniques such as the principles of *lex posterior*[152] and *lex specialis*[153]for disentangling the puzzle. According to authors such as Joost Pauwelyn, the rigorous and principled application of those techniques would allow the interpreter (whether a national tribunal, a WTO panel, a human rights court, or the International Court of Justice (ICJ)) to achieve legal coherence by applying the prevailing rule and 'disapplying' all others.[154] Other scholars have taken a more nuanced position. Instead of focusing on the application/disapplication dichotomy, they have called on courts to *balance* human rights and trade concerns on a case-by-case basis.[155]

Giving Effect to Public International Law Before Domestic Courts: A Comparative Analysis of the Practice of Consistent Interpretation, 14(3) EUR. J. OF INT'L L. 569 (2003).

[150] *See* Hestermeyer, *supra* note 124, at 136.

[151] ILC Report 2006, *supra* note 142, ¶ 42. For the purposes of this article, "normative conflict" is defined in the narrow sense, i.e., as the situation in which "a party to the two treaties cannot simultaneously comply with its obligations under the two treaties". Wilfred Jenks, *The Conflict of Law-Making Treaties*, 30 BRIT. Y.B. INT'L L. 401, 426 (1953). In recent years some have challenged this definition as being too restrictive, and have argued that a conflict of norms may also exist between a 'permissive' rule that expressly allows a certain conduct and a 'prohibitive' rule that expressly forbids it. *See, e.g.*, Pauwelyn, *supra* note 149, at 551; Erich Vranes, *The Definition of "Norm Conflict" in International Law and Legal Theory*, 17(2) EUR. J. OF INT'L L. 395 (2006). The ILC itself has adopted "a wide notion of conflict as a situation where two rules or principles suggest different ways of dealing with a problem". ILC Report 2006, *supra* note 142, ¶ 25.

[152] *See* ILC Report 2006, *supra* note 142, ¶¶ 223-323. *See also* Pauwelyn, *supra* note 149, at 545; JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW 327-436 (2003).

[153] *See* ILC Report 2006, *supra* note 142, ¶¶ 46-222. *See also* PAUWELYN, *supra* note 152, pp. 327-436.

[154] Pauwelyn, *supra* note 149, at 542, 566, 573.

[155] *See, e.g.*, Mads Andenas & Stefan Zleptnig, *Proportionality: WTO Law: In Comparative Perspective*, 42(3) TEX. INT'L L.J. 371, 377-79 (2007). For a comprehensive analysis of the balancing posture in domestic and international adjudication, see Alec Stone Sweet & Jud Mathews, *Proportionality Balancing and Global Constitutionalism*, 47 COLUM. J. TRANSNAT'L L. 72 (2008).

This focus on the role of adjudicators betrays a common reflex in much of international legal scholarship which tends to perceive the interpretation and application of legal rules as the "functional equivalent of truth, helping to curb power".[156] Indeed, the proliferation of specialised legal regimes and adjudicative mechanisms has been accompanied by an explosion of treatises devoted to the VCLT, dissecting the interpretive devices contained therein and suggesting ways in which courts may ensure an acceptable level of consistency in deriving meaning from legal texts. Legal interpretation has become, so to speak, a scientific exercise whereby the 'true', 'objective' meaning of the law can be "excavated" from the relevant legal texts.[157] Arguably, this enthusiasm goes beyond even the aims of the ILC Report which expressly acknowledges that the relationship between specialized regime rules "cannot be justifiably attained by what is merely an elucidation of the process of legal reasoning".[158]

Such a technical approach to fragmentation[159] may appear attractive as it allows the tackling of most issues within the formal confines of the international legal orderwith minimal disturbance to its current operation. At most, should it be found that the system has lacunae, lawmakers and courts may develop more satisfying conflict rules so as to provide new ways to solve conflicts.[160] Specifically in the context of the relationship between pharmaceutical patents and access to medicines multiple authors have observed that several TRIPS-plus provisions leave intact, and explicitly refer to, the general principles and flexibilities enshrined in the TRIPS Agreement. This may enable a reading of such provisions in a manner that is supportive of domestic healthcare policy space. In order to do so, it has been said, one may invoke the preamble to the TRIPS Agreement which stipulates, among other things, that the treaty is intended to promote "developmental and technological objectives"[161] and to prevent IP protection from itself becoming a "barrier to legitimate trade".[162] Alternatively, one may refer to the objectives and

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[156] Jan Klabbers, *Virtuous Interpretation*, *in* TREATY INTERPRETATION AND THE VIENNA CONVENTION ON THE LAW OF TREATIES: 30 YEARS ON 15, 20 (Olufemi Elias, Malgosia Fitzmaurice & Panos Merkouris eds., 2010) (referring to David W. Kennedy, *The Turn to Interpretation*, 58(1) S. CAL. L. REV. 251, 265 (1985)).

[157] Klabbers, *supra* note 156, at 23. *See also* IAN JOHNSTONE, THE POWER OF DELIBERATION: INTERNATIONAL LAW, POLITICS AND ORGANIZATIONS 35 (2011); Ingo Venzke, *The Role of International Courts as Interpreters and Developers of the Law: Working Out the Jurisgenerative Practice of Interpretation*, 34(1) LOY. L.A. INT'L & COMP. L. REV. 99, 100 (2011).

[158] ILC Report 2006, *supra* note 142, ¶ 484.

[159] Ralf Michaels & Joost Pauwelyn, *Conflict of Norms or Conflict of Laws? Different Techniques in the Fragmentation of Public International Law*, 22(3) DUKE J. COMP. & INT'L L.349, 350 (2012).

[160] William W. Burke-White, *International Legal Pluralism*, 25(2) MICH. J. INT'L L.963, 971 (2004).

[161] TRIPS Agreement, *supra* note 2, preambular recital 5.

[162] TRIPS Agreement, *supra* note 2, preambular recital 1.

principles embodied in Articles 7 and 8 of the Agreement which include the "dissemination of technology ... in a manner conducive to social and economic welfare"[163] and the protection of "public health".[164] Finally, and obviously, the Doha Declaration and the subsequent WTO instruments may add weight to a pro-health interpretation of TRIPS-plus provisions.[165] According to some, these and other elements of the TRIPS Agreement reveal that the treaty does not only lay down minimum thresholds but indeed imposesmaximum ceilings on IP protection.[166] However, from a human rights perspective, this focus on formal textualism may become a shackle when (and as it often happens) TRIPS-plus provisions do *not* refer to the principles and flexibilities contained in the TRIPS Agreement. Absent any explicit textual connection between the two sets of norms, an interpreter following the standard conflict-resolution rules would likely conclude that TRIPS-plus provisions "prevail either as the later in time ... or as the more specific provision".[167] Such an outcome would clearly prove unsatisfactory to those advocating for policy space that may adequately resolve the problem of access to medicines.

Faced with this conundrum, several scholars have pushed their views one step further and have asserted the legal primacy of human rights over trade and economic concerns. For instance, they have argued that the provision of basic

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[163] TRIPS Agreement, *supra* note 2, art. 7.

[164] TRIPS Agreement, *supra* note 2, art. 8.1.

[165] For a comperenesive overview of these interpretive elements, see Carlos M. Correa, *supra* note 108, at 10-14.

[166] *See, e.g.*, Henning Grosse Ruse-Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1(1) TRADE L.& DEV. 56 (2009); Annette Kur & Henning Grosse Ruse-Khan, *Enough is Enough: The Notion of Binding Ceilings in International Intellectual Property Protection*, *in* INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM: PROPOSALS FOR REFORM OF TRIPS 359 (Annette Kur & Marianne Levin eds., 2011); MAX PLANCK INST. FOR INTELLECTUAL PROP. & COMPETITION LAW, PRINCIPLES FOR INTELLECTUAL PROPERTY PROVISIONS IN BILATERAL AND REGIONAL AGREEMENTS, part 1, § II, *available at* http://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/06_principles_for_intellectua/principles_for_ip_provisions_in_bilateral_and_regional_agreements_final1.pdf (last visited May 17, 2017). Some of these proposals have been endorsed by certain WTO member states in committee discussions. For instance, in 2010 China requested the TRIPS Council to establish a general principle that TRIPS-plus provisions shall not breach the TRIPS Agreement and that the enforcement of IP rights shall not create distortive effects on legitimate international trade. Similarly, India maintained that Article 1 of the TRIPS Agreement should be interpreted as prohibiting WTO member states from implementing more extensive IP protection if that entails contravening the Agreement. *See* TRIPS Council, Minutes of the Meeting Held on 8-9 June 2010, ¶¶ 248-73, IP/C/M/63 (Oct. 4, 2010). S*ee also* Yu, *supra* note 44, at 330-31.

[167] Pauwelyn, *supra* note 89, at 384.

healthcare "*must be prioritized* over the provision of intermediate public goods such as legal regimes that facilitate innovation through the grant of [IP] rights"; after all, "basic education and adequate health status are prerequisites to any capacity-building for the technological progress".[168] Similarly, since "human rights necessarily *claim priority* over all other considerations", governments must "marshal all the resources needed for their satisfaction, up to the point that this would infringe upon the satisfaction of other human rights".[169] Therefore, according to these authors, should a conflict arise between an IP and a human rights obligation, "it is likely that human rights would generally take precedence".[170] Some UN human rights bodies have adopted a similar stance and have reminded states of "the primacy of human rights obligations over economic policies and agreements".[171] Far from reflecting mere ethical preferences these attempts pursue a specific agenda: namely, to overcome the traditional absence of a formal hierarchy of norms in international law–whereby "neither trade nor non-trade related principles can be considered, from a legal point of view, as unconditionally preeminent"[172]–in favour of a progressive verticalization of the system. The arguments deployed in support of this view are well known and need not be restated in full. Some see the signs of a burgeoning hierarchy between international legal rules in the emergence of peremptory norms, *orga omnes* obligations, and non-derogable rights (i.e., human rights that cannot be subject to any limitations even in the presence of countervailing public interests).[173] Others have put the emphasis on the role of Article 103 of the UN Charter which stipulates that in the event of a conflict between an obligation under the Charter and one under any other international agreement, the former shall prevail.[174] Yet others have re-imagined the system of international courts and tribunals as a pyramid with the ICJ at the

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[168] Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV.2813, 2828 (2006) (emphasis added).

[169] Robert E. Robertson, *Measuring State Compliance with the Obligation to Devote 'Maximum Available Resources' to Realizing Economic, Social and Cultural Rights*, 16 HUM. RTS. Q. 693, 700 (1994) (emphasis added).

[170] Cullet, *supra* note 13, at 159.

[171] U.N. Sub-Comm. on the Promotion and Prot. of Human Rights Res. 21 (LIII), ¶ 3, 53rd Sess., July 13-Aug. 17, 2001, U.N. Doc. E/CN.4/Sub.2/RES/2001/21 (Aug. 16, 2001) [hereinafter U.N. Sub-Commission Resolution].

[172] Mads Andenas & Stefan Zleptnig, *supra* note 155, at 377.

[173] *See, e.g.*, Teraya Koji, *Emerging Hierarchy in International Human Rights and Beyond: From the Perspective of Non-Derogable Rights*, 12(5) EUR. J. OF INT'L L. 917, 939 (2001); Andreas L. Paulus, *Jus Cogens in a Time of Hegemony and Fragmentation: An Attempt at a Re-Appraisal*, 74(3)NORDIC J. OF INT'L L. 297, 332 (2005); Beiter, *supra* note 120, at 470-74.

[174] *See, e.g.*, Beiter, *supra* note 120, at 474-75; Dinah Shelton, *International Law and "Relative Normativity"*, *in* INTERNATIONAL LAW 137, 157 (Malcolm Evans ed., 4th ed. 2014).

top[175], or have at least predicted the emergence of a "global community of courts"[176] engaged in an "integrated and interconnected system".[177]

Despite variations, all these efforts share a belief in an "international constitutional order" consisting of "an international community, an international value system and rudimentary structures for its enforcement".[178] It should come as no surprise that human rights and fundamental freedoms constitute the moral cornerstone of this imagined edifice. For instance, on the pages of this journal, Enrst-Ulrich Petersmann once wrote that the "constitutional foundation" of international law in the 21st century requires "justifying, interpreting, designing and developing [international economic law] in conformity with human rights and 'principles of justice'".[179] In a similar vein, the proponents of a global community of courts see the progressive affirmation of a "global jurisprudence"[180] centred around a set of "common fundamental values" such as "checks and balances", "due process"[181], and "the spread and enhanced protection of universal human rights".[182]

A thorough discussion of these constitutional ambitions and the odds of their success would far exceed the scope of this article. What they bring to the table is a

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[175] *See, e.g.*, Christian Leathley, *An Institutional Hierarchy to Combat the Fragmentation of International Law: Has the ILC Missed an Opportunity?*, 40(1) N.Y.U. J. INT'L L.& POL. 259, 271 (2007). *See also* Karin Oellers-Frahm, *Multiplication of International Courts and Tribunals and Conflicting Jurisdiction: Problems and Possible Solutions*, 5 MAX PLANCK Y.B. U.N. L. 67 (2001).

[176] *See, e.g.*, Anne-Marie Slaughter, *A Global Community of Courts*, 44(1) HARV. INT'L L.J.191 (2003); ANNE-MARIE SLAUGHTER, A NEW WORLD ORDER (2005).

[177] Burke-White, *supra* note 161, at 971.

[178] Erika de Wet, *The International Constitutional Order*, 55(1) INT'L & COMP. L. Q. 51, 51 (2006). *See also* Erika de Wet, *The Emergence of International and Regional Value Systems as a Manifestation of the Emerging International Constitutional Order*, 19(3) LEIDEN J. OF INT'L L. 611 (2006); JAN KLABBERS, ANNE PETERS & GEIR ULFSTEIN, THE CONSTITUTIONALIZATION OF INTERNATIONAL LAW 77 (2009). The possibility to consider some widely recognized international treaties, especially the UN Charter, as some sort of 'world constitution' has been long discussed in international legal literature. *See generally* Thomas M. Franck, *Is the United Nations a Constitution?*, in VERHANDELN FÜR DEN FRIEDEN: NEGOTIATING FOR PEACE: LIBER AMICORUM TONO EITEL 95 (Jochen Abr. Frowein et al. eds., 2003).

[179] Ernst-Ulrich Petersmann, *Human Rights and International Economic Law*, 4(2) TRADE L. & DEV. 283, 284 (2012). *See also* Ernst-Ulrich Petersmann, *Time for a United Nations "Global Compact" for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration*, 13(3) EUR. J. OF INT'L L. 621 (2002); ERNST-ULRICH PETERSMANN, INTERNATIONAL ECONOMIC LAW IN THE 21ST CENTURY: CONSTITUTIONAL PLURALISM AND MULTILEVEL GOVERNANCE OF INTERDEPENDENT PUBLIC GOODS (2012).

[180] Slaughter, *A Global Community of Courts*, *supra* note 176, at 202.

[181] Slaughter, *A Global Community of Courts*, *supra* note 176, at 217.

[182] Anne-Marie Slaughter, *A Typology of Transjudicial Communication*, 29 U. RICH. L. REV. 99, 134 (1994).

desire for clarity which could be achieved by establishing an order of priorities amid the myriad artifacts of international law. As Jan Klabbers put it, "constitutionalism carries the promise that there is some system in all the madness, some way in which the whole system hangs together and is not merely the aggregate of isolated and often contradictory movements". Seen through a constitutional lens, conflicts such as that between IP and public health might appear manageable thanks to the existence of "some values which simply cannot be affected".[183]

However, for all their high-minded cosmopolitanism these ambitions do not seem to reflect the current dynamics of global lawmaking in the fields of IP and socio-economic human rights.[184] First, the two legal regimes *both* assert their 'absolute' nature and struggle for primacy over each other. Consider, for instance, the conflict rules contained in the relevant treaties. On the one hand, Article 4 of the ICESCR provides that states may subject the enjoyment of the protected rights to limitations "*only in so far as this may be compatible with the nature of these rights* and solely for the purpose of promoting the general welfare in a democratic society".[185] On the other hand, Article 8 of the TRIPS Agreement, mentioned above, stipulates that states may "adopt measures necessary to protect public health … 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*".[186] More broadly, the IP and the human rights regimes share a similar, symmetrical structure. The sweeping provisions of the TRIPS Agreement and their oversight by an international dispute settlement system have "brought the international economic system much closer to the conceptual foundations and assumptions of the human rights framework".[187] Even the enactment of the global IP ratchet through the mechanisms of minimum baselines and MFN mirrors the "accumulation only" principle of the human rights doctrine

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[183] Jan Klabbers, *Constitutionalism Lite*, 1(1) INT'L ORG. L. REV. 31, 49 (2004).

[184] For the sake of brevity, I will not address one important critique levied against 'universal constitutionalism', namely the allegations of disguised Western imperialism. For a discussion of these arguments, see, for example, STEPHEN GILL, POWER AND RESISTANCE IN THE NEW WORLD ORDER (2003).

[185] Emphasis added.

[186] Emphasis added. For discussion, see Ley, *supra* note 21, at104; Cullet, *supra* note 13, at 145; Bartelt, *supra* note 65, at 286; Olivier Cattaneo, *The Interpretation of the TRIPS Agreement*, 3(5) J. OF WORLD INTELL. PROP. 627, 644 (2000).

[187] Ruth L. Okediji, *The Limits of Development Strategies at the Intersection of Intellectual Property and Human Rights*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 355, 358 (Daniel J. Gervais ed., 1st ed. 2007).

according to which a successive agreement or national legislation can only grant individuals *stronger* protection.[188]

While the Doha Declaration and the WTO decision and amendment that followed helped bridge the gap between the two regimes by recognizing health-related objectives in the disciplines of the TRIPS Agreement, the spread of TRIPS-plus provisions pushed in the opposite direction and accentuated centripetal tendencies. Indeed, the return to IP bilateralism has marked a shift from a normative center to an intentionally incoherent maze of peripheral agreements inspired by highly particular logics[189] which "are impossible to monitor at the global level and therefore to respond to in a systematic way."[190] Against this backdrop, any comprehensive effort to establish a legally certain order of priority between IP and human rights concerns, or at least to bring them under within the scope of the same regime, seems doomed to fail. The more flexible doctrine of a judicial balancing of IP and human rights principles does not hold great promise either. Absent a 'meta-court' capable of weighing such competing commands in an impartial way, the balancing exercise is necessarily left to regime-specific institutions (such as the ESCR Committee, WTO panels, or FTA-based tribunals) that do not share the same "normative roots"[191] and may be prone to privilege the preoccupations and assumptions of their respective regimes.

Ultimately, a strict adherence to the formal techniques and categories of international law essentially downplays the role of fragmentation to the fruits of hazard or a mere 'technical glitch' of the system. In doing so it obscures the socio-political struggles brewing beneath the smooth surface of the law. In the previous Part, I have offered an account of such struggles in terms of a diplomatic standoff between developed and developing countries. But one may think about other fault lines which I explore in the next and final Part: in particular, one may construe the conflict between IP and public health as part of a confrontation between different international organisations and their underlying constituencies.[192]As will be seen, there is much to be said about the role of institutions with their embedded policy preferences, their specialized knowledge, and their technical vocabularies, in the level of fragmentation or cohesion of the global order. Neglecting their role is, at best, a truncated attempt at making sense of the deep essence of normative

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[188] *See* Kur & Ruse-Khan, *supra* note 169, at 363; Pauwelyn, *supra* note 149 149, at 551.
[189] *See* Correa, *supra* note 42, at81; Mercurio, *supra* note 75, at 222; Collins-Chase, *supra* note 87, at 780; BRAITHWAITE & DRAHOS, *supra* note 89, at 564-77; Helfer, *supra* note 4, at42.
[190] Liberman & Mitchell, *supra* note 109, at 158.
[191] Ruth L. Okediji, *supra* note 190, at 367.
[192]*See* Allyn L. Taylor, *Governing the Globalization of Public Health*, 32(3) J.L. MED. & ETHICS 500, 502-03 (2004). *See also* Helfer, *supra* note 4, at 18-27.

conflicts and at worst a deliberate strategy to close off the debate rather than opening it.[193]

IV. THE INSTITUTIONAL NARRATIVE: SPECIALIZED EXPERTISE, TUNNEL VISIONS, AND THE QUEST FOR INSTITUTIONAL HEGEMONY

The third and final narrative describes the conflict between pharmaceutical patents and access to medicines as part of a contest for supremacy between the international institutions involved (such as the WTO, the UN human rights bodies, the WHO, and the WIPO) and the socio-political systems they represent. One may think of this approach as a response to the analytical blind spots of the accounts explored thus far. On the one hand it maintains the focus on the transnational dimensions of the conflict, thus avoiding the state-centric outlook inherent in the North vs. South dichotomy.[194] On the other hand it digs deeper into the intricacies of normative conflicts than a simple technical analysis would, thereby resisting the pitfalls of legal reductionism and the obsession for formal coherence.[195]

The institutional narrative draws inspiration from neither traditional international relations nor formalistic legal thought but rather from social theory. The core idea, expressed most notably by Gunther Teubner and Andreas Fischer-Lescano, is that the fragmentation of international law and the normative conflicts it generates are nothing but an epiphenomenon of deep contradictions between colliding sectors of a global society which crystallize into "institutionalized rationalities".[196] Instead of promoting social uniformity, globalization has accelerated the emergence of autonomous social systems in fields such as economics, science, culture, technology, and politics.[197] Each such sectoral system is operationally closed, meaning that its structures, priorities, and preoccupations "condense and are confirmed as a result of the system's own operations"[198], with little cognizance of other systems or of the broader social environment. Social and professional practices within each system are patterned over time and space[199], in the sense that they respond to specific assumptions and expectations and tend to reproduce them

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[193] Andrew Lang, *Rethinking Trade and Human Rights*, 15(2) TUL. J. INT'L & COMP. L. 335, 380 (2007).
[194] *See supra* notes 105-106 and accompanying text.
[195] *See supra* notes 184-193 and accompanying text.
[196] Gunther Teubner & Andreas Fischer-Lescano, *Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law*, 25(4) MICH. J. INT'L L. 999, 1004 (2004).
[197] *Id.* At 1006.
[198] Niklas Luhmann, *Operational Closure and Structural Coupling: The Differentiation of the Legal System*, 13 CARDOZO L. REV. 1419, 1424 (1992).
[199] Emanuel Adler & Vincent Pouliot, *International Practices*, 3(1) INT'L THEORY 1, 6 (2011).

through communication and transmission of knowledge. Progressively, each system develops its own logics and priorities but also a distinct professional style, a technical vocabulary, and foundational mythologies that all contribute to differentiating it from its environment.

As anticipated in Part 1, these autonomous systems do not operate solely within national borders but rather create transnational networks to better pursue their agendas and maximize their rationalities at the global level. One tangible result of this activity is the establishment of sectoral international organisations with partial mandates and limited spheres of jurisdiction.[200] For instance, it is often said that the creation of both the WTO and its predecessor, the General Agreement on Tariffs and Trade (GATT), rested on the belief, typical of *mercatores* from industrialized countries, that the liberalization of international commerce is a crucial component of welfare and prosperity.[201] In a similar vein, the progressive institutionalization of socio-economic human rights is regarded as a means to protect the world's poor and marginalized–with a socialist flavor to it.[202]

Rather than pursuing an abstract, universal idea of the common good, each institutional regime deploys a specific discourse and a distinct "repertoire of categories and concepts with which to make sense of the world"[203] while at the same time promoting certain types of interests and suppressing others.[204] Thus, as Martti Koskenniemi put it, what once was the international world has been sliced into myriad "institutional projects", i.e., special regimes of knowledge and expertise catering to specific audiences, pursuing particular interests, and suffering from epistemic and structural biases.[205] Given the irreducible pluralism of the global (dis)order, attempts at achieving harmony and coherence through mainstream international law have dim chances of success. In a world where most issues stand

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[200] It has been argued that limiting the analysis to formal international organisations tells only part of the story, in that transnational networks often engage in normative production entirely divorced from the formalities of state and inter-state lawmaking. *See, e.g.*, Teubner & Fischer-Lescano, *supra* note 196, at 1009-12; Robert Wai, *The Interlegality of Transnational Private Law*, 71(3) L. & CONTEMP. PROBS. 107 (2008); Brian Z. Tamanaha, *Understanding Legal Pluralism: Past to Present, Local to Global*, 30(3) SYDNEY L. REV. 375 (2008).

[201] For a critical discussion of this political premise, see Anne Orford, *Beyond Harmonization: Trade, Human Rights and the Economy of Sacrifice*, 18 LEIDEN J. OF INT'L L.179 (2005).

[202] *See supra* notes 127-128 and accompanying text.

[203] Lang, *supra* note 193, at 357-58.

[204] Boaventura de Sousa Santos, *Law: A Map of Misreading: Towards a Postmodern Conception of Law*, 14(3) J. OF L.& SOC'Y 279, 297 (1987). *See also* ILC Report 2006, *supra* note 142, ¶ 488.

[205] Koskenniemi, *The Politics of International Law*, *supra* note 119, at 9. *See also* MARTTI KOSKENNIEMI, FROM APOLOGY TO UTOPIA: THE STRUCTURE OF INTERNATIONAL LEGAL ARGUMENT FROM APOLOGY TO UTOPIA – REISSUE WITH NEW EPILOGUE 600-15 (2006).

at the crossroads of multiple regimes different institutions will inevitably compete to attract them under their sphere of operation and will "collide with their respective institutionally ingrained problem definitions and their respective strategies for solution".[206] Seen through this lens fragmentation ceases to be a contingent flaw of the legal system and becomes the vehicle of a struggle for institutional hegemony whereby conflict "is waged on the description and re-description of aspects of the world so as to make them fall under the jurisdiction of particular institutions".[207]

These theoretical premises seem to capture well the processes and interactions that gave rise to the conflict between pharmaceutical patents and access to medicines. For many decades the IP and the health discourses developed and evolved within different social systems with minimal points of contact with one another.[208] Both systems were mostly concerned with consolidating and expanding their respective rationalities through the progressive establishment of dedicated rules, policies, and institutions and devoted little or no attention to what was happening on the other side of the fence.[209] Those involved in public health largely considered economic concerns from the perspective of healthcare and population effects with the objective of "maximising health indicators such as life expectancy"; conversely, those involved in the trade arena considered health concerns as "a potential barrier to trade, with the objective of maximizing economic indicators, such as gross domestic product".[210] This, of course, does not mean that the processes of discursive definition of the respective spheres were internally pacified or homogenous. For instance, the inclusion of IP concerns in the Uruguay Round

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[206] Gunther Teubner & Andreas Fischer-Lescano, *Cannibalizing Epistemes: Will Modern Law Protect Traditional Cultural Expressions?*, *in* INTELLECTUAL PROPERTY AND TRADITIONAL CULTURAL EXPRESSIONS IN A DIGITAL ENVIRONMENT 17, 20 (Christopher Graber & Mira Burri-Nenova eds., 2008).

[207] Koskenniemi, *The Fate of Public International Law*, *supra* note 119, at 7. *See also* Andrew Lang, *Legal Regimes and Professional Knowledges: The Internal Politics of Regime Definition*, *in* REGIME INTERACTION IN INTERNATIONAL LAW: FACING FRAGMENTATION 113, 113 (Margaret A. Young ed., 2012).

[208] Strikingly, however, the protection of the moral and material interests of scientific creators is recognized as a fundamental right under Article 27 of the Universal Declaration of Human Rights and Article 15(1) of the ICESCR. *See* Helfer, *supra* note 52, at 979-82.

[209] Helfer, *supra* note 37, at 320. Joseph Weiler has emphasized the "self-referential and even communitarian ethos" of the trade community resulting, among other things, from the supposed "technical" and "professional" nature of the subject matter and the consequent "media indifference". 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(2) J. WORLD TRADE 191, 194-95 (2001).

[210] Richard D. Smith, Kelley Lee & Nick Drager, *Trade and Health: An Agenda for Action*, 373 THE LANCET 768, 770 (2009) [hereinafter Smith et al.].

agenda raised more than an eyebrow in the trade community (including some developed countries as well). Indeed, the intrinsic logics of IP protection, with their focus on temporary restrictions on public access to the protected goods, seemed at odds with longstanding assumptions about trade liberalization.[211] Similarly, as mentioned in Part 2, the human rights community saw a deep divide between the supporters of civil and political vs. social, economic and cultural rights.[212]

Despite these *internal* conflicts, the expansion of the respective spheres of influence was *externally* unencumbered with little environmental barriers standing in the way. This is how, according to some, IP protection standards have progressively been "elevated from servants [of public welfare] to masters–crucial for their own sake".[213] But at the same time this is also how the human rights movement has sanctified a conception of society based on individual entitlements without pausing to consider the analytical and practical limitations of its doctrine.[214] Absent meaningful cross-fertilization, both spheres showed a preference for one-size-fits-all solutions and did not contemplate the spillover effects of their proposals.

This splendid isolation came to an end in the mid-1990s when the adoption of the TRIPS Agreement marked the sudden expansion of the trade/IP system and its trespassing into the field of the health/human rights system. The WHO, it is said, was the "main victim" of this sudden shift, as it found itself "removed from power and deprived from planning and controlling the world health strategies in favour of the WTO".[215] But other international agencies such as the WIPO and the UN human rights bodies also saw their influence over the definition of IP and public health matters decrease significantly.[216] Seen from this angle, the entry into force of the TRIPS Agreement was less a victory of developed over developing countries than the opening salvo of a turf war between two institutionalized epistemes. More

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[211] *See, e.g.*, Jagdish Bhagwati, *Don't Cry for Cancún*, 83 FOREIGN AFF. 52, 56-57 (Jan./Feb. 2004) (stating that IP protection "is a matter of collecting royalties" and that including it in the WTO "seriously distorted what the organization should accomplish.").

[212] *See supra* notes 130 and 131 and accompanying text.

[213] Sell, *supra* note 68, at 58. *See also* Chon, *supra* note 168, at 2815.

[214] *See* Okediji, *supra* note 190, at 367-72.

[215] ONORI, *supra* note 10, at 28.

[216] The WTO disciplines on IP protection were not meant to supplant the WIPO. Indeed, the TRIPS Agreement speaks to the establishment of "a mutually supportive relationship" between the two institutions, TRIPS Agreement, *supra* note 2, preambular recital 7, which was formalized in 1995 with the adoption of an Agreement Between the World Intellectual Property Organization and the World Trade Organization, Dec. 22, 1995, 35 I.L.M. 754 (1996). Yet, the entry into force of the TRIPS Agreement fundamentally redesigned the role of the WIPO in the IP arena: no longer the enforcer of traditional IP rules, the WIPO has turned into a forum for the elaboration of new IP standards in areas such as the Internet and digital copyright. *See, e.g.,* Helfer, *supra* note 4, at 25-26.

precisely, the issues arising from pharmaceutical patents and access to medicines created a conflict between two "fragmented and operationally closed functional systems", which, in their expansionist fervor, "ma[d]e use of global law in order normatively to secure their own highly refined sphere logics".[217]

At the same time, however, this initial clash established a relationship between the two systems in the form of "mutual observation".[218] Given the absence of a legal hierarchy or a centralized site of collective decision-making neither discourse could prevail unconditionally. However, the two could at least attempt to influence, control, and provoke one another through non-hierarchical, decentralized network interactions.[219] Indeed, the health/ human rights system was quick to respond to the adoption of the TRIPS Agreement. As discussed in Part 2, the ESCR Committee has intensified its practice of issuing general comments and has included access to essential medicines in the list of "core obligations" pertaining to the human right to health.[220] Starting in the early 2000s numerous other UN bodies have issued statements and resolutions urging states to make sure that stronger IP standards do not "negatively impact … international human rights instruments by which they are bound".[221] For instance, the UN Human Rights Council recommended that WTO members use, to the full, the provisions of the TRIPS Agreement that provide flexibility for this purpose.[222] In a more recent report, the UN Secretary General's High-Level Panel on Access to Medicines has voiced similar concerns with regard to TRIPS-plus provisions and stated that agreeing to such provisions without a robust assessment of public health consequences "is

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[217] Teubner &Fischer-Lescano, *supra* note 196, at 1007.

[218] Teubner &Fischer-Lescano, *supra* note 196, at 1018.

[219] Among the numerous works dealing with the impact of network logics upon public governance, see YOCHAI BENKLER, THE WEALTH OF NETWORKS 212-72 (2006); FRANÇOIS OST & MICHEL VAN DE KERCHOVE, DE LA PYRAMIDE AU RÉSEAU? POUR UNE THEORIE DIALECTIQUE DU DROIT 14 (2002).

[220] *See supra* note 135 and accompanying text.

[221] U.N. Sub-Commission Resolution, *supra* note 171, ¶ 5. *See also* U.N. Secretary-General, *Economic, Social and Cultural Rights, Intellectual Property Rights and Human Rights:Rep. of the Secretary-Genral*, U.N. Doc. E/CN.4/Sub.2/2001/12 (June 14, 2001); U.N. High Comm'r for Human Rights, *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Rep. of the High Comm'r*, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001); U.N. Special Rapporteurs on Globalization and Human Rights, *Globalization and its impact on the full enjoyment of human rights*, ¶¶ 19-34, U.N. Doc. E/CN.4/Sub.2/2001/10 (Aug. 2, 2001).

[222] U.N.H.R.C. Res. 24 (XII), ¶ 2, 12th Sess., U.N. Doc. A/HRC/RES/12/24 (Oct. 12, 2009). *See also* U.N.H.R.C. Res. 16/28, 16th Sess., U.N. Doc. A/HRC/RES/16/28 (Apr. 13, 2011); U.N.H.R.C. Res. 23/24, ¶ 5(h), Sess. 23, U.N. Doc. A/HRC/RES/23/14 (June 24, 2013); U.N.H.R.C. Res. 32/15, ¶ 3, Sess. 32, U.N. Doc. A/HRC/RES/32/15 (July 18, 2016).

tantamount to a neglect of state duties to safeguard the right to health".[223] This framing of pharmaceutical patents as a human rights issue "influenced the dynamic of that debate in powerful ways,"[224] in that it added weight to the awareness campaigns led by NGOs and advocacy groups discussed in Part 1.[225]

This transnational backlash against the spiraling of IP protection of pharmaceuticals gained enough momentum to eventually push the WTO members to adopt the Doha Declaration and the subsequent decisions to reaffirm and broaden the scope of TRIPS flexibilities in favour of access to medicines. Seen from this perspective such instruments were not so much a victory of developing countries against the hegemony of their developed counterparts. Rather, they provided the arena in which "the fundamental principles of two global operational spheres, economy and health" could interact and confront each other.[226] Importantly, the external pressures applied to the boundaries of the WTO regime did not impinge upon its prerogatives through the imposition of overriding principles nor did they cause its collapse. Instead, the WTO regime reacted to such pressures by *internally* incorporating public health concerns into its IP framework as a sort of "limitation on its own logic".[227] In a polycentric, non-hierarchical social and institutional world, this form of bringing about piecemeal compatibility through mutual irritation is the best result that the champions of legal and political harmony can hope for.[228] Incidentally, the broadening of the contact surface between the IP and the health spheres also fostered cooperation between the international organisations involved in the conflict. In 2009 for instance, the WHO, the WIPO, and the WTO commenced a trilateral cooperation programme for "strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies".[229]

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[223] *Report of the U.N. Secretary-General's High-Level Panel On Access To Medicines: Promoting Innovation and Access to Health Technologies 25* (Sept. 2016), *available at* http://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf.

[224] *See* Lang, *supra* note 193, at 396.

[225] For a comprehensive account, see Helfer, *supra* note 37, at 325-30.

[226] Teubner & Fischer-Lescano, *supra* note 196, at 1029.

[227] Teubner & Fischer-Lescano, *supra* note 196, at 1030.

[228] *See* Teubner &Fischer-Lescano, *supra* note 206, at 9.

[229] World Health Org., World Intell. Prop. Org. & World Trade Org., *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* 9 (2012), *available at* http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf [hereinafter Trilateral Report].

If these multilateral developments showed the possibility of constructive dialogue and epistemic cross-fertilization between institutionalized rationalities, the proliferation of TRIPS-plus provisions marked yet another morphing of the IP regime-complex and dislocated the modes of inter-systemic interaction. From the perspective of the dominant actors the maze of highly particular regulatory frameworks created through the spread of IP bilateralism constitutes an ideal tool to prevent a systemic solution equivalent or similar to the Doha Declaration.[230] At the same time, this new configuration may foster the emergence of fresh and unexpected solidarities among the oppressed and lead to the consolidation of countervailing claims.[231] One thing is certain: in a TRIPS-plus era the sites of regime interaction, inter-institutional dialogue, domination, and resistance have been dislocated once again. The fault lines of the longstanding struggle between pharmaceutical patents and access to medicines have been reshuffled.

From an institutional and epistemic perspective, the path forward is unclear. On the one hand, the UN human rights bodies, transnational advocacy networks, and numerous scholars are continuing to apply pressure on treaty negotiators for them to internalize healthcare concerns in the texts of new bilateral agreements.[232] In this sense, the post-Doha WTO is no longer the boogeyman of the human rights movement; rather, it has become a platform for the convergence of the IP and health discourses.[233] On the other hand, a number of proposals seek to expand the cognitive horizon of the professionals and experts operating within each relevant governance node–from foreign ministries to international institutions, from NGOs to domestic and international courts and tribunals–in order to promote mutual

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[230] *See supra* notes 189 & 190 and accompanying text.

[231] Consider, for instance, the transnational mobilization that halted the adoption of the Anti-Counterfeiting Trade Agreement (ACTA) by the European Union. The anti-ACTA movement saw an unprecedented alliance between heterogenous and loosely organized social groups, from the Anonymous collective to civil rights activists, from academic centres to private internet users. For discussion, see, for example, Andreas Dür & Gemma Mateo, *Public Opinion and Interest Group Influence: How Citizen Groups Derailed the Anti-Counterfeiting Trade Agreement*, 21(8) J. OF EUR. PUB. POL'Y 1199 (2014); James Losey, *The Anti-Counterfeiting Trade Agreement and European Civil Society: A Case Study on Networked Advocacy*, 4 J. OF INFO. POL'Y 205 (2014).

[232] *See, e.g.*, U.N. DEVELOPMENT PROGRAMME & JOINT U.N. PROGRAMME ON HIV/AIDS, THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH 5 (2012), *available at* http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf (last visited May 18, 2017). *See also* Paul Schiff Berman, *A Pluralist Approach to International Law*, 32 YALE J. INT'L L. 301, 318 (2007); Yu, *supra* note 5, at 10.

[233] Indeed, the post-Doha WTO has called for an evaluation of the potential health effects of TRIPS-plus. Trilateral Report, *supra* note 229, at 190.

observation and enable the exercise of "responsible discretion".[234] One way to do so may be staffing the trade agecneis of key developed countries, such as the Office of the USTR and the European Commission's DG Trade, in a manner more reflective of the broad range of policy areas that may be affected by trade negotiations. Placing officials with diverse backgrounds side-by-side within the same institutional structure may foster dialectical interaction and common engagement.[235] Existing practices in some developing countries may provide useful guidance. For instance, the government of Thailand has established an "intergovernmental committee on Trade in Health and Social Services" composed of representatives from the ministries of public health, commerce, food and agriculture, as well as members of the Private Hospitals' Association and other professional bodies. The committee is tasked with analyzing the impact of trade liberalization on national healthcare services, assisting negotiators in including health-related policies into bilateral and multilateral trade agreements, and coordinating the governmental institutions involved in the process.[236] At the international level, similar efforts are reflected in Resolution 59.26 of the World Health Assembly, the plenary organ of the WHO, which expressly called for greater integration between domestic institutions–such as finance, trade, health, and foreign affairs ministries–to foster the inclusion of health-related principles in trade negotiations.[237]

Whether these proposals will succeed in promoting further communication between the IP and the health systems–and, ultimately, to ease the frictions between the two discourses–remains to be seen. What matters here is that, according to their proponents, the solution to the conflict between pharmaceutical patents and public health resides neither in diplomatic standoffs between developed and developing countries nor in the mechanistic application of existing international legal rules. The best chances of success, if they exist at all, lie with greater inter-professional and inter-institutional communication, the reinforcement of horizontal and heterarchical connections between competing rationalities, and ultimately the ability of the actors concerned to contemplate the moral and political consequences of their action. Crucially, an institutional and epistemic approach

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[234] The expression is borrowed from David W. Kennedy, *Challenging Expert Rule: The Politics of Global Governance*, 27(1) SYDNEY L. REV. 1, 23 (2005).

[235] *See* Smith et al., *supra* note 210, at 771.

[236] *See* Smith et al., *supra* note 210, at 770. *See also* Cha-aim Pachanee & Suwit Wibulpolprasert, *Policy Coherence Between Health-related Trade and Health System Development: Case Study of Thailand*, *in* TRADE AND HEALTH: COMPILATION OF PRESENTATIONS MADE AT THE INTER-REGIONAL WORKSHOP NEW DELHI 113 (2004); David P. Fidler, *Achieving Coherence in Anarchy: Foreign Policy, Trade and Health*, *in* TRADE AND HEALTH: SEEKING A COMMON GROUND (Chantal Blouin et al. eds., 2007).

[237] World Health Assembly Res. 59.26, 59th Sess. (May 27, 2006), *available at* http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R26-en.pdf.

must reject the idea that the preferences ingrained in the competing systems are predetermined, static, and immutable, for that would essentially reduce the competing rationalities to "billiard balls" endlessly clashing with one another.[238] Instead, further research may usefully focus on the "myriad of everyday practices"[239]–the recursive operations, the professional debates, and the processes of reinforcement and contestation–by which certain preferences and implicit assumptions come to be embedded in a given system at a particular moment of its "historical trajectory".[240] Such a micro-level examination would help shed light on the concrete ways in which the politics of regime definition play out in a world of specialized experts, and would enhance our understanding of how projects of convergence and divergence, domination and resistance trickle down through "the capillaries of social and economic life".[241]

V. CONCLUSION

After more than twenty years of heated debates the precise contours of the conflict between pharmaceutical patents and access to medicines remain somewhat elusive. Throughout this article, I have sought to disentangle the maze of scholarly narratives built around this issue. The political, legal, and institutional accounts each reflect a valuable effort to reduce the complexity of the debate and to set out a tentative agenda for action. Yet, precisely because of this complexity, each approach has its blind spots and analytical fallacies and seems inadequate to fully grasp the nuances of the problem. Indeed, it is very likely that my selection of the relevant narratives itself suffers from biases and undue simplifications. For one thing, describing the relationship between pharmaceutical patents and access to medicines in terms of 'conflict' deliberately puts the emphasis on the elements of divergence and clash between these two policy objectives and ignores the many ways in which they may mutually support and strengthen each other. If it is true that "global convergence and divergence … are two sides of the same coin",[242] I chose to look at one side only.

Moreover, my focus on *academic* discussions may sound anodyne at best and cynical at worst. After all, while we fiddle with theory tens of thousands of people are dying every day out of neglected epidemics, and many more remain without access to essential drugs. Yet, there is great practical value in unearthing the hidden

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[238] Bruno Simma & Dirk Pulkowski, *Of Planets and the Universe: Self-Contained Regimes in International Law*, 17(3) EUR. J. OF INT'L L. 483, 484 (2006).
[239] Adler & Pouliot, *supra* note 199, at 2.
[240] Lang, *supra* note 207, at 113.
[241] Kennedy, *supra* note 234, at 3.
[242] Philip G. Cerny, *Competition State*, *in* ROUTLEDGE ENCYCLOPEDIA OF INTERNATIONAL POLITICAL ECONOMY298, 301 (R.J. Barry Jones ed., 2001).

reflexes of scholarly thought. Whether we realize it or not our perception of the deep structures of the global order guides our actions, defines the boundaries of our imagination, and ultimately determines our ability to push for change. Through an exercise in self-reflexivity we may become more aware of our agency in shaping the direction of future debates–knowing that, whatever we do, our blackbird will remain very, very difficult to catch.