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ACTA and Its Complex Politics

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4 Counterfeiting; Enforcement; Intellectual property; International relations; International trade; Politics

Introduction

On October 1, 2011, eight countries—Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the United States—gathered together in a ceremony in Japan to sign the Anti-Counterfeiting Trade Agreement (ACTA).¹ Aiming to set a new and higher benchmark for international intellectual property enforcement, this highly controversial plurilateral agreement was the result of three years and eleven rounds of formal negotiations among developed and like-minded countries. This agreement was finally adopted on April 15, 2011. As of this writing, it is still awaiting ratification and has not yet entered into force.²

Commentators have widely criticised the ACTA negotiation process for its lack of transparency and accountability. By ushering in a new "country club" approach to setting international intellectual property norms, the negotiations have also raised important international concerns. This approach is likely to have serious ramifications for both the structural integrity and continued vitality of the existing international intellectual property regime.

As China and India noted at the June 2010 meeting of the WTO Council for Trade-Related Aspects of Intellectual Property Rights, ACTA has raised a wide variety of systemic problems within the international trading system.³ The agreement's heightened enforcement standards will upset the delicate balance struck in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It will also increase the incoherence and unpredictability of the international regulatory framework.⁴

Similarly, Francis Gurry, the director general of the World Intellectual Property Organization (WIPO), expressed his concern that, in negotiating ACTA, countries have "tak[en] matters into their own hands to seek solutions outside of the multilateral system to the detriment of inclusiveness of the present system".⁵

^{*} An earlier version of this article was presented at the 11th Intellectual Property Scholars Conference at DePaul University College of Law and the 6th European Consortium for Political Research General Conference at the University of Iceland. The author would like to thank Sebastian Haunss and Jeanette Hofmann for their kind invitations and Richard Gruner, Sebastian Haunss, Jeanette Hofmann, Patricia Judd, Ingrid Schneider, Mary Wong and the participants of these events for their valuable comments and suggestions. He is also grateful to Linzey Bachmeier, Erica Liabo and Lindsey Purdy for excellent research and editorial assistance.

¹Office of the United States Trade Representative, "Joint Press Statement of the Anti-Counterfeiting Trade Agreement Negotiating Parties", October 1, 2011, available at http://www.ustr.gov/about-us/press-office/press-releases/2011/october/joint-press-statement-anti-counterfeiting-trade-ag [Accessed November 17, 2011].

² Pursuant to art.40.1, ACTA will "enter into force thirty days after the date of deposit of the sixth instrument of ratification, acceptance, or approval as between those Signatories that have deposited their respective instruments of ratification, acceptance, or approval".

³ Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, October 4, 2010, IP/C/M/63, paras 248–273.

⁴ Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, 2010, paras 253–255.

⁵ Catherine Saez, "ACTA a Sign of Weakness in Multilateral System, WIPO Head Says", *Intellectual Property Watch*, June 30, 2010, available at http://www.ip-watch.org/weblog/2010/06/30/acta-a-sign-of-weakness-in-multilateral-system-wipo-head-says/[Accessed November 17, 2011].

Michael Geist, a law professor at the University of Ottawa, also noted that "some might wonder whether ACTA is ultimately designed to replace WIPO as the primary source of international IP [intellectual property] law and policy making".⁶

ACTA has indeed provided an excellent case study for examining the complex politics and institutional dynamics behind the development of the international intellectual property regime. As with the past two volumes of this journal, Volume 3 will devote its first issue to a topic of great importance to intellectual property scholars. Focusing on the politics of intellectual property, this special issue reminds readers that intellectual property developments are not just about law and economics—the primary foci of the previous two special issues. Intellectual property can also be about politics. Although scholarship on the politics of intellectual property is only emerging in the scholarly literature, policymakers and activists have long recognised the importance of such issues.⁷

As an introduction to this special issue, this article examines the country club approach the ACTA negotiating parties embraced to establish new and higher international intellectual property enforcement standards. It points out that the agreement is flawed not only because it is a country club agreement but also because it is a bad country club agreement. The article then situates ACTA in the context of a recent trend of using bilateral, plurilateral and regional trade and investment agreements to circumvent the multilateral norm-setting process. It contends that this disturbing trend could upset the political dynamics in the current international intellectual property regime. The article concludes with a discussion of the multiple layers of complex politics behind the ACTA negotiations: international, domestic and global. It focuses on developments both within the new intellectual property enforcement club and without.

The ACTA Country Club

At the global level, the major criticisms of ACTA concern the limitation of its membership to developed and like-minded countries, the lack of representation by countries in the developing world and the agreement's potential negative impact on the international intellectual property regime.⁸ To highlight the problematic nature of ACTA, some commentators, such as Daniel Gervais, have described the agreement as a "country club agreement".⁹

Within this country club, members set rules to govern its membership. Article 36 provides details on the ACTA Committee, which is charged with the agreement's administration and management and is granted broad powers to establish ad hoc committees. Article 42 delineates the procedure for amending the agreement. Article 43 further specifies the time the agreement will be open for signature and how countries can accede to it after the expiration of the specified period.

⁶ Michael Geist, "Toward an ACTA Super-Structure: How ACTA May Replace WIPO", March 26, 2010, available at http://www.michaelgeist.ca/content/view/4910/125/ [Accessed November 17, 2011].

⁷ Thus far, there are few book-length studies on the politics of intellectual property: e.g. Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford: Oxford University Press, 2009); Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (New York: New Press, 2003); Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property: Contestation Over the Ownership, Use, and Control of Knowledge and Information* (Cheltenham: Edward Elgar Publishing, 2009); Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (London: Routledge, 2002); Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements* (Cheltenham: Edward Elgar Publishing, 2011); Valbona Muzaka, *The Politics of Intellectual Property Rights and Access to Medicines* (New York: Palgrave Macmillan, 2011); Meir Perez Pugatch, *The International Political Economy of Intellectual Property Rights* (Cheltenham: Edward Elgar Publishing, 2004); Michael P. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property Rights*. Brookings Institution Press, 1998); Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* Cambridge Cambridge University Press, 2003). ⁸ Peter K. Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64 SMU L. Rev. 975.

⁹ e.g. Daniel Gervais, "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights" (2009) 103 Am. J. Int'l L. 549, 555; IQsensato, "The Proposed Anti-Counterfeiting Trade Agreement (ACTA): Global Policy Implications", *In Focus*, June 2, 2008, p.4; Gabriel J. Michael, "ACTA, Fool: Explaining the Irrational Resort to a New Institution", pp.4–7, available at *http://sites.google.com/site/iipenforcement/acta-papers-for-wcl-meeting-june-16-18-2010/* [Accessed November 17, 2011].

Although the country club approach used by the ACTA negotiating parties has garnered considerable attention from policymakers and commentators, the use of clubs to coordinate international regulatory standards is not unprecedented. Developing countries, for instance, have frequently used coalitions to shape their negotiating agenda, articulate more coherent positions and establish a united negotiating front.¹⁰ By using these organisational structures, countries seek to achieve leverage that otherwise would not have existed for each country on its own.

What is interesting and somewhat different this time, however, is the developed countries' aggressive use of club arrangements to enhance their already very powerful bargaining position. In political science, a burgeoning literature has been devoted to examining the use of club standards to set international norms. In All Politics Is Global, for example, Daniel Drezner advances a typology of regulatory coordination.¹¹ Based on the variations between the costs of adjusting national regulatory standards confronting "great powers"¹² and those confronting the rest of the world, he identifies four different types of international regulatory standards: (1) harmonised standards; (2) sham standards; (3) rival standards; and (4) club standards.¹³ Professor Drezner's four-field matrix is highly useful to our analysis of ACTA (see Table 1).¹⁴

Table 1: A Typology of Regulatory Coordination¹⁵

Tuble 1.11 Typology of Regulatory Coordination			
	Low Adjustment Costs (The Rest)	High Adjustment Costs (The Rest)	
Low Adjustment Costs (Great Powers)	Harmonised Standards	Club Standards	
High Adjustment Costs (Great Powers)	Rival Standards	Sham Standards	

According to Professor Drezner, harmonised standards come into existence when adjustment costs are low for both great powers and the rest of the international community. The minimum substantive and enforcement standards in the TRIPS Agreement provide instructive examples. Because harmonised standards are usually the product of political compromises, they tend to be low and are therefore open to future upward adjustment. The TRIPS enforcement provisions, for instance, have been widely criticised by developed countries and their intellectual property industries for being primitive, constrained, inadequate, and ineffective.¹⁶ To some extent, the ACTA negotiations represent the attempt by developed countries to make an upward adjustment to the weak harmonised standards in the TRIPS Agreement.

In contrast to harmonised standards, sham standards are developed when adjustment costs are high for both great powers and the rest of the world. Examples of these standards are those concerning the transfer of technology, abuse of rights and restraints on trade. One could arguably include the standards for the protection of traditional knowledge and cultural expressions, which have yet to become fully developed. As the quality of these standards improves, however, they may find their way to another category.

¹⁴ Michael, "ACTA, Fool", available at http://sites.google.com/site/iipenforcement/acta-papers-for-wcl-meeting-june-16-18-2010/ [Accessed November 17, 2011].
 ¹⁵ This table draw on Dramer. All Boliting Is Global (2008), p. 72.

¹⁶ Peter K. Yu, "TRIPS and Its Achilles' Heel" (2011) 18 J. Intell. Prop. L. 479, 483.

¹⁰ Peter K. Yu, "Access to Medicines, BRICS Alliances, and Collective Action" (2008) 34 Am. J.L. & Med. 345, 370; Peter K. Yu, "Building Intellectual Property Coalitions for Development" in Jeremy de Beer (ed.), Implementing the World Intellectual Property Organization's Development Agenda (Waterloo: Wilfred Laurier University Press, 2009).

Daniel W. Drezner, All Politics Is Global: Explaining International Regulatory Regimes (Princeton: Princeton University Press, 2008), pp.119–148: Heba M. Shams, "Club Multilateralism' and Global Supranationalism: The Case of FATF" in J.B. Attanasio and J.J. Norton (eds), Multilateralism v Unilateralism: Policy Choices in a Global Society (London: British Institute of International and Comparative Law, 2004).

¹² Professor Drezner defines "great powers" as those having "a combination of internal market size and reduced vulnerability to external disruptions". Drezner, All Politics Is Global (2008), p.35. Only the United States and the European Union fit his criteria at the moment. Drezner, All Politics Is Global (2008), p.36.

Drezner, All Politics Is Global (2008), pp.71-85.

This table draws on Drezner, All Politics Is Global (2008), p.72.

When adjustment costs are high for great powers but low for the rest of the international community, negotiations usually result in the creation of rival standards. The textbook example of this type of standard is the provision concerning the protection of geographical indications. While the European Union favours greater protection in this area, the United States insists that the use of certification and collective marks would provide adequate protection to rights holders.¹⁷ The disagreement between these two major trading powers eventually led to a World Trade Organization (WTO) dispute between the United States on the one hand and the European Union and Australia on the other.¹⁸ Such disagreement has also led to the inclusion in US free trade agreements (FTAs) of provisions governing the relationship between geographical indications and trademarks.¹⁹

Finally, when adjustment costs are low for great powers but high for the rest of the world, negotiations tend to result in the development of club standards. As Professor Drezner explains:

"[A] great power concert will generate enough market power to lock in the concert's preferred set of regulatory standards. The combined market size of a great power concert will induce most recalcitrant states into shifting their standards. However, states with severe adjustment costs will still resist, and the Prisoner's Dilemma aspect of enforcement can tempt some governments into noncompliance; under this constellation of interests, the enforcement of standards becomes an issue. The crucial step for coordination to take place is a coalition of the willing among the greater powers."20

Although developing countries and their supportive commentators have widely criticised the arbitrariness and exclusiveness of club standards, those standards have been used in other fields of international law. In 1989, the Group of Seven (G-7) established the Financial Action Task Force in the Paris Summit to combat money laundering (and later terrorist financing).²¹ In the early 1990s, this task force was extended to countries in the Organisation for Economic Cooperation and Development (OECD) as well as to a select group of non-OECD members, such as Hong Kong and Singapore, and to regional organisations, such as the Gulf Cooperation Council.²²

While club standards have not been widely used in the intellectual property arena, one could arguably trace the development of the TRIPS Agreement back to a two-stage process involving these standards. The first stage took place when the United States, the European Communities and Japan banded together to develop "highest common denominator" standards for the protection and enforcement of intellectual property rights.²³ Once these standards had been accepted, the second stage kicked in when these trading powers sought to multilateralise the standards by extending them to other members of the General Agreement on Tariffs and Trade (GATT), and later the WTO.

While many have considered the developed countries' use of club standards undemocratic and inequitable, the standards' more effective outcomes can justify such use.²⁴ As Moisés Naím, the former editor in chief of Foreign Policy, has noted: "[A] smart multilateral approach to illicit trade has to be selective."²⁵

¹⁷ Justin Hughes, "Champagne, Feta, and Bourbon: The Spirited Debate about Geographical Indications" (2006) 58 Hastings L.J. 299, 305–311. ¹⁸ "European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs", Report of the Panel, March 15, 2005, WT/DS174/R; "European Communities-Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs", Report of the Panel, March 15, 2005, WT/DS290/R.

e.g. Central America-Dominican Republic Free Trade Agreement, August 5, 2004, art.15.3.7.

²⁰ Drezner, All Politics Is Global (2008), p.75.

²¹ Shams, "Club Multilateralism' and Global Supranationalism" in Attanasio and Norton (eds), *Multilateralism v Unilateralism* (2004), p.461. ²² Shams, "Club Multilateralism" and Global Supranationalism" in Attanasio and Norton (eds), *Multilateralism v Unilateralism* (2004), p.464.

²³ Daniel J. Gervais, "The TRIPS Agreement and the Doha Round: History and Impact on Economic Development" in Peter K. Yu (ed.), Intellectual Property and Information Wealth: Issues and Practices in the Digital Age (Westport: Praeger Publishers, 2007), Vol.4, p.43. ²⁴ Drezner, All Politics Is Global (2008), p.75; Yu, "Access to Medicines, BRICS Alliances, and Collective Action" (2008) 34 Am. J.L. & Med.

^{245, 384. 25} Moisés Naím, Illicit: How Smugglers, Traffickers, and Copycats Are Hijacking the Global Economy (New York: Anchor Books, 2005), p.255.

Moreover, club standards can help to avoid gridlocked situations where developed and developing countries fail to achieve progress in multilateral negotiations—the notorious stalemate over the revision of the Paris Convention being a good example.²⁶ As Professor Drezner observes:

"Club IGOs, such as the ... G-7 ... or the OECD, use membership criteria to exclude states with different preference orderings and bestow benefits for in-group members as a way to ensure collective action. Compared to universal IGOs, clubs have reduced legitimacy because of their limited membership, though this can be partially compensated through other sources of legitimacy such as a reputation for effectiveness. Clubs also have the advantage of a membership with a more homogenous set of preferences. The smaller number of actors also increases a club's ability to coordinate and enforce policy."²⁷

Finally, it is important to keep in mind the geopolitical reality behind traditional international intellectual property negotiations. Regardless of what forum is ultimately used, countries—especially the weaker ones—rarely participate equally in the development of multilateral standards, due in part to their lack of resources, capacity and bargaining power. Even during the TRIPS negotiations, the discussions were dominated by developed countries and a small group of hardliner developing countries, such as Argentina, Brazil, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia.²⁸ Participation by smaller developing countries remained rather limited.

Thus, when examining ACTA, we need to compare its standards with those achievable under the present conditions of international intellectual property negotiations. We should not focus on an *ideal* arrangement that does not exist. Nevertheless, even if we take the present conditions into account, ACTA, as the next section will show, is still a rather disappointing plurilateral agreement.

A bad country club agreement

In discussing club standards, commentators have widely noted the need to include in the negotiation process those countries that have a significant impact on the issue area. Consider, for example, the standards for international financial regulation established by the G-7 and the OECD. Because all the important players in the field belong to either one of the two organisations, club standards were strategically chosen to enable powerful developed countries to establish high standards without the worry of dilution by marginalised players.

Once these standards have been established, an important goal of the G-7 and the OECD is to expand the club to outside players. As Professor Drezner explains:

"In dealing with nonmembers, a club IGO can encourage the pooling of resources to induce outsiders into agreeing to the core's regulatory regime. Material inducements, such as aid or technical assistance, can encourage peripheral states to accept the imposed standard. Small country leaders that are sympathetic to the core position can also use pressure from an international organization to bypass entrenched domestic interests and other institutional roadblocks. For the most recalcitrant states, a club IGO greatly enhances the utility of multilateral coercion. Once they join, they then have an incentive to pressure other governments into altering their regulatory standards. This dynamic produces a cascade effect in which a club IGO expands to near-universal size."²⁹

²⁹ Drezner, All Politics Is Global (2008), pp.75–76.

²⁶ Peter K. Yu, "A Tale of Two Development Agendas" (2009) 35 Ohio N.U.L. Rev. 465, 508–511.

²⁷ Drezner, All Politics Is Global (2008), pp.67–68.

²⁸ Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (The Hague: Kluwer Law International, 2001), p.19, fn.17.

Over the years, new conditions have arisen, while the geopolitical make-up has changed. At times, clubs have adjusted their membership to accommodate these changing circumstances. For example, in the wake of the recent global economic crisis and in response to the rise of the so-called BRICS countries (Brazil, Russia, China, India and South Africa), developed countries smartly redesigned their norm-setting approach. By initiating discussions in the so-called G-20, which include emerging countries such as Argentina, Brazil, China, India, Indonesia, Mexico, Russia, Saudi Arabia and South Africa, the G-7 countries successfully expanded the "club" in the area of international financial regulation to cover new players that have increasingly significant impacts on the field.³⁰ Such an expansion is unsurprising. After all, it is hard to imagine how the club could effectively respond to the sovereign debt crisis without the cooperation of powerful emerging economies.

To some extent, the transformation of the GATT to the WTO reveals a similar need to adapt to changing circumstances. In the beginning, the GATT, like the G-7,

"was perceived of as a 'rich nations' club,' focusing on the needs of the developed nations, though some of the more prominent developing nations such as Brazil and India played a role."³¹

Most other developing countries received merely special and differential treatment. Today, however, the WTO includes 153 members, including three different groups of countries: developed, developing and least developed. Although the TRIPS Agreement includes transitional periods for both developing and least developed countries, the latter two groups of countries still take on key obligations on the protection and enforcement of intellectual property rights, similar to those assumed by developed countries.

If one is willing to go back even further in time, one will notice a similar dilemma confronting members of the Berne Union, the well-known international copyright club. Following the decolonisation movement after the Second World War and the arrival of a large number of newly emerging countries in the 1960s, developed countries in the Union had to decide whether they wanted to maintain their high Euro-centric copyright standards or offer significant concessions to entice developing countries to join the Union.³² In the end, the Berne Union members drafted the Stockholm Protocol Regarding Developing Countries, which was eventually adopted as an optional appendix to the Paris Act of the Berne Convention.³³

Notwithstanding the insights and lessons provided by these helpful precedents, ACTA fails to follow the formula for success for developing club standards. While the agreement was ambitiously designed to include high standards, similar to those international financial regulatory standards established by the G-7 or the OECD, the agreement does not include all the important players in the field of intellectual property enforcement. Notably excluded from the ACTA negotiations were Brazil, China and Russia, key players whose cooperation is badly needed to reduce cross-border piracy and counterfeiting.

Even worse, unlike the other club standards discussed in this article, ACTA has a very limited ability to induce other countries to join the club after it has been formed. In all fairness, the agreement was originally conceived as one involving two consecutive stages. As stated in an early discussion paper:

³⁰ Professor Drezner questions whether the G-20 is actually a club in light of the fact that it "meets only once a year, and has no secretariat or working groups". Drezner, *All Politics Is Global* (2008), p.146. Whether the G-20 is a club, however, is not important for our purposes. The most important insight is that the G-7 has been expanded in response to changing circumstances.

³¹ John H. Barton, Judith L. Goldstein, Timothy E. Josling and Richard H. Steinberg, *The Evolution of the Trade Regime: Politics, Law, and Economics of the GATT and the WTO* (Princeton: Princeton University Press, 2006), p.153.

³² Sam Ricketson and Jane C. Ginsburg, International Copyright and Neighbouring Rights: The Berne Convention and Beyond, 2nd edn (Oxford: Oxford University Press, 2006), p.885.

³³ Yu, "A Tale of Two Development Agendas" (2009) 35 Ohio N.U.L. Rev. 465, 471-484.

"In the initial phase, it is important to join a number of interested trading partners in setting out the parameters for an enforcement system that will function effectively in today's environment. As a second phase, other countries will have the option to join the agreement as part of an emerging consensus in favor of a strong IPR enforcement standard."³⁴

Nevertheless, it remains unclear which countries this second phase will target. A leaked US government cable, for example, has revealed that Japan and the United States initially disagreed over whether "Italy and Canada ... should be approached in the second group".³⁵ The US position that these countries should be included eventually prevailed.

In contrast to Canada and Italy, major developing countries, such as Brazil, China and India, were excluded from the very beginning of the negotiations, even though Japan emphasised early on that "the intent of the agreement is to address the IPR [intellectual property right] problems of third-nations such as China, Russia and Brazil, not to negotiate the different interests of like-minded countries".³⁶ From the standpoint of intellectual property protection, there is no doubt that these emerging countries are important to the successful operation of the international enforcement regime.

Consider China for example. The country's piracy and counterfeiting problems have provided a major impetus for the development of new international intellectual property enforcement norms. China was also involved in a recent WTO dispute with the United States over the protection and enforcement of intellectual property rights.³⁷ Given the negotiating parties' conscious and determined choice to exclude China from the negotiations, it is unclear how they can now entice China to join this new exclusive club.

It is worth comparing ACTA with the WTO, an international trade club China joined a decade ago. In the 1990s and early 2000s, China was very eager to join this club and accede to the TRIPS Agreement even though it had to revamp a large array of laws and regulations and agree to high WTO-plus standards.³⁸ As Samuel Kim observed at that time, China was willing "to gain WTO entry at almost any price".³⁹ The country's approach was understandable. To many Chinese, the WTO membership helped secure China's rightful place in the international community. Even if the economic costs were high, the symbolic value of the WTO accession and an improved standing in the international community would more than compensate for the short-term costs.

ACTA, however, is not the WTO. It does not give China a rightful place in the international community. Nor does the club membership seem to have any bearing on China's dignitary interests. While it could be unattractive for China to be branded as a pirating nation, ACTA is not limited to countries that have always respected intellectual property rights. The chequered pasts of Japan and the United States, the two major proponents of this agreement, speak for themselves. More importantly, at the time of the negotiations, Canada, South Korea and a few EU member states were on the United States Trade Representative's Special 301 Watch List.⁴⁰ Even under the standards set unilaterally by the United States, the ACTA country club is a den filled with known pirates.

Even worse, the illegitimate nature of ACTA heavily undercuts the argument's moral basis. To begin with, the negotiating parties' insistence on completing the agreement through a shady backdoor deal has greatly undermined the legitimacy of the adopted standards. As Kimberlee Weatherall reminds us:

³⁴ "Discussion Paper on a Possible Anti-Counterfeiting Trade Agreement", p.1, available at http://ipjustice.org/wp/wp-content/uploads/ACTA -discussion-paper-1.pdf [Accessed November 17, 2011].
³⁵ Michael Geist, "Japan Wanted Canada Out of Initial ACTA Group", February 25, 2011, available at http://www.michaelgeist.ca/content/view

³³ Michael Geist, "Japan Wanted Canada Out of Initial ACTA Group", February 25, 2011, available at http://www.michaelgeist.ca/content/view /5656/125/ [Accessed November 17, 2011].

³⁶ Geist, ³Japan Wanted Canada Out of Initial ACTA Group", February 25, 2011, available at http://www.michaelgeist.ca/content/view/5656/125/ [Accessed November 17, 2011].

 ³⁷ "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights", Report of the Panel, January 26, 2009, WT/DS362/R.
 ³⁸ Peter K. Yu, "The Middle Kingdom and the Intellectual Property World" (2011) 13 Or. Rev. Int'l L. (forthcoming).

³⁹Samuel S. Kim, "China in World Politics" in Barry Buzan and Rosemary Foot (eds), *Does China Matter? A Reassessment: Essays in Memory of Gerald Segal* (London: Routledge, 2004), p.49.

⁴⁰ Office of the United States Trade Representative, "Fact Sheet: Anti-Counterfeiting Trade Agreement (ACTA)", August 4, 2008, p.3, available at http://www.ustr.gov/sites/default/files/uploads/factsheets/2008/asset_upload_file760_15084.pdf [Accessed November 17, 2011].

"The secrecy [in the ACTA negotiations] is ... operating, once again, to bring intellectual property law into disrepute. To the extent that at some later point governments and IP owners will ask people to accept the outcomes as 'fair' and ones that should be adopted, it will be more difficult to convince them when the agreement has the appearance of a secret deal done with minimal public input."41

Indeed, the adopted standards tell us more about like-mindedness than moral wrongs. At the international level, there remains no philosophical or normative consensus on the enforcement of intellectual property rights.42

Like China, Brazil and India have shown no urgent desire to join ACTA. Nor have they found the club membership advantageous. As Anand Sharma, the Indian commerce and industry minister, emphatically declared: "If [the TRIPS Agreement] has to be revisited in any stage in future, it will be only in multilateral forum-the WTO, it cannot be done outside".43 Likewise, Brazilian officials refused to "recognize the legitimacy of the treaty".44

The reactions of Brazil, China and India are indeed no surprise. In today's age, these increasingly powerful developing countries are unlikely to buy into a system they did not help to shape. With their now considerable increase in economic power and geopolitical leverage, those days where a system could be created in developed countries and then shoved down their throats are long gone. If "enhanced international cooperation and more effective international enforcement" are some of ACTA's key goals, as stated in the preamble, it is simply ill-advised to ignore these crucial partners in the negotiations. It is also short-sighted to consider countries unclubable by virtue of their lack of like-mindedness.

Compared with Brazil, China and India, small middle-income or low-income countries do not have the same bargaining leverage vis-à-vis the United States or the European Union. Nevertheless, it is still unclear how effective ACTA actually will be in inducing these countries to adopt higher intellectual property enforcement standards. After all, those countries that are overly eager to obtain trade benefits from the United States or the European Union are likely to agree to ACTA-like standards in non-multilateral agreements regardless of whether ACTA is adopted. By contrast, those countries that remain on the fence and that have enough power to resist pressure from the United States or the European Union are unlikely to find ACTA attractive. The reason is simple: ACTA offers neither carrots nor sticks.

The two "carrots" developed countries typically dangle in front of developing countries to entice them to offer stronger protection and enforcement of intellectual property rights are (1) increased foreign direct investment (FDI) and (2) accelerated transfer of technology. After more than 15 years of disillusionment in the TRIPS Agreement, many developing countries have begun to realise that the oft-presented carrots may be illusory.

To date, economists have widely questioned the link between intellectual property protection and FDL⁴⁵ As Keith Maskus noted, if stronger intellectual property protection always led to more FDI:

"recent FDI flows to developing economies would have gone largely to sub-Saharan Africa and Eastern Europe ... [rather than] China, Brazil, and other high-growth, large-market developing economies with weak IPRs".46

⁴¹ Kimberlee Weatherall, "The Anti-Counterfeiting Trade Agreement: What's It All about?", available at http://works.bepress.com/cgi/viewcontent .cgi?article=1017&context=kimweatherall [Accessed November 17, 2011]. ⁴² Peter K. Yu, "Enforcement, Enforcement, What Enforcement?" (2011) 52 IDEA (forthcoming).

^{43 &}quot;India Will Not Accept Any Intellectual Property Talks Outside WTO: Anand Sharma", Economic Times, April 9, 2011, available at http://articles .economictimes.indiatimes.com/2011-04-09/news/29400634_1_intellectual-property-trips-agreement-anand-sharm [Accessed November 17, 2011]. ⁴Michael Geist, "Brazil, India Speak Out against ACTA", October 12, 2010, available at http://www.michaelgeist.ca/content/view/5362/196/ [Accessed November 17, 2011].

Peter K. Yu, "Intellectual Property, Economic Development, and the China Puzzle" in Daniel J. Gervais (ed.), Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS Plus Era (Oxford: Oxford University Press, 2007), pp.176–180.

Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer" (1998) 9 Duke J. Comp. & Int'l L. 109, 129.

More importantly, developed countries have a longstanding history of failing to respect technology transfer obligations in international intellectual property agreements—art.66.2 of the TRIPS Agreement, for example. Although the Doha Ministerial Decision of November 14, 2001 reaffirmed the mandatory nature of these obligations, developed countries, thus far, have yet to take these obligations seriously. Thus, whether in the form of FDI or technology transfer, ACTA does not offer any attractive carrot.

The "stick" developed countries typically use in response to low intellectual property standards involve unilateral sanctions. However, in *United States—Sections 301–310 of the Trade Act of 1974*, the WTO dispute settlement panel made it clear that members are not allowed to use sanctions to resolve TRIPS-related disputes until they have exhausted all the remedies permissible under WTO rules.⁴⁷ Because ACTA is designed as a TRIPS-plus agreement and covers rights falling largely within the scope of the TRIPS Agreement,⁴⁸ unilateral sanctions are unlikely to constitute a permissible stick.

To be certain, the United States could still rely on the monitoring mechanism in s.301 of the Trade Act of 1974 to "punish" those countries that have failed to abide by ACTA standards. After all, the US Trade Act of 2002 stipulates that the United States Trade Representative can take s.301 actions against countries that have failed to provide "adequate and effective protection of intellectual property rights *notwithstanding the fact that [they] may be in compliance with the specific obligations of the [TRIPS] Agreement*".⁴⁹ Nevertheless, without the teeth provided by unilateral sanctions, the s.301 process is at best a shaming device.⁵⁰ As annoying as this device may be to developing countries, the process's ability to induce developing countries to join ACTA or adopt its standards is significantly constrained.

In sum, by leaving out the key parties needed for cooperation and by providing neither carrots nor sticks to induce non-members to subsequently join the agreement, ACTA has failed dismally even under its own theoretical model. ACTA is flawed not only because it is a country club agreement but also because it is a bad country club agreement. Given this weakness, and its many well-documented negative side-effects,⁵¹ one cannot help but wonder why countries negotiated this agreement in the first place.

The non-multilateral era

Although it is bad enough that ACTA fails under its own theoretical model, the use of the country club approach to international norm-setting has raised additional concerns. For example, commentators have expressed considerable fears that, by circumventing the multilateral process, ACTA will undermine the stability of the international trading system. The resulting instability is particularly disturbing considering the large amount of time, energy, resources and efforts developed countries have expended to create the TRIPS Agreement and present international intellectual property enforcement regime. The ACTA negotiating parties' insensitive push for tougher enforcement standards regardless of a country's local conditions has also alienated many trading partners.⁵² Such alienation is likely to make it more difficult for the international community to undertake future multilateral discussions.

Nevertheless, non-multilateralism has some benefits. For example, it can help achieve outcomes that otherwise cannot be achieved under a multilateral setting.⁵³ It can also help key parties to develop a preliminary common position that can be easily extended to other less important parties in the future.⁵⁴ In

⁴⁷ "United States—Sections 301–310 of the Trade Act of 1974", Report of the Panel, December 22, 1999, WT/DS152/R.

⁴⁸ Article 5(h) of ACTA specifically provides: "[I]intellectual property refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement".

^{49 19} U.S.C. § 2411(d)(3)(B)(i)(II) (2006) (emphasis added).

⁵⁰ Peter K. Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 970.

⁵¹ Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64 SMU L. Rev. 975.

⁵² Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64 SMU L. Rev. 975, 1078.

⁵³ Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 967–968.

⁵⁴ Jeffrey J. Schott, "Free Trade Agreements: Boon or Bane of the World Trading System" in Jeffrey J. Schott (ed.), Free Trade Agreements: US Strategies and Priorities (Washington: Institute for International Economics, 2004), p.13; Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 963–964.

fact, the negotiations of many key international agreements began with mini-negotiations among a small group of key players before the negotiations were finally extended to other members of the international community—the TRIPS Agreement being a very good example.

Thus, the question concerning ACTA is not so much about whether the agreement is a significant departure from the usual multilateral path, but whether the agreement's non-multilateral approach can eventually help consolidate the countries' positions through the multilateral process.⁵⁵ As the previous section has shown, the answer to this question is mostly negative. By ignoring major developing countries and key players in the intellectual property enforcement area, ACTA is unlikely to facilitate the development of practical compromises that can be multilateralised in future negotiations.

More importantly, when ACTA is juxtaposed with the many recent bilateral, plurilateral and regional trade and investment agreements, it makes salient a recent and highly disturbing trend of using non-multilateral arrangements to circumvent the multilateral norm-setting process. Indeed, if ACTA represents the future of international norm-setting, non-multilateralism will not be the passing phase many policymakers and commentators expect—a short, inevitable transitional period before the development of a new multilateral arrangement, such as TRIPS II. Instead, the world will likely go through a long period of non-multilateralism, thereby generating interesting political dynamics that commentators have not yet studied in depth.⁵⁶

Such a development is consistent with the commentators' repeat reminders that the TRIPS Agreement should not be seen as the endpoint in the development of the international intellectual property regime. As Susan Sell observes: "The TRIPS agreement is hardly the end of the story. In many ways, it is just the beginning."⁵⁷ Likewise, Carolyn Deere Birkbeck writes:

"After a decade of tense North-South debates, TRIPS emerged a contested agreement. It was quickly apparent that far from a final deal, TRIPS was rather the starting point for further negotiations..."

In an article examining the development of bilateral trade and investment agreements established by the United States since the turn of the millennium, Ruth Okediji traces the agreements back to those bilateral agreements the country has signed since its founding period. As she explains:

"The so-called new bilateralism is actually more consistent with historical uses of the foreign relations/treaty power of the United States, as well as the general framework of international law, in its dealings with developing countries since the independence era. Consequently, it is probably the TRIPS Agreement that is the aberration in international intellectual property law, and not the recent spates of bilateral and regional agreements."⁵⁹

Based on Professor Okediji's insightful observation, the TRIPS Agreement should therefore not be considered as the endpoint of the international intellectual property regime. Nor is ACTA a drastic deviation from the traditional path of regime development. Instead, both agreements merely represent the ups and downs of such development.

To complicate matters further, countries have used different approaches to establish their interstate relationships outside the multilateral process. While the United States and the European Union have actively introduced free trade and economic partnership agreements,⁶⁰ emerging countries such as China

⁵⁵ Cho Sungjoon, "A Bridge Too Far: The Fall of the Fifth WTO Ministerial Conference in Cancun and the Future of Trade Constitution" (2004) 7 J. Int'l Econ. L. 219, 238; Guy de Jonquières, "Comment" in Schott (ed.), *Free Trade Agreements* (2004), p.32; Ruth L. Okediji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection" (2004) 1 U. Ottawa L. & Tech. J. 125, 143; Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 972.

⁵⁶ Peter K. Yu, "Intellectual Property and Human Rights in the Nonmultilateral Era" (2012) 64 Fla. L. Rev. (forthcoming).

⁵⁷ Sell, *Private Power, Public Law* (2003), p.121.

⁵⁸ Deere, *The Implementation Game* (2009), p.304.

⁵⁹ Okcdiji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection" (2004) 1 U. Ottawa L. & Tech. J. 125, 130. ⁶⁰ Schott (ed.), *Free Trade Agreements* (2004).

and India have been busy negotiating their own forms of non-multilateral agreements.⁶¹ As I have noted elsewhere, the agreements negotiated by China have very different goals and emphases from their US and EU counterparts. The approaches used to negotiate those agreements are also quite different.⁶²

If these differences continue—or, worse, escalate—the international intellectual property regime will become even more fragmented. Such fragmentation, most certainly, will result in what Jagdish Bhagwati and other commentators have described as the "spaghetti bowl", the "noodle bowl" or the "curry bowl".⁶³ Although commentators have widely studied the growing fragmentation of the international regulatory regime, it remains unclear whether such growing complexity would benefit developed or developing countries.

On the one hand, greater complexity will allow weaker countries to better protect their interests by mobilising in favourable fora, developing the needed political and diplomatic groundwork and establishing new "counter-regime norms" that help restore the balance of the international intellectual property system.⁶⁴ The existence of multiple fora will also help promote "norm competition across different fora as well as … inter-agency competition and collaboration".⁶⁵

On the other hand, a proliferation of fora will benefit more powerful countries by raising the transaction costs for policy negotiation and co-ordination, thereby helping these countries to retain the status quo.⁶⁶ The higher costs, coupled with the increased incoherence and complexities in the international intellectual property regime, are particularly damaging to developing countries, which often lack resources, expertise, leadership, negotiation sophistication and bargaining power.

More disturbingly, if significant differences exist between the terms found in the non-multilateral agreements established by developed countries and those established by emerging countries, the agreements may eventually precipitate what I have described as the "battle of the FTAs".⁶⁷ As countries continue to dispute over what norms they should obey, the conflicting norms in non-multilateral agreements will create complications that will eventually undermine the existing international intellectual property regime.

In fact, as Kimberlee Weatherall points out insightfully, ACTA tells us as much about the disagreement between the negotiating parties as it does about what higher standards these countries wanted to adopt.⁶⁸ Among the conflicts revealed by the ACTA negotiations are the protection of geographical indications and the criminal enforcement of patent rights. These two disagreements have troubled the negotiations so much that the negotiators eventually had to strike a compromise by adopting a much lighter version (the so-called "ACTA Lite") than what was originally advanced by the treaty's proponents. In the wake of such drastically reduced protection, some commentators have wondered whether the final text would be so unattractive that some key negotiating parties would simply walk away from the treaty. To date, the European Union and Switzerland, two of the treaty's major proponents, have not yet signed on to the agreement.

⁶⁶ Eyal Benvenisti and George W. Downs, "The Empire's New Clothes: Political Economy and the Fragmentation of International Law" (2007) 60 Stan. L. Rev. 595; Yu, "A Tale of Two Development Agendas" (2009) 35 Ohio N.U.L. Rev. 465, 556.

⁶⁸ Kimberlee Weatherall, "ACTA as a New Kind of International IP Lawmaking" (2011) 26 Am. U. Int'l L. Rev. 839, 841–842.

⁶¹ Wang Jiangyu, "The Role of China and India in Asian Regionalism" in Muthucumaraswamy Sornarajah and Wang Jiangyu (eds), *China, India and the International Economic Order* (Cambridge: Cambridge University Press, 2010), pp.356–358; Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953.

⁶² Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 986-1018.

⁶³ See, e.g. Richard Baldwin, *Managing the Noodle Bowl: The Fragility of East Asian Regionalism* (London: Centre for Economic Policy Research, 2006); Jagdish Bhagwati, "US Trade Policy: The Infatuation with Free Trade Areas" in Jagdish Bhagwati and Anne O. Krueger (eds), *The Dangerous Drift to Preferential Trade Agreements* (Washington: AEI Press, 1995), pp.2–3; Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 978.

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 &</sup>lt;sup>64</sup> Laurence R. Helfer, "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29
 Yale J. Int'l L. 1; Donald J. Puchala and Raymond F. Hopkins, "*International Regimes*: Lessons from Inductive Analysis" in Stephen D. Krasner (ed.), International Regimes (Ithaca: Cornell University Press, 1983), p.66.

⁶⁵ P. Bernt Hugenholtz and Ruth L. Okediji, *Conceiving an International Instrument on Limitations and Exceptions to Copyright: Final Report* (New York: Open Society Institute, 2008), p.41.

⁶⁷ Yu, "Sinic Trade Agreements" (2011) 44 U.C. Davis L. Rev. 953, 1018–1027.

Equally salient from the ACTA negotiations is the disagreement between developed countries and major developing countries. Among the issues they continue to disagree about are access to essential medicines, software and information technology; the protection of traditional knowledge and cultural expressions; enforcement in the digital environment; special and differential treatment; obligations concerning transfer of technology, abuse of rights and restraints on trade; and the need to allow for alternative forms of innovation and modalities for protection. If one is willing to include such new issues as global climate change, the list can be extended even further.

Finally, the establishment of ACTA and the ongoing negotiation of the Trans-Pacific Partnership Agreement and other non-multilateral agreements have raised important questions about the future development of South-South agreements—or what I have described earlier as IPC4D (intellectual property coalitions for development).⁶⁹ Discussions have already taken place among the fast-growing developing countries, in the form of IBSA trilateral cooperation (including India, Brazil and South Africa) and the BRICS summit (featuring Brazil, Russia, India, China and South Africa).

In a recent WIPO Development Agenda meeting, some developing countries specifically demanded the development of a project focusing on South-South collaboration.⁷⁰ Although such demands were reasonable in light of the developing countries' common plight, the proposal met with vehement opposition from developed countries. While the latter had a valid argument that events organised by a multilateral organisation like WIPO should not be limited to selected members, the position they took bordered on hypocrisy. After all, developed countries opposed the development of South-South collaboration at the same time when they were moving full steam ahead toward the completion of ACTA, a clearly North-North collaborative effort.

Indeed, without the complex questions raised by the mission of a multilateral organisation, one could logically argue that, by establishing ACTA, developed countries are estopped from complaining about similar efforts undertaken by developing countries. As Professor Gervais has recently warned us, the change initiated by ACTA is likely to be "irreversible".⁷¹ Nevertheless, it remains to be seen whether developing countries can take full advantage of the precedent set by developed countries to establish a better and more sustainable "club" for countries with like-minded pro-development approaches.

In sum, ACTA is problematic not only as a standalone agreement. It is also problematic because it is emblematic of the disturbing trend by both developed and less developed countries to push for non-multilateral arrangements that reflect their preferred norms, values and development models. If this non-multilateral movement continues, ACTA will not be the only club deviating from the traditional multilateral path. Other clubs will most certainly emerge from both the North and the South, further fragmenting the existing international intellectual property regime.

Multiple layers of complex politics

Commentators have widely blamed the establishment of ACTA on the lack of progress in enforcement discussions at both the WTO and WIPO.⁷² While this observation is somewhat correct, it oversimplifies the complex politics behind the formation of the new ACTA country club. In fact, the internal club politics are quite complex. So are the politics concerning the protesters outside the club. This section discusses in turn three different types of politics implicated by ACTA: international, domestic and global.

 ⁶⁹ Yu, "Building Intellectual Property Coalitions for Development" in de Beer (ed.), *Implementing the World Intellectual Property Organization's Development Agenda* (2009).
 ⁷⁰ Catherine Saez, "WIPO Committee on Development Agenda Suspended, Discussions Bogged Down", *Intellectual Property Watch*, May 7, 2011,

[&]quot;Catherine Saez, "WIPO Committee on Development Agenda Suspended, Discussions Bogged Down", Intellectual Property Watch, May 7, 2011, available at http://www.ip-watch.org/weblog/2011/05/07/wipo-committee-on-development-agenda-suspended-discussions-bogged-down/ [Accessed November 17, 2011]

November 17, 2011]. ⁷¹ Remarks of Daniel J. Gervais, Professor of Law, Vanderbilt University Law School, at the "Economic Partnership Agreements of the EU: A Step Ahead in International IP Law?" Workshop in Frauenchiemsee, Germany, June 27, 2011.

⁷² Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64 SMU L. Rev. 975, 988–998.

The first type of politics implicated by the agreement is obviously international. To date, the divide in the international intellectual property debate is not as simple as one between the North and the South. Indeed, it is increasingly common to find developed countries standing side by side with emerging or fast-growing developing countries. An excellent illustration concerns the reluctance to publish the negotiating text of ACTA. The first draft text was not released until after the eighth round of negotiations in Wellington.⁷³ Although commentators generally criticised the United States for preventing this important text from being publicly released, one has to appreciate the greater political complexity behind the decision not to release the negotiating draft.

As a leaked document has shown, the major holdouts before the Wellington Round were the United States, some members of the European Union (Belgium, Denmark, Germany and Portugal), Singapore and South Korea.⁷⁴ Although the United States has been widely faulted for the non-transparent approach used in negotiating ACTA, due in part to its geopolitical and economic strengths, this country was unlikely to suffer the most politically if the negotiating draft were released. In fact, negotiators from Singapore and South Korea could have been more concerned about the release than their counterparts in the United States.⁷⁵ After all, those governments were already under heavy criticism domestically for negotiating the arguably one-sided FTAs with the United States. If the draft ACTA text were released early on, the timing of such release could not have been worse for those governments.

To be certain, the United States was also very concerned about the release. However, its concern was mainly due to the fear that such disclosure would result in parties walking away from the negotiation table (in addition to further complications in the ongoing negotiations of other trade and investment agreements).⁷⁶ As far as the agreement's impact on domestic politics is concerned, however, the US negotiators are likely to have much less to worry about than their counterparts in emerging countries.

After all, the American public is unlikely to be heavily disturbed by the treaty terms, most of which are similar or identical to those found in existing FTAs signed by the United States. The administration's clear reluctance to introduce laws to implement the new agreement has also alleviated some of the reported concerns. If such reluctance is not sufficient, it remains unclear how much attention the public has actually paid to the ACTA negotiations. Other than internet websites, blogs and specialised newspapers, such as *Inside US Trade*, the media have provided very limited coverage of the negotiations. It is also unclear how many Americans are actually sympathetic to the positions held by developing countries and their supporters in the developed world.

The second type of politics implicated by ACTA is domestic. As Robert Putnam has convincingly shown, the negotiation of international treaties involves a two-level game: one domestic and one international.⁷⁷ The TRIPS Agreement provides an excellent illustration of how negotiators need to take into consideration not only the preferences at the international level but also those at the domestic level.⁷⁸ The same can be said for ACTA, where negotiators have to be sensitive to domestic demands and concerns.

As far as domestic politics are concerned, there is a tendency to simplify the overall picture within each country. For example, developed countries are often identified with the maximalist approach that ensures greater protection and enforcement of intellectual property rights. Meanwhile, less developed countries are noted for their need for limitations, exceptions, transitional periods and special and differential treatment.

⁷³ Office of the United States Trade Representative, "The Office of the U.S. Trade Representative Releases Draft Text of ACTA", April 21, 2010, available at http://www.ustr.gov/about-us/press-office/press-releases/2010/april/office-us-trade-representative-releases-draft-text-a [Accessed November 17, 2011].

^{17, 2011].} ⁷⁴ Michael Geist, "New ACTA Leak: U.S., Korea, Singapore, Denmark Do Not Support Transparency", February 25, 2010, available at *http://www*. *michaelgeist.ca/content/view/48191125/* [Accessed November 17, 2011]; Michael Geist, "Talks on Anti-Counterfeiting Treaty Spring a Leak", *Toronto Star*, April 12, 2010, p.B2.

⁷⁵ Yu, "Six Secret (and Now Open) Fears of ACTA" (2011) 64 SMU L. Rev. 975, 1009.

⁷⁶ James Love, "Ambassador Kirk: People Would Be 'Walking away from the Table' If the ACTA Text Is Made Public", December 3, 2009, available at http://keionline.org/node/706 [Accessed November 17, 2011].

⁷⁷ Robert D. Putnam, "Diplomacy and Domestic Politics: The Logic of Two-Level Games" (1988) 42 Int'l Org. 427.

⁷⁸ Deere, *The Implementation Game* (2009), pp.196–232; Ryan, *Knowledge Diplomacy* (1998), p.92

While these caricatures are generally correct, they overlook the internal politics within each group of countries. Even in developed countries, where intellectual property rights holders prefer strong protection and enforcement of intellectual property rights, these countries continue to disagree over how high those standards should actually be and whether those standards should vary from sector to sector. A good example is the disagreement over appropriate patent reform in the United States between the major companies in the software and information technology industries and those in the biotechnology and pharmaceutical industries.79

Cross-sector disagreements can also be found when analysing what measures the United States would find acceptable in ACTA. While the US movie, music and software industries have actively pushed for the inclusion of criminal enforcement provisions in ACTA, the Intellectual Property Owners Association insisted that those provisions should not be extended to patents.⁸⁰ Such opposition continued the years-long fight against the incorporation of criminal sanctions into the EU directive on criminal enforcement of intellectual property rights, the so-called IPRED2.⁸¹ As Tim Frain, the director of intellectual property at Nokia, explained to the International Herald Tribune at that time:

"[P]atent holders wanted protection but not penalties of imprisonment as they tested the boundaries of other patents. 'It's never black and white,' he said. 'Sometimes third-party patents are so weak that I advise managers to go ahead and innovate because, after making a risk analysis, we feel we can safely challenge the existing patent.'

He added, 'But with this law, even if I'm certain the existing patent is no good, the manager involved would be criminally liable."82

In the end, fn.2 of ACTA struck a compromise by enabling parties to "exclude patents and protection of undisclosed information" from the agreement's civil enforcement provisions.

Similar cross-sector divides are present in many fast-growing developing countries, in which intellectual property stakeholders are slowly emerging. In China and India, for example, filmmakers and computer programmers repeatedly complain about the lack of intellectual property protection and its adverse impact on their livelihood. To a large extent, their concerns parallel those of their counterparts in developed countries.

In many developing countries, the interests of fast-growing stakeholders differ significantly from those of the rest of the country. It is therefore increasingly difficult for these countries to establish cohesive nation-based positions on intellectual property law and policy. As I have noted in the past, China may want to have stronger protection for computer programmes, movies, semiconductors and selected areas of biotechnology but much weaker protection for pharmaceuticals, chemicals, fertilisers, seeds and foodstuffs.⁸³ Similar "schizophrenic" preferences can be found in other large middle-income countries, such as Brazil and India.

Even more complicated, the positions taken by national leaders can be heavily skewed by political payoffs—or, worse, nepotism and corruption.⁸⁴ Due to a lack of coordination and other reasons, the positions taken by policymakers in the capitals can be quite different from those residing in diplomatic outposts.⁸⁵ As I was recently reminded, even the positions held by diplomatic corps in Geneva could be quite different from those held by their colleagues in Brussels. It is therefore no surprise that "[d]eveloping

⁸³ Peter K. Yu, "International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia" [2007] Mich. St. L. Rev. 1, 25–26. 84 Chad Damro, "The Political Economy of Regional Trade Agreements" in Lorand Bartels and Federico Ortino (eds), Regional Trade Agreements

and the WTO Legal System (Oxford: Oxford University Press, 2006), p.37. ⁸⁵ Deere, *The Implementation Game* (2009), p.122.

⁷⁹ Jay P. Kesan and Andres A. Gallo, "The Political Economy of the Patent System" (2009) 87 N.C. L. Rev. 1341, 1368–1376.

⁸⁰ Monika Ermert, "US Rightsholders Seek Narrower Scope of ACTA, Clarity on Trademark Infringement vs. Counterfeiting", Intellectual Property Watch, July 10, 2010, available at http://www.ip-watch.org/weblog/2010/07/10/us-rightsholders-seek-narrower-scope-of-acta-clarity-on-trademark -infringement-vs-counterfeiting/ [Accessed November 17, 2011].

¹ Irina D. Manta, "The Puzzle of Criminal Sanctions for Intellectual Property Infringement" (2011) 24 Harv. J.L. & Tech. 469, 491.

⁸² Paul Meller, "Prison Over Patents? Proposed EU Law Unites Foes", International Herald Tribune, December 10, 2005, p.13.

country diplomats working on IP issues in Geneva frequently expressed frustration with IP reforms underway at home that sacrificed TRIPS flexibilities".86 As we analyse the positions and interests of developing countries, it is important we take these variations into account.

The final type of politics implicated by ACTA concerns what commentators have identified as global politics-the type of politics that transcends the Westphalian order of nation states. While a significant part of the critique of ACTA addresses interests of countries in the South, many of the agreement's most trenchant critics reside in the North. Examples of these critics are Michael Geist from Canada; the Electronic Frontier Foundation, Essential Action, Knowledge Ecology International, Public Citizen and Public Knowledge from the United States; the Foundation for a Free Information Infrastructure (FFII) and La Quadrature du Net from Europe; and global nongovernmental organisations such as Médecins Sans Frontières and Oxfam.

The active participation of critics from the North makes a lot of sense, considering their significant resources and capacity.⁸⁷ Nevertheless, the collaboration between these players in the North and developing countries in the South has clearly shown that the developments in the international intellectual property arena have now gone beyond negotiations among nation states. Such developments also highlight the growing opportunity for the South to collaborate with the North-through academics, mass media or nongovernmental organisations.88

Indeed, nongovernmental organisations have been increasingly successful in pushing for a greater recognition of the changing nature of global governance models. The World Summit on the Information Society and later the Internet Governance Forum provide good examples of how these models have shifted. So do the ongoing discourse on access to medicines and the emerging debate on access to knowledge.⁸⁹ While non-state actors still have a long road to travel before they can become highly influential in the international intellectual property debate, there is no denying that the governance model has slowly evolved to cover these new and increasingly powerful actors.

In sum, ACTA offers not only insights into the development of club standards and the emerging non-multilateral era but also an important case study on the various layers of politics behind the development of the international intellectual property regime. While the agreement is both disappointing and disturbing, it does inspire us to think more deeply about the role politics can play in the future development of this regime.

Conclusion

Only a few years ago, commentators were widely criticising WIPO for its lack of legitimacy. As Christopher May noted shortly after the establishment of the WIPO Development Agenda, "[a]t the centre of [this] Agenda is a critique of the WIPO that suggests it represents a narrowly focused set of political economic interests that seek to expand the realm of commodified knowledge and information for their own commercial advantage".90 Likewise, Sisule Musungu and Graham Dutfield observed:

 ⁸⁶ Deere, *The Implementation Game* (2009), p.314.
 ⁸⁷ Ahmed Abdel Latif, "The Emergence of the A2K Movement: Reminiscences and Reflections of a Developing-Country Delegate" in Gaëlle Krikorian and Amy Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (New York: Zone Books, 2010), p.116.

Yu, "A Tale of Two Development Agendas" (2009) 35 Ohio N.U.L. Rev. 465, 552–553; Yu, "Access to Medicines, BRICS Alliances, and Collective Action" (2008) 34 Am. J.L. & Med. 345, 378.

Amy Kapczynski, "The Access to Knowledge Mobilization and the New Politics of Intellectual Property" (2008) 117 Yale L.J. 804; Krikorian and Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (2010). ⁹⁰ Christopher May, The World Intellectual Property Organization: Resurgence and the Development Agenda (London: Routledge, 2007), p.4

"There are perceptions that the Bureau is acting not as the servant of the whole international community but as an institution with its own agenda. That agenda seems more closely attuned to the interests and demands of some Member States than to others, and more to pro-strong intellectual property protection interest groups and practitioner associations, which are ostensibly observers but sometimes behave and are treated like Member States, than to the interest of developing countries."⁹¹

In the midst of the ACTA negotiations, however, commentators have begun calling on the ACTA negotiations to be moved back to WIPO. As the Wellington Declaration, which was drafted by the participants of the PublicACTA Conference in New Zealand, proclaims:

"We note that the World Intellectual Property Organisation has public, inclusive and transparent processes for negotiating multilateral agreements on (and a committee dedicated to the enforcement of) copyright, trademark and patent rights, and thus we affirm that WIPO is a preferable forum for the negotiation of substantive provisions affecting these matters."

For those of us who have paid close attention to the establishment of the WIPO Development Agenda, it was indeed astonishing to see this quick change of public perception of WIPO—from an organisation widely criticised for being heavily captured by developed countries and their industries to a totally different one that is noted for having "public, inclusive and transparent processes". Such a swift about-turn is indeed indicative of the highly dynamic nature of international intellectual property developments. It also underscores our need for greater appreciation of the complex political dynamics behind such developments.

Although intellectual property is a largely legal construct,⁹² it is not just about law and economics. It is also about politics. As Sebastian Haunss and Ken Shandlen write in the introduction to their timely collection of essays on the politics of intellectual property:

"[M]ost studies [of intellectual property policy-making] focus on national and international IP laws. But while laws are solidified results of social struggles and political conflicts, understanding the law itself tells us little about the social processes that lay behind laws and even less about the social dynamics that will eventually challenge and often change them. Laws establish opportunities for action, and strictly legal perspectives in most cases say little about different actors' motivations and capacities to exploit these opportunities and how the motivations and capacities change over time. It is time, therefore, to reorient analysis of the politics of IP to the processes by which conflicts over the ownership, use, and control of information are manifest and resolved in regional, national and sub-national settings."⁹³

While the political aspects of intellectual property have been largely understudied, the academic landscape has been slowly changing. As more scholars become interested in the subject, we will have a deeper and fuller understanding of the international intellectual property regime. We will also be in a better position to anticipate potential struggles and conflicts while designing appropriate reforms to resolve them. By bringing together leading scholars studying the politics of intellectual property and players at the frontline of international intellectual property policymaking, it is my hope that this special issue will help generate more attention in this under-explored area.

⁹¹ Sisule F. Musungu and Graham Dutfield, Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organisation (WIPO) (Geneva: Quaker United Nations Office, 2003), p.4.

⁹² Amy Kapczynski and Gaëlle Krikorian, with Harini Amarasuriya, Vera Franz, Heeseob Nam, Carolina Rossini and Dileepa Witharana, "Virtual Roundtable on A2K Strategies: Interventions and Dilemmas" in Krikorian and Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (2010), p.548.
⁹³ Sebastian Haunss and Kenneth C. Shadlen, "Introduction: Rethinking the Politics of Intellectual Property" in Sebastian Haunss and Kenneth C.

⁹³ Sebastian Haunss and Kenneth C. Shadlen, "Introduction: Rethinking the Politics of Intellectual Property" in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property: Contestation Over the Ownership, Use, and Control of Knowledge and Information* (Cheltenham: Edward Elgar Publishing, 2009), p.2.

Everything Old Is New Again: The Development Agenda Then and Now

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Developing countries; WIPO

The Development Agenda at the World Intellectual Property Organisation (WIPO) has been controversial, exciting, and long overdue. However, it is not the first time that WIPO has been deeply engaged in discussions about the role of intellectual property in development. And here I am not referring to Kamil Idris' *Intellectual Property: A Power Tool for Economic Growth*.¹ This earlier episode, like the most recent version, came about in response to developing countries' expressed request to gain better access to intellectual property. Beginning in 1980, and ending in March 1984, WIPO conducted negotiations to revise the Paris Convention for the Protection of Industrial Property (Paris Convention). The negotiations ended badly, but the discussion was remarkably similar to current deliberations on the Development Agenda. This essay highlights historical similarities between the two initiatives. It also points to some important changes in the contemporary context.

In 1980 the Organisation for Economic Cooperation and Development (OECD) member countries were reeling from a succession of steep oil price hikes, first in 1973 and then in 1979. The Organisation for Petroleum Exporting Countries (OPEC) collaborated to raise prices, in part, to punish the United States for its support of Israel. The prospect of developing countries wielding commodity power in the global economy concerned OECD policymakers. The promise of commodity power was uncertain. Would developing countries be able to turn the tables by forming bauxite, copper, or coffee cartels? Would they be able to hold resource-dependent rich countries hostage to their demands? Faced with this looming uncertainty OECD negotiators agreed to participate in a series of multilateral negotiations specifically to address the global South's concerns. In 1975, then-US Secretary of State Henry Kissinger addressed the Seventh Special Session of the United Nations General Assembly and said that the United States was willing to "turn away from confrontation" and was ready to take the needs of developing countries more seriously.²

The newly found oil power over resource-dependent OECD states sparked a broader effort under the rubric of the New International Economic Order (NIEO), in which developing countries and former colonies would get a better deal in the world economy and enjoy resource and technology transfers from the North to the global South.³ The UN adopted a Declaration on the Establishment of a NIEO in 1974.⁴ Developing countries pressed for an NIEO and many of its provisions were drawn from their own domestic and regional legislation and policies. A number of developing countries had been experimenting with different approaches to economic development. For example, in the 1970s India imposed very substantial

¹K. Idris, Intellectual Property: A Power Tool for Economic Growth (Geneva: WIPO, 2003).

² Kissinger quoted in R.D. Hansen, *Beyond the North-South Stalemate* (New York: McGraw-Hill Book Co., 1979), p.25.

³ For a more detailed account of this effort, see S.K. Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (Albany: State University of New York Press, 1998).

⁴ Declaration on the Establishment of a New International Economic Order, General Assembly, Resolution 3201, GAOR, 6th Special Session, Supp. No.1, May 1, 1974, UN Doc A/9559, available at http://www.un-documents.net/s6r3201.htm [Accessed October 31, 2011].

restrictions on foreign direct investment in order to build up indigenous capacity. Many Latin American countries were practicing import-substituting industrialisation that restricted foreign direct investment, profit repatriation, and foreign ownership in local enterprises. Regional legislative experiments, such as the Andean Pact, made technology transfer a high priority.

A NIEO for technology transfer would be promoted in three sets of negotiations: the Negotiations of United Nations Conference of Trade and Development (UNCTAD) on a Code of Conduct for the Transfer of Technology; UNCTAD's Negotiations on a Code of Conduct for the Control of Restrictive Business Practices; and WIPO's Negotiations on the Revision of the Paris Convention. The focus on patents and licensing was reflected in the 1967 Group of 77's *Charter of Algiers*.⁵ The Charter emphasised the importance of acquiring technology from the North but intimated that the terms of transfer were unfair. The Charter stated that "developed countries should encourage the transfer of knowledge and technology to developing countries by permitting the use of industrial patents on the best possible terms and eliminate the restrictions on the granting of licenses and the use of patents and trademarks".⁶ Significantly, the NIEO proposals embraced the view that scientific and technological knowledge should be considered to be the "Common Heritage of Mankind" and freely available to all.

A 1977 UNCTAD study concluded that developing countries' national laws—in many instances, either copied from the Paris Convention or a holdover of the laws of their former colonial masters—amounted to "a reverse system of preferences granted to foreign patent holders in the markets of developing countries".⁷ Constantine Vaitsos, head of the Andean Pact Secretariat's policies on foreign investment and technology, produced an influential study on the role of the patent system in developing countries, highlighting its potential for abuse.⁸ His study concluded that overall, the patent system had negative effects on developing countries' economies. He argued that the patent system favoured multinational corporations and was primarily a vehicle for maximizing the profits of these corporations. Vaitsos further maintained that patents became substitutes for foreign investment and were means to capture developing countries' markets. He saw patents as a powerful means for restricting technology transfer from North to South and highlighted abuses such as patent cartels, restrictive business practices and market control.⁹

Earlier, in 1969, Vaitsos had helped to craft the Andean Pact's provisions on foreign investments, patenting and licensing. In 1974 the Treaty of Cartagena Commission adopted Resolution 85, providing member countries with a common intellectual property law. Article 28 of Resolution 85 was designed to allow "the unhampered flow into the country of the results of patented technology".¹⁰

Resolution 85 conflicted with the Paris Convention by denying a patent holder the exclusive right to import the patented product or a product manufactured by the patented process, which the Convention gave to the patent holder. Key provisions of Resolution 85 underscored the priority of technology transfer on favourable terms. For example, it included a provision to keep patent-free from the outset any technology that was important for a nation's development policy. Patents were to be granted for five years, renewable once only if the holder could show reasonable working of the patented product or process. Patents deemed essential for national development could be subject to compulsory licensing at any time, and all licensing contracts had to be filed with a national authority for review of public interest considerations. At this time member countries, Bolivia, Colombia, Ecuador and Venezuela, were not parties to the Paris Convention.

⁶ Quoted in A. Graham, "The Transfer of Technology: A Test Case in the North-South Dialogue" (1979) 33 Journal of International Affairs 2.

- ⁷ A. Ramachandran, "Self-Reliance in Technology and the Patent System" in WIPO, *World Symposium on the Importance of the Patent System to Developing Countries* (Geneva: 1977), p.304.
- ⁸ C. Vaitsos, "Patents Revisited: Their Function in Developing Countries" (1972) 9 Journal of Development Studies 1.
 ⁹ Vaitsos, "Patents Revisited: Their Function in Developing Countries" (1972) 9 Journal of Development Studies 1, 77, 83.

¹⁰ P. Kunz-Hallstein, "Patent Protection, Transfer of Technology and Developing Countries: A Survey of the Present Situation" (1975) 6 International Review of Industrial Property and Copyright Law 427, 434, fn.32.

⁵G-77 was the name of the developing countries' negotiating bloc in the UN at that time.

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India also had adopted patent laws aimed at achieving technology transfer on more favourable terms. After lengthy study, in 1970 India passed The Patents Act No.39, which did not allow patents for food, drugs and medicines. The Indian Patents Act also included provisions that required commercial exploitation of foreigners' patents in the country to prevent import monopolies. It further allowed for the issuing of compulsory licenses in the public interest. At this time, India was not yet a member of the Paris Union.

In 1974 India sought improvements in the Paris Convention before it would consider joining. The author of an important Indian study of patents wrote, "[W]e look forward to the modification of the International Convention so that such measures which the developing countries may take are not rendered ineffective."¹¹ Several important studies appeared in 1974 and 1975 that examined the patent system in the context of development. They offered sweeping critiques of the patent system and urged reforms to help developing countries.¹² The suggested reforms reflected some of the regional and national legislative experiments in both the Andean Pact and India, as previously described. Not surprisingly, the United States sharply criticised these studies and argued that the kind of revisions recommended would be detrimental to developing countries' objectives.

The Diplomatic Conference for the Revision of the Paris Convention began in February 1980, and from the outset the negotiating positions were far apart. The core issues at stake were special treatment for developing countries and the introduction of flexibilities to expedite technology transfer and development. Developing countries sought to ensure that foreign patents would be worked in their countries. They wanted to amend the Convention to obligate foreign patent holders to work the invention, either themselves or through licensees, or face the threat of compulsory licensing. They sought clarification that non-working constituted an abuse of patent rights. They insisted that importation was not "working", and abuses should be subject to sanctions of exclusive compulsory licensing and forfeiture or revocation within fairly short time frames. The existing 1967 Stockholm text of the Paris Convention allowed for non-exclusive compulsory licensing, but developing countries felt that such licensing was too weak to curb patent abuse. The main focus of the negotiations was art.5(A)(3) of the Stockholm Text, which states:

"Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the

first compulsory license."¹³

Brazil thought this provision was too weak; the country was a signatory of Hague Act of 1925 that allowed one to revoke a patent without *first* issuing a compulsory license.

At the second negotiating session in Nairobi, negotiators devised a compromise over the objections of the United States and Switzerland. The so-called Nairobi text allowed for the issue of exclusive compulsory licenses in circumstances constituting abuse of patent rights. At the end of the session negotiators believed that they had made significant progress on Article 5(A). But at the outset of the third negotiating session Group B made it clear that they flatly rejected the Nairobi Text.

The focus on art.5(A) had some unintended consequences. Over the course of the negotiations, developing countries embraced the highly regarded Bodenhausen interpretation of the existing 1967 Stockholm Text of art.5(A). According to Bodenhausen, art.5(A) allowed for *non*-exclusive compulsory licenses only for failure to work:

¹¹ S. Vedaraman, "Patent Law in India as a Means Toward Accelerating Industrial Development" in WIPO, World Symposium on the Importance of the Patent System to Developing Countries (1977), p.147.
¹² UNCTAD, The Role of the Patent System in the Transfer of Technology to Developing Countries (Geneva: United Nations, 1974), TD/B/AC.11/19;

¹⁴ UNC1AD, The Role of the Patent System in the Transfer of Technology to Developing Countries (Geneva: United Nations, 1974), 1D/B/AC.11/19; UNCTAD, The International Patent System as an Instrument for National Development (Geneva: United Nations, 1975), TD/B/C.6/AC.2/3. Also see special issue of (1974) 2(9) World Development.
¹³ G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (Geneva: United International

¹³ G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (Geneva: United International Bureau for the Protection of Intellectual Property, 1968), p.67.

"the member states are ... free to provide analogous or different measures, for example, compulsory licenses ... in cases where the public interest is deemed to require such measures."¹⁴

In other words, under this interpretation exclusive compulsory licenses were viable options for public interest considerations. At the fourth session of the negotiations, the United States expressed dissatisfaction with the 1967 Stockholm text and rejected the possibility of issuing exclusive licenses *at all*. This was the first hint that the United States sought not merely to block developing countries' proposals, but to close loopholes and possibly seek stronger rights for patent holders.

The negotiations ended in a deadlock after this exchange over the Stockholm Text of art.5(A). The United States and its intellectual property allies went on to push for a trade-related intellectual property agreement in a forum that gave them greater negotiating leverage than WIPO. At the General Agreement on Trade and Tariffs (GATT) negotiations they could wield market access as both a carrot and a stick to induce developing countries to adopt higher standards of intellectual property protection. This forum shift produced consternation and worry at WIPO. WIPO personnel fretted over the organisations' continued relevance after the United States and its allies brought their intellectual property concerns to GATT. The recently negotiated Anti-Counterfeiting Trade Agreement has elicited similar anxieties, as its institutional contours and relationship to WIPO and WTO remain unclear.

In the wake of the failed Paris Convention Revision negotiations, the broader context for economic development profoundly changed. OECD countries, once so fearful of "commodity power" discovered that oil was, indeed, the exception, and they had little to fear from commodity cartels after all.¹⁵ Engaging developing countries' agendas suddenly seemed far less urgent. In the 1980s Latin American countries endured a debilitating debt crisis; the 1980s was widely considered a "lost decade" for Latin American economies. East Asian economies adopted aggressive export-oriented industrialisation and experienced remarkable economic growth. Ronald Reagan and Margaret Thatcher extolled the virtues of free markets, and the globalisation of finance proceeded apace. Import-substituting industrialisation had lost its lustre, and the so-called Washington Consensus of privatisation, reduced government spending and integration with the global economy dominated economic thinking.

Most significantly for intellectual property policies, developing countries began to compete with each other to attract foreign capital and investment. In a sharp reversal of protectionist policies designed to channel foreign investment into priority development sectors and greater economic autonomy, countries welcomed investment on investors' terms. Many countries were desperate for foreign exchange to pay off their mountains of debt. Multinational corporations with intellectual property assets fanned out across the globe and increasingly demanded higher standards of intellectual property protection. In 1994 their quest for a broad-ranging multilateral agreement was achieved with Agreement on Trade-Related Aspects of Intellectual Property (TRIPs).

TRIPs eliminated some development-oriented policy space and required states to offer patent protection for pharmaceutical products. TRIPs also settled the earlier controversy by making clear that importation "counted" as working. Thus "failure to work" did *not* qualify as an abuse of patent rights. However, TRIPs was merely the beginning of a concerted effort to obtain more protection.

In the years since TRIPs, governments that are homes to intellectual property-based multinational corporations have continued to ratchet up standards of intellectual property protection outside of multilateral channels. US Free Trade Agreements, bilateral investment treaties, European Economic Partnership Agreements, and plurilateral efforts like the Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership negotiations have all included stricter standards for protection and enforcement of intellectual property rights.

¹⁴Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (1968).

¹⁵ S. Krasner, "Oil Is the Exception" (1974) 13 Foreign Policy 68

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Other important changes have included developing countries' much greater knowledge and sophistication in their engagement in intellectual property issues. In particular, the access to medicines campaign mobilised a number of developing countries' governments to oppose multilateral efforts to raise intellectual property protections beyond TRIPs levels. Rather than being an arcane and dusty subject, intellectual property policies have emerged as among the most sharply contested and politically charged issues on the international economic and social agendas. Many new actors have joined the fray, with many non-governmental organisations, academics and activists participating in intellectual property governance.

Many of the critical conversations of the 1970s and early 1980s are being resuscitated now in the context of the contemporary development agenda. Clearly the controversies over compulsory licensing have not disappeared. For example, even though TRIPs permits compulsory licensing, the post-TRIPs bilateral, regional and plurilateral agreements have narrowed substantially the scope conditions for issuing such licenses.

Yet there are some interesting new twists. In the 1970s developing countries declared that science and technology should be considered to be the "common heritage of mankind" and thus freely available to all. In the 2000s, in response to so-called biopiracy¹⁶ in which OECD firms treated developing countries' biodiversity as the "common heritage of mankind", the Convention on Biological Diversity introduced access and benefit sharing provisions. Beginning with Costa Rica, biologically diverse countries have claimed property rights over their biodiversity. Many have hoped that by charging bio-prospectors for access, and insisting on prior informed consent and shared benefits from follow-on products or processes, they might benefit from their "green gold".¹⁷

This shift from being anti-property to pro-property for biodiversity, germplasm, geographical indications and traditional knowledge is significant but not without controversy. Some access to knowledge campaigners and open source advocates are not comfortable with such property rights.¹⁸ Others see the shift in terms of social justice and believe that claiming property rights in products and processes unique to the global South, and historically plundered by empires and multinational corporations without compensation, is a positive move. There is no consensus on the merits however.

Another very important change is that some countries that once thrived by imitation and reverse engineering are now embracing robust intellectual property regimes. South Korea is a case in point. It has negotiated a very high standard bilateral agreement with the United States. In Peter Yu's terms South Korea is just one country that has "crossed over" from imitation to innovation.

Since TRIPs, the institutional environment around intellectual property has gotten much denser, much thicker, and much more heavily populated with new forums and new actors. The result is an increasingly incoherent and internally inconsistent intellectual property regime. Much of this incoherence is a product of strategic forum shifting, in which actors take their intellectual property concerns to the forums in which they expect to better achieve their goals.¹⁹ Various interest groups and government agencies have become heavily invested in increasingly ineffective approaches to property protection and enforcement. For example, firms in the United States pay untold dollars to their lobbyists to pursue action through the Office of the US Trade Representative. This has helped them to name and shame countries as intellectual property rights violators each year with the USTR's annual 301 Report. Yet given the continued activities in making treaties with higher standards and the obvious shortcomings in enforcement, it is questionable whether

¹⁶ I. Mgbeoji, *Global Biopiracy: Patents, Plants and Indigenous Knowledge* (Ithaca: Cornell University Press, 2006); A. Mushita and C. Thompson, *Biopiracy of Biodiveristy: Global Exchanges as Enclosure* (Trenton: Africa World Press, 2006); S. Vandana, *Biopiracy: The Plunder of Nature and Knowledge* (London: South End Press, 1999); R. Wynberg, D. Schroeder and R. Chennells (eds), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case* (New York: Springer, 2009).

¹⁷ J. Kuanpoth, "Closing in on Biopiracy: Legal Dilemmas and Opportunities for the South" in R. Melendez-Ortiz and V. Sanchez (eds), *Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainability* (London: Earthscan, 2006).

¹⁸ G. Krikorian and A. Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (New York: Zone Books, 2010).

¹⁹L. Helfer, "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29 Yale Journal of International Law 1.

this is money well spent. Trademark brand managers abroad work with private security firms to conduct enforcement raids; in a system with perverse incentives, the outcome seems to be more enforcement activity *and* more counterfeiting.²⁰

Since the 2008 financial crisis, a global economic power shift has become sharply evident. The Washington Consensus has fallen out of favour, and the world is watching Brazil, India, China, and South Africa as their economies continue to thrive and grow. Indeed, China is patenting up a storm in agricultural and other forms of biotechnology and wind energy. It has become the fourth largest user of the Patent Cooperation Treaty that WIPO administers. While China has joined India in raising questions about the Anti-Counterfeiting Trade Agreement in the WTO TRIPs Council, it remains to be seen whether China will press very hard for a development agenda. Nonetheless, these countries will shape the future of global intellectual property regulation.

While some analysts are optimistic about the WIPO Development Agenda, the United States has made it clear that it is not interested and has pursued its quest for higher standards outside of WIPO. Structurally WIPO may be constrained in how far it may veer from OECD intellectual property holders and their interests because the Patent Cooperation Treaty provides the lion's share of WIPO's revenue. Some have discussed setting up a trilateral (US/EU/Japan) patent arrangement to bypass WIPO, and the role of the ACTA Committee and its relationship to pre-existing multilateral organisations such as WIPO and WTO remain unclear. Others have complained that the Development Agenda has become so watered-down that it has already lost its promise.²¹ Yet, as Ruth Okediji points out:

"That an explicit affront on the rights-centered focus of WIPO's constitution should succeed even on paper was rightly regarded as a landmark achievement by a network of actors whose penetration of and influence on WIPO's core functions has long been stymied by procedural rules directed at insulating the institution from external pressures."²²

A recent External Review of WIPO Technical Assistance Programs is certainly a step in a more constructive and transparent direction.²³

The United States' aggressive decades-long push to ratchet up intellectual property protections may come back to haunt it sooner than later. It is easy to imagine that in the not-too-distant future, US consumers will be paying more royalties to foreign rights holders. Pharmaceutical innovation virtually has come to a halt in the US, with many blockbuster drugs about to come off patent and very little new drugs in the pipeline. Many critics contend that the US patent system is choking off innovation with strategic patenting, patent thickets, and overly broad claims. Numerous in-depth critiques of the US patent system have raised profound questions about the wisdom of exporting our broken and dysfunctional system.²⁴

In many respects, the contemporary Development Agenda resurrects the issues of the NIEO era. The problem of technology transfer has not been solved. The role of intellectual property in economic development remains controversial. The old "North-South" terminology conceals many important differences between stakeholders within countries, rich and poor, as well as shared interests of consumers across the globe. The Development Agenda will be successful if it manages to fundamentally recast

²⁰ D. Chow, "Anti-Counterfeiting Strategies of Multi-National Companies in China: How a Flawed Approach Is Making Counterfeiting Worse" (2010) 41 *Georgetown Journal of International Law* 749.

⁽²¹⁾K. Maskus, "The WIPO Development Agenda" in Neil Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford: Oxford University Press, 2009), p.167 (emphasising that the technology transfer provisions in the Development Agenda are actually weaker than what already exists in arts 7 and 66.2 of TRIPs).

²² R.L. Okediji, "History Lessons for the WIPO Development Agenda" in Netanel (ed.), *The Development Agenda* (2009), p.156.

²³ C. Deere Birkbeck and S. Roca, An External Review of WIPO Technical Assistance in the Area of Cooperation for Development (Geneva: WIPO, 2011), available at http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf [Accessed October 31, 2011].
²⁴ J. Bessen and M. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk (Princeton: Princeton University Press,

²⁻¹ J Bessen and M. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk (Princeton: Princeton University Press, 2009); M. Boldrin and D.K. Levine, Against Intellectual Monopoly (Cambridge: Cambridge University Press, 2008); M. Heller, The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives (New York: Basic Books, 2008); A. Jaffe and J. Lerner, Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress and What to Do About It (Princeton: Princeton University Press, 2009).

intellectual property protection as just one tool for public policy, embedded in a broader strategy for building technological capabilities, innovation and economic progress. It will have to inject explicit protections against abuses of property rights and offer capacity building for competition policy. If property holders seek enforcement, they will have to come up with policies that developing countries will want to enforce.

It is a tall order to undo decades of discourse, norm setting and rule making that have treated intellectual property protection as valuable for its own sake—the more the better. Many property holders have lost sight of intellectual property rights' fundamental role as a *means* to an end that should be flexible and tailored to better meet the needs of different countries, sectors, and stakeholders. One-size-fit-all rarely fits anyone all that well.

From Punta Del Este to Doha and Beyond: Lessons from the TRIPs Negotiating Processes

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P Compulsory licensing; Negotiations; Patents; Pharmaceuticals; TRIPs

Introduction

This article seeks to review the results of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) negotiating processes and to evaluate the degree of success achieved by different parties. It takes into account the influence of spatially and chronologically dispersed events both inside and outside the negotiating contexts. This article does not attempt to describe the full content of the negotiated changes in international IP law. Nor does it explain their meaning or interpretation or judge their importance.

TRIPs negotiations were launched in Punta del Este in Uruguay and lasted about seven years—from September 1986 to December 1993. TRIPs came into being on the first day of 1995, with the establishment of the WTO. Since then WTO Members have engaged in negotiations over the TRIPs Agreement and public health during 2001–2005, with three successful outcomes—the Doha Declaration on the TRIPs Agreement and Public Health in November 2001¹ (Doha Declaration or Declaration); the Decision on the Implementation of Paragraph 6 of the Doha Declaration in August 2003² (Para.6 Decision or the Decision); and the Protocol Amending the TRIPs Agreement in December 2005 (Protocol).³

One objective measure of the success or failure of negotiating strategies could be the proportion of the original known negotiating positions or objectives achieved in the final output.⁴ All four agreements mentioned above will be judged in this article by that yardstick, through the use of some key examples,⁵ to see whether they were successes or failures from the developing countries' perspective. Throughout this article the term "developed countries" or "North" will be used to denote the subset that led the negotiations for strengthened intellectual property right (IPR) protection and "developing countries" or "South" for those that led the opposition to such demands.⁶

 5 No attempt is made here at a comprehensive cataloguing of all the provisions of the four agreements.

⁶ These lines are getting increasingly blurred, with the increasing economic clout of some emerging developing country markets and the consequent changes in national interests. Nevertheless, so far in the WTO and other international forums, with a few clear exceptions such as Korea, Mexico and Singapore, Members continue to be aligned largely on North-South lines on intellectual property issues.

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¹ WT/MIN(01)/DEC/2.

 $^{^{2}}$ WT/L/540 and Corr.1.

³ WT/L/641. In addition, since the launch of the Doha Round, work on other TRIPs issues such as geographical indications and TRIPs-CBD began in the context of the Doha Development Agenda (DDA), on which there has been no final outcome yet. This is why these subjects will not be a part of the analysis of this article.

⁴While this has the advantage of being objective, it may well be too narrow an angle for some.

Judging solely by this yardstick,⁷ some developing countries would view the TRIPs Agreement as being mostly a failure from their standpoint. However, there are some important exceptions as we shall see below. In sharp contrast, the North-South negotiations that followed the Doha Declaration a few years later were a success for developing countries as large parts of the original proposal by developing countries are found in the final text. This situation changed again somewhat by the time the Para.6 Decision was negotiated, with some developed countries holding on to their original positions and managing to get them into the final outcome, even if in a diluted form. See-sawing again, the outcome on the Protocol reflected more balance, neither mirroring the initial position of developing countries, nor that of the key developed countries. This article concludes with some observations on the main reasons for success or failure in such negotiations.

Of course, what is clear is that despite formal agreements on the final TRIPs text or the TRIPs Agreement and public health instruments, their implementation has raised many more issues. There has been some attempt to claw back, in the implementation phase, concessions that had been made in the negotiations phase. This topic is not dealt with in the article.

TRIPs Negotiations—Punta Del Este to Marrakesh

At the time of the preparations for a new round in General Agreement on Trade and Tariffs (GATT), international IPR standards were defined by the two main treaties administered by the World Intellectual Property Organisation (WIPO), namely the Berne Convention for the Protection of Literary and Artistic Works (on copyright) and the Paris Convention for the Protection of Industrial Property (on mainly patents and trademarks). The Berne Convention was considered to be largely adequate by most countries, only in need of some tweaking. The Paris Convention, on the other hand, was considered to be too strong in certain respects by some who were not parties to it and too weak by others, mainly developed countries. More significantly, there was a move by developing countries in the early-1980s to lower the standards set in the Paris Convention, which failed in the end. At about this time, Special 301⁸ was introduced and used by the United States against recalcitrant trading partners. The interested parties in developed countries spread the perception that developing countries were pirates and counterfeiters—and by and large, the moral high ground was held by the accusers. From this time on through the end of the TRIPs negotiations, developing countries remained on the defensive with regard to IPRs. These are important factors outside the TRIPs negotiations that influenced the final outcome.⁹

Taking the starting point as the July 1990 text,¹⁰ it can be seen that the most controversial issue between developed and developing countries was whether there should be a comprehensive agreement on all aspects of IPRs, called "Approach A" in this document (developed country proposals), or whether the negotiations should be confined to trade in counterfeit and pirated goods, the only subjects seen as trade-related, described as "Approach B".¹¹ Approach B was a failure as a negotiating modality, although it was mentioned formally in the Brussels text,¹² the idea of confining negotiations to trade in counterfeit and pirated goods was not considered credible and was eventually abandoned.

⁷ Again no attempt is made in this article to situate trade-offs in the IPR area with other trade areas. There were attempts made in the Uruguay Round by developing countries to link IP negotiations to agriculture and textiles.

⁸ Special 301 was introduced in 1989. Section 301 of the US Trade Act itself dates from 1974. The use of Special 301 (an annual review held by the US Trade Representative) did result in several key developing countries falling in line with the demands in the TRIPs Agreement, especially on the introduction of pharmaceutical product patents or even "pipeline" protection as happened for example in Brazil.

⁹ See more details on this in J. Watal, Intellectual Property Rights in the WTO and Developing Countries (The Hague: Kluwer Law International, 2001), Ch.2.

¹⁰ MTN.GNG/NG11/W/76, available at http://www.wto.org/gatt_docs/English/SULPDF/92110034.pdf [Accessed October 31, 2011]. This is a composite text drawn from proposals presented by countries to the TRIPs negotiating group and can be considered to be the first draft TRIPs negotiating text. This is taken as the reference point for the sake of convenience as it consolidated the proposals from several original texts into one document, wherever possible.

¹¹ This was proposed by a group of developing countries that submitted MTN.GNG.NG11/W/71, which was prepared with the help of UNCTAD.
¹² MTN.TNC/W/35/Rev.1. This approach was not even pressed by the developing country proponents.

The text of Approach B also had some counter proposals to Approach A (B group proposals).¹³ Of these counter proposals made by developing countries, one can recognise (albeit in a modified form) arts 7 and 8 of the TRIPs Agreement.¹⁴ On standards, the B group proposals were limited to general language about leaving substantive rules up to national legislation, including on the term of protection of various IPRs. This may well have been a mistake as more specific proposals, say a patent term of 15 years, may have been easier to defend or amend in a timely way, in order to negotiate a middle ground on standards as there was no way to achieve consensus on such broad language, especially when pitted against quite specific proposals made by developed countries.

On patent rights and exceptions, one can clearly see the language proposed by the European Communities (EC) in what is now in art.31; later India used this advantage to get this approach accepted by all (see below). However, compulsory working of patents or the freedom to grant compulsory licences in sectors such as food and medicines proposed by the B group¹⁵ does not find place in the final TRIPs text. On the revocation of patents, surprisingly there was no counter proposal from developed countries to the proposal that patents may be revoked on grounds of public interest,¹⁶ and it is unclear what silence in art.32 on this question means.¹⁷

Section 8 on "Remedial Measures for Non-fulfilment of Obligations" proposed by the B group¹⁸ was entirely dropped. On the other hand, s.9 on control of abusive or anti-competitive practices in the July 1990 text proposed by the B group is now somewhat accounted for in art.40 of the TRIPs Agreement, although only four illustrations are given of what could be specified in law as being anti-competitive practices in particular cases, as opposed to the list of 14 per se anti-competitive practices proposed by the group. Nevertheless, with this provision developing countries achieved some progress in international law in getting developed countries to accept, for the first time in a binding treaty, the freedom of countries to control anti-competitive practices in contractual licences pertaining to IPRs.

Under Enforcement, Part IX of the July 1990 text entitled "Trade in Counterfeit and Pirated Goods" proposed by the B group is now largely found in TRIPs Part III, including safeguards against obstacles to legitimate trade. The core idea in art.41.5 about not having to devote additional resources for the enforcement of IPRs as against other laws was first proposed by India in September 1989,¹⁹ and then introduced into the TRIPs text a year later with the support of others, during the course of the negotiations.²⁰

However, it was not so much the developing countries' text with its general language that made a difference to the final TRIPs text as it was negotiating strategies from the second half of 1990. This period saw the importance of North-South issue-based alliances—for example, some Commonwealth members, Hong Kong, China,²¹ Singapore, New Zealand and Australia, took the initiative on the exclusion of the subject of parallel trade from dispute settlement, thus retaining the pre-existing flexibility on differing national policies. Many developing countries enthusiastically supported this, resulting in what is now art.6 on exhaustion.²²

A similar Commonwealth alliance on compulsory licensing and government use of patents, based on the UK patent law, proved untenable. An important proposal was made by India in November 1990, at a critical juncture when developed countries, including those from the Commonwealth, were converging

- ¹⁸ MTN.GNG/NG11/W/76, p.43.
- ¹⁹ MTN.GNG/NG11/W/40, p.3.

²⁰ Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement (1999), p.56, calls art.41.5 "one of the most problematic provisions of the TRIPs text".

²¹ Now Hong Kong, China.

²² Watal, Intellectual Property Rights in the WTO and Developing Countries (2001), Ch.10.

¹³Not to be confused with Group B (developed countries) in WIPO.

¹⁴ MTN.GNG/NG11/W/76, pp.9–10. Article 8, which requires measures taken be consistent with the TRIPs Agreement, was considered to be particularly restrictive, but it does not take away the value of the provision as seen from the panel report in the EU-Canada dispute (WT/DS114/R).

particularly restrictive, but it does not take away the value of the provision as seen from the panel report in the EU-C anada dispute (w 1/DS114/K). ¹⁵ MTN.GNG/NG11/W/76, pp.33–36.

¹⁶ MTN.GNG/NG11/W/76, p.37.

¹⁷ See discussion in the TRIPs Council on this issue in IP/C/M/8, paras 73–79.

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around a more restrictive US position. The United States wanted to confine the grant of compulsory licences to "adjudicated violation of competition laws" and "declared national emergency" situations²³ while allowing for more liberal standards on government use.²⁴ Having recognised the writing on the wall with respect to pharmaceutical product patents, India wanted to safeguard its policy options with respect to compulsory licensing. The Indian proposal backed the approach first proposed by the EC,²⁵ and made these conditions common to both government use and compulsory licences of patents, in exchange for an absence of restrictions on the grounds for such measures. From the mid-November 1990 Brussels text,²⁶ successive TRIPs texts did not refer separately to compulsory licences and government use but instead used the broader term proposed by India, "use without the authorisation of the right holder". By insisting on the same set of conditions for both types of non-voluntary use of patent rights, the Indian negotiating tactic—supported by the EC, Japan and Canada (three of the then Quad,²⁷ excluding only the US)—forced some dilution of conditions and achieved considerable flexibility for developing countries in having no restrictions on the grounds of such authorisation.²⁸

On the other hand, many other "flexibilities" came about because of the inability of developed countries to agree to specificities during this period. This was true, for example, on the permissible exceptions and limitations to IPRs contained in art.13 on copyright and related rights and art.30 on patents, where loosely-worded phrases that these exceptions should not conflict with normal exploitation of the right and should not "unreasonably" prejudice the legitimate interests of the right holder, based on art.9(2) of the Berne Convention,²⁹ were adopted. This was also true of the non-violation and situation complaints—where there were, and continue to be, intra-North differences³⁰—as well as of the protection of test data in art.39.3.³¹

However, in large part, the TRIPs language reflects the texts put forward in the first half of 1990 by developed countries due to the relatively united positions adopted by them from the early stages of the negotiations,³² as against the largely divided South, who could only enunciate very general positions in Approach B. It did not help that there was no support from interested persons in the general public, which were instead hostile, at least in developed countries, to the cause espoused by developing countries. Nevertheless, the achievements of developing countries in maintaining a certain balance between the public interest and strengthened IPR protection were small but surprisingly significant. To a large extent, developing countries joined the consensus on the TRIPs Agreement because the flexibilities negotiated into the agreement were seen as important and, with the other parts of the Marrakesh Agreement, did not warrant rejecting the single package of trade agreements that was to constitute the WTO.³³

Moving forward to the end of the transition period given for developing countries for implementing the TRIPs Agreement (other than provisions relevant to pharmaceutical products), namely to the year 2000, we see a complete paradigm shift in the dynamics of negotiations.

²³ MTN.GNG.NG11/W/70, art.27.

²⁴ MTN.GNG.NG11/W/70, art.10; 28 USC s.1498. See also Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement (1999), p.34, on US negotiators' "schizophrenic" approach to compulsory licences and government use.

²⁵ MTN.GNG.NG11/W/68, art.26. This approach listed only conditions and did not restrict the grounds for the grant of compulsory licences. ²⁶ See art.34 of the TRIPs draft text in MTN.TNC/W/35/Rev.1, p.210.

²⁷ The "Quad" is defined on the WTO website as Canada, EC, Japan and the United States. See http://www.wto.org/english/thewto_e/glossary_e /quad_e.htm [Accessed October 31, 2011].

²⁸ Watal, Intellectual Property Rights in the WTO and Developing Countries (2001), Ch.10; Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement (1999), p.34 (wrongly crediting the EC for this tactic).
²⁹ In the case of art.30, the word "unreasonably" also qualifies "normal exploitation", unlike in art.13 of the TRIPS Agreement or art.9(2) of the

²⁷ In the case of art.30, the word "unreasonably" also qualifies "normal exploitation", unlike in art.13 of the TRIPs Agreement or art.9(2) of the Berne Convention.

 ³⁰ Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement (1999), p.82; IP/C/W/349/Rev.1.
 ³¹ See Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement (1999), pp.46–50.

³² These texts were themselves largely based on a June 1988 document prepared by the European, Japanese and US business communities entitled "Basic Framework of GATT Provisions on Intellectual Property".

³³ The counterfactual facing recalcitrant developing countries was engaging in bilateral negotiations on IPRs. In hindsight, these may not have proven more advantageous.

TRIPs and public health: The journey from Geneva to Doha, Cancún and Hong Kong, China

Responding to the global outcry on inadequate access to patented medicines in poorer countries, particularly HIV/AIDS medicines in the Sub-Saharan Africa, and on the case brought by 40 pharmaceutical companies against the South African government on its parallel import regime,³⁴ the WTO Secretariat took the unusual initiative of co-organising with the WHO Secretariat a Workshop on Differential Pricing and Financing of Essential Medicines in Høsbjør, Norway in April 2001.³⁵ In a related development, a week before this workshop, in a TRIPs Council meeting, the African Group requested a special discussion on IP and access to medicines, which was accepted by all³⁶ and which took place in June 2001.³⁷ Given the keen interest in the public about this subject, thanks to active campaigning by developed country-based civil society groups,³⁸ key delegations made their statements available to the press waiting outside the Council meeting immediately after their presentation to the Council, demonstrating how the statements were made as much for public consumption as for other Members.³⁹

Significantly, further work in the WTO on the issue of differential pricing was not accepted by many developing countries, stating that this subject should fall to other intergovernmental organisations, such as the WHO. A substantial group of developing countries, including the African Group, submitted a joint proposal IP/C/W/296 at this meeting for a special declaration on the TRIPs Agreement and access to medicines, which formed the basis of the Doha Declaration.⁴⁰ Thus developing countries spoke in one voice and set the agenda by focusing on clarification of TRIPs flexibilities.

Developed country Members, including the EC, Japan, Switzerland and the United States,⁴¹ accepted, for the first time on the WTO record, in June 2001 that the TRIPs Agreement contained several flexibilities, including compulsory licensing without restrictions on grounds. The United States only hesitated to accept that under art.6 of the TRIPS Agreement, Members had the freedom to permit parallel imports arguing, along with the EC, that parallel imports would defeat the ability of companies to use differential pricing.

However, when it came to making a counter submission to the developing countries' text or to the later more legalistic text⁴³ to help negotiate a declaration, the United States, joined by Australia, Canada, Japan and Switzerland, only came up with general preambular language even as late as one month before the Doha ministerial meeting.⁴⁴ Some ideas from this latter document did find a place in the first part of the Doha Declaration that contains general statements, but in a modified form after the negotiations. Notably, these countries wanted to confine the scope of the Declaration to access to medicines for treatment of HIV/AIDS and other pandemics, such as malaria and tuberculosis, especially by the poorest populations

³⁴ Abandoned finally in April 2001, see http://www.ncbi.nlm.nih.gov/pubmed/11837037 [Accessed October 31, 2011]. Also see WHO and WTO, WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (Geneva: 2011), p. 17, available at http://www.wto.org/english /res_e/booksp_e/who_wto_e.pdf [Accessed October 31, 2011]. ³⁵See the announcement at http://www.wto.org/english/news_e/news00_e/tn_rodrig_sep00_e.htm [Accessed October 31, 2011], and the final report

and presentations at http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm [Accessed October 31, 2011].

See discussion under "Other Business" in IP/C/M/30, pp.67-73

³⁷ See reproduction of statements made by Members in IP/C/M/31. ³⁸ See http://keionline.org/node/1267 [Accessed October 31, 2011].

³⁹ See IP/C/M/31.

⁴⁰ Submitted by Brazil on behalf of the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, the Philippines, Peru, Sri Lanka, Thailand and Venezuela. Later in October 2001 this was made into a more legalistic text in document IP/C/W/312, submitted by Zimbabwe on behalf of the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, the Philippines, Peru, Sri Lanka, Thailand and Venezuela. Only the EC made a written submission, IP/C/W/280.

⁴² IP/C/M/31, pp.8, 40.

⁴³ IP/C/W/312

⁴⁴ IP/C/W/313, which ends with a note stating that clarification language (presumably on TRIPs flexibilities) would be provided, but this never came.

of the globe.⁴⁵ In the end, para.1 of the Doha Declaration referred to the gravity of the public health problems afflicting developing and least-developed countries, especially concerning HIV/AIDS, malaria, tuberculosis and other epidemics.46

A clearer picture emerges from a comparison of the developing countries' legalistic draft of the Doha Declaration. Important parts of the document are found in the Doha Declaration, with only minor modifications.⁴⁷ For example, on parallel imports, the text demands, "Each Member retains the right to establish its own policy and rules regarding the exhaustion of intellectual property rights." The Declaration is stronger and states:

"The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge..."

On compulsory licences, the text demands:

"Each Member has the right to allow other use⁴⁸ of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, and to determine the grounds upon which such use is allowed" (footnote in original text).

The Declaration states more clearly, "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

On the subject of definition of a national emergency, developing countries did not have a text. They picked up the language used by developed country Members in the negotiations following the anthrax scare,⁴⁹ and the proposed government use in the United States of the patented antidote, ciproflaxicin,⁵⁰ that every country had the right to determine what constituted a national emergency and asked that this be put into the Declaration.⁵¹

On test data protection, there was no agreement. Developing countries gave their interpretation of the TRIPs obligation. They stated that art.39.3 "does not require granting 'exclusive rights' to the owner of the data" and that it

"does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any 'unfair commercial use'."52

Both the United States and EC stated that the most effective way of protecting test data against "unfair commercial use" was to ensure that regulatory authorities do not rely on such data for a reasonable period of time (emphasis added).⁵³ By October 2001, developing countries had lowered their ambition and only

⁴⁵ IP/C/W/313, para.1.

⁴⁶ It should not, however, be forgotten that at the same time, these countries, particularly the United States, were taking several initiatives outside the WTO to help countries get access to medicines, including trying to set up the Global Fund to Fight AIDS, Tuberculosis and Malaria at the international level (established in 2002) and later the US President's Emergency Plan for AIDS Relief (PEPFAR) (set up in 2003).

Developing countries pushed their luck by proposing an extension of transition periods for TRIPs implementation, the moratorium on dispute settlement and other issues that were largely ignored.

[&]quot;Other use" refers to use other than that allowed under art.30 of the TRIPs Agreement.

⁴⁹ This was when several letters containing the anthrax spores were found in the United States in the wake of the terrorist attacks of September 11,

^{2001. &}lt;sup>50</sup> See H. Sun, "The Road to Doha and Beyond" (2004) 15 *European Journal of International Law* 123, 133–134, citing leading news reports at the ⁵¹ Personal notes on file with author.

⁵² IP/C/W/296, paras 39–40.

⁵³ IP/C/M/31, p.40; IP/C/W/280, p.4

wanted use of test data by public authorities for public interest reasons, including where a compulsory licence is granted.⁵⁴ In the end, this issue was not pressed and there was nothing on the interpretation of art.39.3 on test data protection in the final Doha Declaration text.

The text of the draft declaration that went to the Doha ministerial meeting on this issue contained only two areas of disagreement. The first one was on the title, and the choice was between the words "intellectual property" and "access to medicines" favoured by some developed countries and "public health" favoured by some developing countries,⁵⁵ which had initially wanted the scope to include nutrition also. In the end, the title retained "The TRIPs Agreement and Public Health". The second disagreement was on the demand of developing countries that "[n]othing in the TRIPs Agreement shall prevent Members from taking measures to protect public health".⁵⁶ The negotiated language in para.4 of the Doha Declaration said, "We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health."

With respect to exports under a compulsory licence, the developing countries' text did not get accepted in the Declaration. It said:

"A compulsory licence issued by a Member may be given effect by another Member. Such other Member may authorise a supplier within its territory to make and export the product covered by the licence predominantly for the supply of the domestic market of the Member granting the licence. Production and export under these conditions do not infringe the rights of the patent holder."57

And later in the same text:

"Under Article 30 of the TRIPs Agreement, Members may, among others, authorise the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members."58

However, no solution could be found for this and, in para.6 of the Doha Declaration, Ministers referred this issue back to the TRIPs Council for an expeditious solution before 2002. The lengthy negotiating process that ensued took almost two years to find a solution.

Turning to the August 2003 Para.6 Decision,⁵⁹ which dealt with the issue of exports under a compulsory licence, it can be seen that the final solution did not reflect the initial position of some developing countries. A comparison of a composite text of all proposals submitted up to July 2002⁶⁰ with the final Para.6 Decision, along with the Decision and the Chairman's statement,⁶¹ brings this out. One difference with the earlier Doha Declaration process was that the nature of the problem and the technical choices to be made by negotiators were not well understood in the general public, and hence there was relatively less interest.⁶²

Another crucial difference was that the African Group separated itself from other developing countries.⁶³ The main divisive issue was the very basis for negotiations—the African Group was clear from the start that the problem was in art.31(f) of the TRIPS Agreement and the solution should be based on this

⁵⁴ IP/C/W/312, para.8 states: "Nothing in the TRIPs Agreement shall prevent Members from disclosing or using information held by its authorities or the patent holder where it is so required for reasons of public interest, including where such disclosure or use is necessary to implement effectively any compulsory licences or other measures adopted by public authorities in the public interest." ⁵⁵ The TRIPs Agreement and Public Health is the title in IP/C/W/312.

⁵⁶ IP/C/W/312, para.1.

⁵⁷ IP/C/W/312 para.5.

⁵⁸ IP/C/W312 para.9. The placement of this proposal far below the previous one may already indicate differences of view among the co-sponsors of this document.

WT/L/540 and Corr.1. ⁶⁰ IP/C/W/363.

⁶¹ GC/M/82, para.29.

⁶² The situation sought to be addressed was a hypothetical one of future sources of supply of generic medicines in countries lacking the capacity to make their own versions of patented medicines during the existence of the patent.

IP/C/W/351 (presented by Kenya on behalf of the African Group); IP/C/W/355 (presented by Brazil on behalf of Bolivia, Brazil, Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela).

provision⁶⁴, whereas the developing countries' group⁶⁵ wanted to have an authoritative interpretation of art.30.⁶⁶ This time both the EC and the United States had well-considered, complete and timely written submissions, based on respect for all conditions of art.31 except para.(f).⁶⁷ In the end, the art.30-approach was dropped (Brazil being the last country to withdraw from it) in deference to the wishes of the group that was considered from the start to represent the main potential beneficiary countries, namely the African Group.

A reading of the composite text of July 2002 shows that, like in April 2001, there was a good deal of agreement at the start of the negotiations on the Para.6 Decision, especially on what eventually turned out to be two of the most contentious issues: (1) the scope of the solution in terms of disease coverage; and (2) the eligible beneficiary or importing countries.

On scope, the United States wanted it restricted to:

"patented pharmaceuticals needed to address a public health problem, *especially* those resulting from HIV/AIDS, malaria and tuberculosis and other epidemics, afflicting a developing or least-developed country Member." (emphasis added)

Meanwhile, Argentina and Brazil did not want to limit the solution in any way to products meant to address diseases specifically mentioned in the Declaration. The EC wanted to include:

"pharmaceutical products needed to deal with public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

Only the African Group went further and said that pharmaceutical products should be understood to include [all] medicines, related technical processes, and related technical equipment.⁶⁸ However, this latter point of view was never strongly pressed.

In the end, consensus emerged (but not without some hiccups—see below) that "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in para.1 of the Declaration. It was explicitly mentioned that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.⁶⁹

On eligible importing countries, all agreed that the solution should be targeted at developing and least-developed countries, with some nuanced differences of view. For example, the United States said that it should be those developing and least developed countries that are afflicted by public health problems, especially those resulting from HIV/AIDS, malaria and tuberculosis and other epidemics, and that have insufficient or no manufacturing capacities in the pharmaceutical sector. The EC basically agreed with this but said that the focus should be on least developed and low-income countries.⁷⁰ In the end, all countries were included in the Decision as "eligible importing Members" except those that voluntarily opted out

⁶⁴ Part of the reason for this was that the African Group wanted an expansive reading of the art.31(f) term "domestic market" so that the term was understood to mean "regional market". The reasoning was that it was only with such a reading that Africa could attract local production of medicines and the concomitant transfer of technology. Eventually, this demand was accommodated separately in para.6 of WT/L/540 as the regional mechanism waiver where there is no WTO notification requirement. It is noteworthy that an Indian company, Cipla, has now set up a modern pharmaceutical manufacturing plant in Uganda with this incentive to be able to export to countries in the East African Community.

⁶⁵ Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela. At the TRIPs Council meeting of June 2002, the Philippines also associated itself with the proposal.

⁶⁶ IP/C/W/363, p.13. In large part, this position of the African Group can be attributed to one negotiator who saw this as a logical way to go. This showed a change of position from the joint position taken in IP/C/W/312, para.9. Due to the technical nature of this issue, mobilisation of public opinion on this was also not tenable.

⁶⁷ See IP/C/W/352 and IP/C/W/358 respectively.

⁶⁸ IP/C/W/363, p.4.

⁶⁹ WT/L/540, para.1(a).

⁷⁰ IP/C/W/363, p.5.

either fully or partially (meaning that they would use the system only in circumstances of urgency).⁷¹ There were 44 opt-out countries—all developed countries and a set of 11 high- and middle-income developing countries.72

A third contentious issue was the legal form that the decision would take-whether it would be a waiver, an amendment or just an understanding/moratorium on dispute settlement-and this was contentious from the start. The African Group and the EC preferred an amendment to art.31 whereas the developing countries' group proposed an authoritative interpretation of art.30, or if necessary an amendment to art.31 (already anticipating a lack of support from the art.30-approach). The latter, however, opposed the dispute settlement moratorium or the long-term waiver of art.31(f) favoured by the United States.⁷³ In the end, the Decision took the form of a long-term waiver set to expire when an amendment replacing it would take effect for the Member concerned.⁷⁴

On a fourth issue, safeguards against diversion, the EC was the main *demandeur*, with the United States not asking for anything more than what the TRIPs Agreement already required of WTO Members. The African Group and the developing countries' group wanted the onus to be on IP right holders, with obligations restricted to what was already in the TRIPs Agreement.⁷⁵ In the end, there were two types of obligations placed: First, obligations are placed, on exporting companies to mark and label their products differently from originator products. They should also use special packaging and/or special colouring or shaping of the products themselves, provided that was feasible and there was no significant impact on price.⁷⁶ Secondly, importing Members must take measures against diversion, but these were heavily circumscribed in the negotiations to be "reasonable", "within their means", "proportionate to their administrative capacities" and "to the risk of trade diversion".77

On a fifth and relatively minor question of double remuneration, there was already some sympathy, if not agreement, with the position of the developing countries' group that there should be no double remuneration and remuneration should be paid by the importing country; for example, both the developing countries' group proposal and the United States, agreed on this, except for the question of who should pay it, with the United States favouring payment in the exporting Member.⁷⁸ In the end, it was decided that the exporting Member would pay it and the importing Member's obligation under art.31(h) would be waived, but the economic value of the authorisation to the importing Member shall be the basis for calculation, a point pressed by the group of developing countries in the negotiations.⁷⁹

However, despite an agreement on all major points in the text of the Decision, consensus could not be reached until August 2003 as the United States clearly could not join the consensus in December 2002 on the scope of the Decision or the disease coverage. This disagreement first surfaced in late 2002 when it became clear through one version of the draft text that para.1 of the Doha Declaration covered all public health problems afflicting developing and least-developed countries, and in particular that it would be difficult to restrict the usage of the term "epidemic" to infectious communicable diseases. As a result, the United States withdrew from joining the consensus on the scope of application of the Decision and maintained its position until December 2002.80

71 WT/L/540, para.1(b).

⁷⁴ WT/L/540, para.11.

⁷⁵ IP/C/W/363, p.10. This was the position also in IP/C/W/296. Many developing countries were not sure if they would ever use the system as importers and did not want to deal with new obligations.

WT/L/540, para.2(b)(ii). 77 WT/L/540, para.4.

79 WT/L/540, para.3.

⁷² See WT/L/540, fn.3 and GC/C/M/82, para.29 for details. 73 IP/C/W/363, pp.16-17.

⁷⁸ IP/C/W/363, p.16.

⁸⁰ IP/C/M/38, para.34.

In early 2003, the United States, which had resisted the idea until then, began negotiating a Chairman's statement that would be agreed to by consensus before the gavelling of the Decision. The initial text proposed by the United States was negotiated only among five Members: the United States, Brazil, India, Kenya, and South Africa. In the end, the negotiated Chairman's statement was presented as "key shared understandings" and read out by the Chair and agreed to before the Decision of August 2003 was adopted.⁸¹ Other statements were made in the General Council after adoption. It can be seen from the statements made that some developing countries had definitive interpretations of these "understandings".⁸²

By holding out for the first eight months of 2003, the United States and its supporters, principally Japan and Switzerland, certainly gained the addition of Chairman's statement. The legal status of the statement is yet to be defined in any dispute at the WTO.⁸³

The fourth and final negotiating process discussed in this article began by end of 2003 with a view to adopting a decision by June 2004 on the amendment to the TRIPs Agreement that would replace the Decision.⁸⁴ The main controversial points were whether the Chairman's statement should form a part of the amended TRIPs text or not (i.e. content) and what legal form the amendment should take.⁸⁵ The US position was that there must be a footnote to art.31(f) of the TRIPs Agreement referring to both the Decision and the Chairman's statement without changing the relationship between them.⁸⁶ Some developing country Members disagreed and claimed that this would give the Chairman's statement a legal status equal to that of the Decision, which was unacceptable.⁸⁷ However, developing countries did not have a clear unified position. Some possibly saw this as an opportunity to open up the art.30 approach, harping upon the words "as appropriate" found in para.11 of the August 2003 decision, which provided for the preparation of an amendment. The African Group, using the same two words, made a submission late in 2004 of a new provision, art.31bis which selectively chose text from the Decision of August 2003-notably deleting para.4 of the August 2003 decision on anti-diversion measures by importing countries—and introduced other changes into the TRIPs text. This did not find support with others, although general statements were made by developing countries that this could be the basis for further work.⁸⁸ Yet others, notably the EC and Switzerland, while open to the footnote approach, were alarmed by the developing countries', and in particular the African Group's, attempt to modify the content of the Decision, and so increasingly favoured a literal and technical transposition of the Decision into the TRIPs text, art.31bis and an annex, with as close a rendering of the scenario as possible to the one leading to the adoption of the Decision in August 2003.89

This stalemate continued until November 2005, even while some Members reported on their national implementing legislation.⁹⁰ The TRIPs Council was suspended in October 2005 to keep open the possibility of recommending a solution by consensus to the General Council before the Hong Kong, China Ministerial conference scheduled for December 13–18, 2005. Mere weeks before the crucial meeting, the United States began negotiating with the African Group and later other key developing countries to find a solution. On December 6, 2005, mere days before the Hong Kong, China meeting, a solution was found by consensus

⁸¹ GC/C/M/82, para.29.

⁸² GC/C/M/82, especially statements of Argentina, Brazil and India.

⁸³ On the legal status of the Chairman's statement, see the discussions in the TRIPs Council prior to the adoption of the Protocol Amending the TRIPs Agreement: Agenda Item H, IP/C/M/43 (meeting of March 8, 2004); Agenda Item H, IP/C/M/44 (meeting of June 16, 2004); Agenda Item H, IP/C/M/47 (meeting of March 8, 9 and 31, 2005); Agenda Item G, IP/C/M/49 (meeting of October 25, 26 and 28, November 29, and December 6, 2005).
⁸⁴ In accordance with WT/L/540, para.11. Much of this part of the article is drawn from the author's notes, but reference to WTO documents in the

⁸⁴ In accordance with WT/L/540, para.11. Much of this part of the article is drawn from the author's notes, but reference to WTO documents in the public domain is made where appropriate.
⁸⁵ This controversy even led to WT/L/540/Corr.1, which makes it clear that the asterisked fn. in WT/L/540 is a Secretariat note for information

²⁴ This controversy even led to W1/L/540/Corr.1, which makes it clear that the asterisked in. in W1/L/540 is a Secretariat note for information purposes only and without prejudice to Members' legal rights and obligations.

⁸⁶ IP/C/W/444, para.9.

⁸⁷ See in particular the African Group's submission IP/C/W/440 and Corr.1, and Argentina's arguments from IP/C/M/44, paras 78–84.

⁸⁸ IP/C/W/437; IP/C/M/48 (statement by Brazil).

⁸⁹ IP/C/M/43–49.

⁹⁰ IP/C/M/43-49.

to technically adapt the August 2003 Decision as an amendment and adopt the Protocol to amend the TRIPs Agreement, with the text of a new art.31bis, along with an annex and an appendix,⁹¹ with a re-reading of the chairman's statement of August 2003 with another statement to prevent any a contrario reading of the applicability of non-violation and situation complaints to the TRIPs Agreement. Much time was spent on procedural issues such as what would go into the main text of art.31bis, the annex and the appendix. In the end, the approach of the United States and its supporters was not accepted.

Conclusion

So what are the main lessons to be drawn from the results of the methodology used in this article to judge success or failure in TRIPs negotiating processes? One important lesson seems to be that a genuine coalition presenting a coherent, united front is more likely to succeed than not; negotiating proposals need to be specific and credible. An important factor contributing to the credibility of negotiating positions appears to be support gained from the interested public outside, especially civil society groups in developed countries.

In the Uruguay Round TRIPs negotiations, at least on most North-South issues,⁹² the *demandeurs*, US, EC, Japan, and Switzerland, presented fairly coordinated and specific written proposals by early 1990, demanding substantially higher standards of intellectual property protection from developing countries, despite significant differences in initial positions and laws or practices among themselves. The key developing countries were, on the other hand, disunited, and presented incoherent or general positions in their written proposal.⁹³ They also were seen by key opinion-making public as pirates and counterfeiters. However, despite this, just prior to the Brussels meeting, developing countries did attempt to participate constructively in the TRIPs negotiations and made strategic issue-based alliances presenting specific proposals, which improved their credibility and led to successes such as on parallel imports and compulsory licences. As can be seen from a comparison of the July 1990 text, the Brussels text and the final TRIPs text, much of the progress on TRIPs flexibilities was achieved by developing countries in the second half of 1990.

Again in the public health negotiations on the Doha Declaration between Geneva and Doha, the main reason for the successes won by developing country negotiators was the considerable preparatory work done, the unity in the ranks and the coherence and consistency of positions. This was backed by global public opinion, which in the face of the tragic consequences of the HIV/AIDS pandemic in sub-Saharan Africa had swung against the research and development-based pharmaceutical industry, leading to the African Group in particular gaining the moral high ground in WTO negotiations. In contrast, developed countries were divided in 2001 (especially the two majors: the EC and the United States). There was a lack of coherence and focus, with no complete text proposal possible before the Doha ministerial meeting.

However, in contrast, the final Para.6 Decision did take account of the initial positions of the United States and EC, which were both better prepared and coordinated than in 2001. The developing countries' group was split between the African Group and other key developing country delegations. Here pressures from the civil society-informed public, while key to concluding negotiations, did not play a role in differentiating between the various technical positions taken therein.⁹⁴ The Para.6 Decision deals with a more nuanced problem, and the pros and cons of its technical details were probably more difficult to grasp.

⁹¹ IP/C/M/49; WT/L/641.

⁹² The major issues in the TRIPs negotiations were of a "North-South" nature although there were a number of contentious issues within the North, notably geographical indications, on which future work on a multilateral register for wines and spirits incorporated into the TRIPs Agreement continues to date.

As can be seen from a reading of GNG.NG11/W/71 as against the detailed texts put forward by developed countries.

⁹⁴ For instance, there was no public support to developing countries who wanted to follow the art.30 approach.

Negotiations on the Protocol were limited in content. In the end, the US position on introducing only a footnote into the TRIPs text was not accepted and the position that had a broader North-South support, namely the technical transposition of the August 2003 scenario, won the day. Again, while there was pressure from the informed public as well as from the African Group to conclude negotiations, there could hardly be any inputs on what the technical details of the decision should be.

Finally, bearing testimony to the immense influence of public opinion in concluding the public health negotiations, especially during WTO ministerial meetings held since Seattle in 1999, it is striking that the final rush to reach agreements on public health happened either at WTO ministerial meetings or just before them, the pattern being repeated from Doha to Cancún to Hong Kong.

Change and Continuity in the International Intellectual Property System: A Turbulent Decade in Perspective

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Proveloping countries; Intellectual property; International trade; TRIPs

The international intellectual property system has witnessed a "turbulent" decade. In the span of a few years, it has been confronted with a series of major challenges including the implementation of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the exponential growth in the demand for intellectual property rights, the proliferation of international fora dealing with intellectual property matters, the conclusion of bilateral, regional and plurilateral agreements with far reaching intellectual property provisions and growing tensions between on one hand a potent drive for stronger enforcement of intellectual property rights and on the other hand a forceful push for greater access to medicines, technologies and knowledge.

This article will focus on the two most important set of challenges from the perspective of developing countries and civil society, namely the relationship between the international intellectual property system and public policy objectives in the areas of health, biodiversity and climate change and the manner in which the system has addressed public interest demands and development concerns. Coincidentally, these are also the challenges that brought worldwide attention to intellectual property, which had remained until the late 1990s a self-contained technical area of regulation largely absent from wider policy debates.

In examining the responses by the international intellectual property system to these challenges, the article will seek to answer several pressing questions which have become the "elephant in the room" of the global intellectual property policy debate: To what extent has the international intellectual property system changed? Have efforts to achieve a more balanced and development-oriented intellectual property system borne their fruits—and should the page thus be turned on the mobilisation around these issues that characterised the past decade? Seeking to answer these questions is a perilous task. Because there is no shared understanding of what constitutes "change" in the international intellectual property system or of any agreed "indicators" to measure such a change, perceptions of change are likely to vary considerably from one stakeholder to another. Bearing this in mind, this article seeks to identify changes at four different levels: policy discourse, normative landscape, technical solutions and outcomes. It is at best a preliminary and partial contribution towards a better understanding of the dynamics at work in the international intellectual property system and of the direction in which it might be heading.

* The views expressed in this article are those of the author and do not necessarily reflect the views of any institution with which he is affiliated.

Intellectual property and public policy objectives: Denial, recognition and persistent controversy?

During the past decade, the relationship between intellectual property and public policy objectives—in areas such as public health and access to medicines, biodiversity and climate change¹—has been at the forefront of the globalisation debates.

From the traditional viewpoint of the intellectual property system, public policy objectives in these areas lay beyond the realm of the system, and solutions to tackle these objectives should thus be sought "outside" of it. However, there has been a growing recognition, particularly at the level of the policy discourse in recent years, that the international intellectual property system should not shy away from policy debates relating to these objectives. Instead, the system should actively "engage" with these debates and consider possible means of making a "positive" contribution to broader efforts and solutions to address them.

This evolution has been particularly noticeable at the World Intellectual Property Organization (WIPO) where a Global Challenges Division was established to address public policy issues as part of the strategic realignment process led by Francis Gurry, the new WIPO Director General elected in 2008. Commenting on this move, Gurry stated: "In the past, WIPO has not engaged in these issues, so we want to move from isolationism to engagement."² In July 2009, WIPO organised a major Conference on Intellectual Property and Public Policy Issues to address:

"the interface of intellectual property with other areas of public policy, notably health, the environment, climate change ... and serve as a global forum to discuss issues and solutions to some of the major challenges in relation to intellectual property the world faces today."³

The evolution has also been perceptible at the WTO where the intellectual property division, headed by a new director since 2009, has been active, for instance, in the policy debate on intellectual property and climate change, even though that topic has not been formally raised in TRIPs Council discussions.⁴

The debate on patents and access to medicines has been instrumental in fostering this policy change. The Doha Declaration on TRIPs and Public Health (Doha Declaration) was a particularly important milestone in this regard. In it, WTO members, while reiterating their commitment to the TRIPs Agreement, affirmed 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."⁵

The WTO General Council Decision of August 30, 2003 subsequently authorised WTO Members to grant compulsory licenses for the production and export of generic medicines to developing countries and least developed countries (LDCs) with insufficient or no manufacturing capacity in the pharmaceutical sector.⁶ This so-called "Paragraph 6 solution" was formalised as an amendment to the TRIPs Agreement in 2005.

¹ The relationship between intellectual property and food security and between intellectual property and agriculture will not be addressed in this section as there is no specific policy process devoted to discussing these issues at the international level.

² A. Smith, "Gurry Evaluates Historic WIPO Reform Project", World Trademark Review, February 3, 2009, available at http://www .worldtrademarkreview.com/daily/detail.aspx?g=73312b61-f7f5-410e-88dd-1389c01429f8 [Accessed November 17, 2011].

³ "WHO conference on Intellectual Property and Public Policy Issues", July 2009, available at *http://www.wipo.int/meetings/en/2009/ip_gc_ge/* [Accessed November 17, 2011].

⁴ e.g. Symposium for Policymakers on "Trade, Technology and Climate Change Linkages: The Current Debate", jointly sponsored by the WTO and the Faculty of Law at the University of Copenhagen, December 12, 2009, available at *http://www.wto.org/english/tratop_e/envir_e/sym_dec09_e/sym_dec09_e.htm* [Accessed November 17, 2011].

⁵ "Declaration on the TRIPs Agreement and Public Health", November 14, 2001, WT/MIN(01)/DEC/2, para.4, available at http://www.wto.org /english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [Accessed November 17, 2011]. ⁶ "WTO General Council Decision of August 30, 2003", WT/L/540 and Corr.1, September 1, 2003, available at http://www.wto.org/english/tratop

^o "WTO General Council Decision of August 30, 2003", WT/L/540 and Corr. 1, September 1, 2003, available at *http://www.wto.org/english/tratop* _e/trips_e/implem_para6_e.htm [Accessed November 17, 2011].

In 2008, the World Health Organization (WHO) adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), which aims to:

"promote new thinking in innovation and access to medicines, which would encourage needs-driven research rather than purely market-driven research to target diseases which disproportionately affect people in developing countries."7

The following year, UNITAID established the Medicines Patent Pool (MPP) as an independent entity with the mission to increase access to affordable medicines, focusing on HIV/AIDS by negotiating with patent holders to share their intellectual property with the Pool and then licensing it to other producers to facilitate the production of affordable generic medicines.⁸ In addition, the WTO, WHO and WIPO have strengthened their cooperation on the interface between intellectual property and public health,⁹ jointly organising a number of technical meetings to examine challenges facing access to medicines, such as pricing and procurement practices¹⁰ and patent information.¹¹

Public private and product development partnerships have also become an important feature of the global health landscape in the context of efforts to expand access to medicines and to develop new treatments. For instance, the Drugs for Neglected Diseases Initiative (DNDi) was established in 2003 as a non-profit drug research and development (R&D) organisation that is developing new treatments for neglected diseases such as sleeping sickness and the Chagas disease.¹²

At the level of the policy debate, the evolution in WIPO's positioning is one of the noticeable changes that have taken place in recent years. In effect, during most discussions on patents and access to medicines and particularly in the earlier phase, WIPO had adopted a rather low profile and stayed at a cautious distance. The views of WIPO's Secretariat on the matter were reflected in a publication whose stated aim was to challenge a number of "myths" such as the one that "high drug costs are primarily due to the patent system".¹³ In 2002, the organisation's approach to promoting intellectual property—in particular, its technical assistance and legislative advice to developing countries, in the context of TRIPs implementation—came under criticisms for not adequately incorporating health-related TRIPs flexibilities.¹⁴

Since then, WIPO's views have become more nuanced.¹⁵ The organisation's growing cooperation with the WTO and WHO stands in contrast to its past isolation. More generally, WIPO is becoming a more active player in this area. On October 26, 2011, it launched WIPO Re: Search, an initiative aimed at encouraging research and development of medicines, vaccines and diagnostics for neglected tropical diseases and facilitating the discovery of new solutions to tackle the diseases.¹⁶

⁷ See http://www.who.int/phi/implementation/phi globstat action/en/index.html [Accessed November 17, 2011]. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was adopted by World Health Assembly Resolution WHA 61.21, available at http://www.who.int/phi/documents/en/ [Accessed November 17, 2011].

See Medicines Patent Pool, "Mission: Increasing Access to Appropriate Medicines", available at http://www.medicinespatentpool.org/WHO-WE -ARE2/Mission [Accessed November 17, 2011].

 ⁹ See http://www.wio.org/english/tratop_/trips_issues_e.htm [Accessed November 17, 2011].
 ¹⁰ WHO, WIPO and WTO, "Access to Medicines: Pricing and Procurement Practices: A Joint Technical Symposium", July 16, 2010, available at //www.wipo.int/pressroom/en/articles/2010/article_0022.html [Accessed November 17, 2011].

http://www.wipo.int/pressroom/en/articles/2010/article_0022.html [Accessed November 17, 2011]. ¹¹ WHO, WIPO and WTO, "Access to Medicines, Patent Information and Freedom to Operate: A Joint Technical Symposium", February 18, 2011, available at http://www.who.int/phi/access_medicines_feb2011/en/ [Accessed November 17, 2011].

See http://www.dndi.org/index.php/overview-dndi.html?ids=1 [Accessed November 17, 2011].

¹³ WIPO, "Striking a Balance: The Patent System and Access to Drugs and Health Care", available at http://www.wipo.int/freepublications/en/archive *jsp* [Accessed November 17, 2011]. The publication is not dated, but a document search on WIPO's website indicates its availability for 2003.

Health Action International, Médecins sans Frontières, Consumer Project on Technology and Oxfam, "Implementation of the Doha Declaration on the TRIPs Agreement and Public Health: Technical Assistance-How to Get It Right", March 28, 2002, available at http://www.haiweb.org/campaign /access/reportpostDoha.html [Accessed November 17, 2011]; Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (London: 2002).

See http://www.wipo.int/patent-law/en/developments/publichealth.html [Accessed November 17, 2011].

¹⁶Roundtable Discussion, "WIPO Re: Search—Sharing Innovation in the Fight Against Neglected Tropical Diseases", October 26, 2011, available at http://www.wipo.int/meetings/en/2011/wipo_gc_inn_ge_11/[Accessed November 17, 2011]

In May 2011, the African Group and the members of the Development Agenda Group (DAG), a group of like-minded developing countries at WIPO, made a submission to the WIPO Standing Committee on Patents (SCP), calling for the adoption of a work programme on patents and health.¹⁷ In their submission, they emphasised that "the patent system should be consistent with fundamental public policy priorities, and in particular the promotion and protection of public health".¹⁸ The debate seems to have come to a full circle a decade after African countries and other developing countries raised the matter at the WTO TRIPs Council for the first time.

The situation on the ground has also changed drastically. As of December 2009, an estimated 5.2 million people living with HIV in low- and middle-income countries were receiving antiretroviral therapy, a 12-fold increase since 2003.¹⁹ The annual price of first-line antiretroviral drugs significantly decreased from over US \$10,000 per person in 2000 to less than US \$116 for the cheapest WHO-recommended first-line antiretroviral regimen in the first quarter of 2010, a reduction of nearly 99 per cent.²⁰

Despite positive developments at the policy, normative and technical levels, the record in terms of outcomes remains mixed with regard to the implementation of the Doha Declaration. According to one study:

"between 2001 and 2007, 52 developing and least developed countries have issued post-Doha compulsory licenses for production or import of generic versions of patented medicines, given effect to government use provisions, and/or implemented the non-enforcement of patents. In addition, many countries have used the flexibilities as leverage in price negotiations with patent-holding pharmaceutical companies."²¹

However, reactions have been "harsh" by industrialised countries and multinational companies when TRIPs flexibilities are used in emerging economies, particularly when used for addressing non-communicable diseases, such as in the case of Thailand during 2006–2008. It is also pointed out that "TRIPs-plus provisions in free trade agreements, trade retaliation and political pressures all have seriously impeded the full use of the Doha Declaration".²²

In a joint publication released in March 2011, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP) and the WHO expressed their "concerns about the long-term sustainability of access to affordable HIV treatment". These organizations:

"urged countries, where appropriate, to use the intellectual property and trade flexibilities set out in the TRIPs Agreement and the Doha Declaration on the TRIPs Agreement and Public Health, in order to reduce the price of HIV medicines and expand access to people most in need."²³

The publication found that, "despite the opportunities provided by TRIPs flexibilities, many countries have yet to amend their laws to incorporate optimally the flexibilities, which is a precondition for their use".²⁴ In addition, only a handful of developing countries—including Brazil, Indonesia, Malaysia, Mozambique, Thailand, Zambia and Zimbabwe—were found to have made effective use of compulsory licensing.²⁵

¹⁷ "Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group", May 18, 2011, SCP/16/7, available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=22164 [Accessed November 17, 2011].

¹⁸ "Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group", May 18, 2011, SCP/16/7, available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=22164 [Accessed November 17, 2011].

¹⁹ WHO, "New Progress and Guidance on HIV Treatment: Fact Sheet" (Geneva: 2010), available at http://www.who.int/hiv/vienna2010/en/index html [Accessed November 17, 2011].

²⁰ See WHO, Global Price Reporting Mechanism, *Transaction Prices for Antiretroviral Medicines and HIV Diagnostics from 2008 to March 2010* (Geneva: 2010), available at http://www.who.int/entity/hiv/pub/amds/GPRMsummary_report_may2010.pdf [Accessed November 17, 2011].

E.F.M. 't Hoen, The Global Politics of Pharmaceutical Monopoly Power (Diemen: AMB Publishers, 2009), p.xvi.
 't Hoen, The Global Politics of Pharmaceutical Monopoly Power (2009), p.xvii.

²³ UNAIDS, WHO and UNDP, Using TRIPs Flexibilities to Improve Access to HIV Treatment (Geneva: 2011).

²⁴ UNAIDS, WHO and UNDP, Using TRIPs Flexibilities to Improve Access to HIV Treatment (2011).

²⁵ UNAIDS, WHO and UNDP, Using TRIPs Flexibilities to Improve Access to HIV Treatment (2011).

In a 2010 submission to the SCP, Brazil provided a revealing account of its experience in using compulsory licensing:

"During the post WTO period, after a long period of negotiations, the government of Brazil decided in May 2007 to sanction the compulsory licensing of an antiretroviral drug in order to address urgent public health problems. Our country then suffered an intense discredit campaign led by some international actors, as if it was ignoring the rules agreed by all WTO Members, with which we fully complied. The defamatory process cast on Brazil an inconvenient image of a piracy-lenient country. Is this what we should expect from the supporters of the current system?"²⁶

A recent high-level United Nations Meeting on the Prevention and Control of Non-communicable Diseases, held in September 2011, witnessed controversy regarding the possible inclusion of a reference to both the term "epidemics" and the Doha Declaration in the final document to be endorsed by the meeting. According to news reports, the European Union and the United States insisted on removing references to the term "epidemic" in the final text to avoid making an implicit link between non-communicable diseases and the Doha Declaration, which recognises:

"the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."27 (emphasis added)

Ultimately, the Declaration adopted by the meeting considers non-communicable diseases a challenge of "epidemic proportions". It does not mention the Doha Declaration, although it makes reference to the "the full use of trade-related aspects of intellectual property rights (TRIPs) flexibilities".28

This example provides a good illustration of the symptomatic efforts by some industrialised countries during the past decade to promote restrictive interpretations of the Doha Declaration, particularly with regard to the scope of diseases covered and of the circumstances triggering its application. From their viewpoint, the Declaration should only apply to infectious diseases (such as HIV/AIDS, tuberculosis and malaria). It should also be invoked in only cases of national emergencies, arguments that have been dismissed by legal scholars closely involved in these discussions.²⁹

With regard to the para.6 solution, it has been used only once since its enactment in 2003 for a shipment of HIV/AIDS drugs from Canada to Rwanda in 2008. The extent of its effectiveness, particularly in light of its procedural requirements, is the subject of a heated debate at the TRIPs Council.³⁰

Overall, there seems to be differing responses from industrialised countries and multinational drug companies. While LDCs in Africa are left alone "when they take measures to set aside patents", middle-income developing countries in Asia and Latin America "face huge trade disputes if they take the same measures".³¹ The explanation seems to lie in the fact that Asian and Latin American countries represent significant growth markets for the pharmaceutical industry at a time when its sales are stagnating in high-income countries. Reflecting on this, one observer makes the following stark prediction:

^{26 &}quot;Proposal from Brazil", January 20, 2010, SCP/14/7, para.17, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=183186 [Accessed November 17, 2011]. 27"Nestle, Glaxo Lobby UN over Biggest 'Epidemic' Battle Since AIDS", *Business Week*, September 16, 2011, available at http://www.businessweek

[.]com/news/2011-09-16/nestle-glaxo-lobby-un-over-biggest-epidemic-battle-since-aids.html [Accessed November 17, 2011].

²⁸ "Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases", September 16, 2011, A/66/L.1, available at http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1 [Accessed November 17, 2011].

F. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005) 9 American Journal of International Law 317.

^{30 &}quot;IP Enforcement Tensions at WTO; Health Amendment Extended Again", Intellectual Property Watch, October 26, 2011, available at http://www *ip-watch.org/weblog/2011/10/26/ip-enforcement-tensions-at-wto-health-amendment-extended-again/*[Accessed November 17, 2011]. ³¹ 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (2009), p.66.

"The de facto position of rich countries that the use of the Doha Declaration should only be condoned in the poorest countries, where manufacturing capacity is extremely limited, may over time have disastrous consequences for access to medicines."³²

In any case, the patents and access to medicines debate appears to have cast its shadow over intellectual property-related discussion in other settings such as climate change, in particular since the 13th Conference of the Parties (COP) of the United Nations Framework Convention on Climate Change (UNFCCC), held in Bali in 2007. The Bali Action Plan called for:

"enhanced action on technology development and transfer ... including, inter alia, consideration of effective *mechanisms* and enhanced means for the removal of *obstacles* ... for scaling up of the development and transfer of technology to developing country Parties in order to promote access to *affordable* environmentally sound technologies."³³ (emphasis added)

In this context, developing countries have argued that intellectual property rights could be one of the possible obstacles to achieve large-scale affordable access to climate-friendly technologies. These countries have also made an explicit analogy with the situation of patents and public health. For example, in his address to the United Nations New Delhi Conference on "Climate Change: Technology Development and Transfer", held in October 2009, the Prime Minister of India stated:

"The climate friendly and environmentally sound technologies should be viewed as global public goods ... Suitable mechanisms must be found that will provide incentives for developing new technologies while also facilitating their deployment in developing countries at affordable cost. Such an approach has been adopted successfully in the case of pharmaceutical technologies for the benefit of HIV/AIDS victims in developing countries. The moral case of a similar approach for protecting our planet and its life support system is equally compelling."³⁴

Consequently, developing countries have advanced a number of options to address the role of intellectual property rights in the climate change discussions. These options range from the exclusion of climate-friendly technologies from patentability in developing countries and LDCs to full and expanded use of existing TRIPs flexibilities, including compulsory licenses, through a "Doha" type solution.³⁵ However, industrialised countries and the private sector have strongly opposed such proposals stressing the need for protecting and enforcing intellectual property rights in order to promote technological innovation and incentivising investments from the private sector. For instance, the European Union stressed prior to the 2009 Copenhagen Conference that:

"a weakening of intellectual property protection of technologies for climate change mitigation and adaptation would risk slowing down technological development in this field, thus hampering the fight against climate change."³⁶

The representative of one major private sector player in the area of clean energy has repeatedly underlined that:

³² 't Hoen, The Global Politics of Pharmaceutical Monopoly Power (2009), p.67.

³³ United Nations Framework Convention on Climate Change, Bali Action Plan, March 14, 2007, FCCC/CP/2007/6/Add.1, para.1(d), available at http://unfccc.int/resource/docs/2007/cop13/eng/06a01.pdf [Accessed November 17, 2011].

³⁴ Prime Minister of India, "Address at the New Delhi High Level Conference on 'Climate Change: Technology Development and Transfer'", October 22, 2009, available at http://pmindia.nic.in/speech/content.asp?id=832 [Accessed November 17, 2011].

³⁵ The pre-Cancun UNFCCC negotiating text lists such options in brackets under option 2 in the chapter on technology development and transfer. Under option 1, there would be "no reference to [intellectual property rights] in the text". See UNFCCC/AWGLCA/2010/14, Ch.4, para.13, available at http://unfccc.int/resource/docs/2010/awglca12/eng/14.pdf [Accessed November 17, 2011].

³⁶European Commission, "Enhancing Development and Transfer of Technology", available at http://ec.europa.eu/clima/events/0013/info_sheet _technology_final_en.pdf [Accessed November 17, 2011].

"owing to the diversity of climate technologies and the fundamental differences with the pharmaceutical and chemical sectors, lessons could not be drawn from the debates ... on access to medicines."³⁷

A strongly polarised policy debate has ensued, resulting in a total impasse. All references to intellectual property rights in the post-Bali UNFCCC negotiating texts have remained in brackets, as it is the practice when there is no agreement on an issue or on its wordings in multilateral negotiations. Although the Cancun Conference in November 2010 agreed to create a Technology Mechanism to enhance accelerated technology transfer of climate-friendly technologies, there was no agreement to mention intellectual property rights in the final text of the Cancun Agreements.³⁸

Since then, several developing countries have indicated the need to "bring back" intellectual property rights into the climate change negotiations. In April 2011, at a workshop on the newly created Technology Mechanism, China, Ecuador, Bolivia, and Bangladesh specifically mentioned that the Mechanism should address the role of intellectual property rights.³⁹ India has made a formal proposal to add intellectual property, among several other issues, to the agenda of the UNFCCC conference to be held in Durban at the end of 2011.⁴⁰

In what concerns the relationship between intellectual property and biodiversity, the past decade has witnessed an extensive policy debate, which has led to greater awareness and better understanding of the issues at stake. The very idea that measures should be envisaged in the context of the international intellectual property system to prevent the misappropriation of genetic resources and associated traditional knowledge is gaining adherence among a growing number of countries. However, strong disagreements persist about the nature of such measures and their legal effects. At the level of the normative landscape and the outcomes, the situation remains virtually the same as the one prevailing a decade ago.

In this regard, the relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD), which was the root cause of the debate on intellectual property and biodiversity, is still unresolved. More than a decade after the TRIPs Council began examining this relationship in 2001, developing countries continue to request an amendment to the TRIPs Agreement with the aim of incorporating, as evidence of prior informed consent and benefit-sharing, a disclosure requirement for determining the country of origin of any biological material and associated traditional knowledge in patent applications. Their latest proposal, in this regard, was submitted to the TRIPs Council in April 2011.⁴¹ However, that proposal continues to face strong opposition and has little chance of being concretised in any near future, more so in the context of the current stalemate in the Doha Round of Trade Negotiations.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation (Nagoya Protocol) represents an important development in the context of the CBD and has bearing for deliberations at the WTO and WIPO. It aims at sharing the "benefits arising from the utilisation of genetic resources in a fair and equitable way".⁴² The latest proposal by developing countries to the TRIPs Council mentioned above, in fact, builds on several of the legal outcomes of the Nagoya Protocol. It is noteworthy to mention that, during the negotiations leading to the Protocol's

³⁷ Intervention by General Electric representative at the 2011 WTO Public Forum, Session 38: "Strategies for Promoting Green Innovation and Disseminating Environmentally Friendly Technologies—What Role for Intellectual Property?", available at *http://www.wto.org/english/news_e/news11 e/pfor_am_21sp11_e.htm* [Accessed November 17, 2011].

^{3§} A. Abdel Latif, *The Climate Technology Mechanism: Issues and Challenges* (Geneva: ICTSD, 2011), available at *http://ictsd.org/i/publications* /103789/[Accessed November 17, 2011].

³⁹ Presentations are available at *http://unfccc.int/meetings/awg/items/5928.php* [Accessed November 17, 2011].

⁴⁰ "Proposals by India for Inclusion of Additional Agenda Items in the Provisional Agenda of the Seventeenth Session of the Conference of the Parties—Addendum", October 7, 2011, FCC/CP/2011/INF.2/Add.1, available at http://unfccc.int/resource/docs/2011/cop17/eng/inf02a01.pdf [Accessed November 17, 2011].

⁴¹ "Draft Decision to Enhance the Mutual Supportiveness Between the TRIPS Agreements and the CBD: Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group", April 19, 2011, TN/C/W/59, available at *http://wto.org/english/tratop_eltrips_elta_docs_el4_tncw59_e.pdf* [Accessed November 17, 2011].

⁴² See http://www.cbd.int/abs/ [Accessed November 17, 2011].

adoption, proposals to include a reference to the disclosure obligation in patent applications were not retained.⁴³ Also rejected was the developing countries' suggestion that patent offices be mentioned as one of the possible "check points" to collect or receive relevant information regarding the utilisation of genetic resources in the context of the monitoring system instituted by the Protocol.⁴⁴ These examples show the reluctance of industrialised countries to have intellectual property related matters addressed in the context of discussions taking place under the aegis of the CBD.

At WIPO, more than a decade after the creation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2001, the Committee has not yet reached any concrete outcome in terms of norm setting. In the past two years, the IGC witnessed an acceleration of its work with the move towards "text based" negotiations and the constitution of expert working groups.⁴⁵ The 2011 WIPO General Assembly renewed the IGC's mandate for two years and asked it to:

"expedite its work with the objective of reaching agreement on a text(s) of an international legal instrument(s) which will ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions."

The IGC is further requested to submit these text(s) to the 2012 General Assembly which will take stock of the texts(s), consider the progress made, and decide on convening a diplomatic conference.⁴⁶

While there has been progress in discussions on a single consolidated text containing specific provisions in relation to the protection of traditional knowledge and traditional cultural expressions (or folklore), the stalemate persists in the area of genetic resources, particularly in view of disagreements concerning the disclosure issue. Even with regard to traditional knowledge and traditional cultural expressions, where progress has been made, important differences in positions continue to exist regarding the legal nature of the future instrument(s), subject matter of protection, beneficiaries, scope of protection and limitations and exceptions.⁴⁷

If consensus is to be reached on an instrument(s) for the protection of genetic resources, traditional knowledge and traditional cultural expressions at the IGC, it is most likely that such instrument(s) will contain weak and largely diluted provisions that would give countries considerable leeway in national implementation. The instruments therefore might be of limited effectiveness in achieving their intended purpose. Most importantly, there will be no obligation on WIPO member states, particularly industrialised countries, to adhere to these instruments—as is the case of international treaties concluded under WIPO. The instruments also will not be backed by dispute settlement mechanisms.

Ultimately, from a developing country perspective, possible outcomes reached at WIPO in the context of the IGC discussions should be seen as complementary to proposals made at the TRIPs Council regarding the adoption of a mandatory disclosure requirement. From the perspective of industrialised countries, however, the conclusion of such instrument(s) at the IGC would have the advantage of leaving international patent rules enshrined in TRIPs untouched. The manner in which developed countries presently consider WIPO as the appropriate forum for addressing these issues is ironic considering that these same countries pushed for the inclusion of intellectual property in the framework of the multilateral trading system, arguing that WIPO agreements had no teeth!

⁴³ "Developed Countries Reject Mandatory Disclosure Requirements", South-North Development Monitor, October 18, 2010, available at http://www.biosafety-info.net/article.php?aid=726 [Accessed November 17, 2011].

⁴⁴ "ABS Text Advances in Montreal, but Much Work Remains", *Bridges Trade BioRes*, July 19, 2010, available at *http://ictsd.org/i/trade-and* -sustainable-development-agenda/81017/ [Accessed October 26, 2011].

 ⁴⁵ "WIPO Committee Increases Pace of Talks on Traditional Knowledge", *Bridges*, May 12, 2010, available at *http://ictsd.org/i/news/bridgesweekly* /75744/ [Accessed October 26, 2011].
 ⁴⁶ "WIPO Traditional Knowledge Committee on Way to New Mandate", *Intellectual Property Watch*, July 22, 2011, available at *http://www.ip*

⁴⁷ WIPO Iraditional Knowledge Committee on Way to New Mandate", *Intellectual Property Watch*, July 22, 2011, available at *http://www.ip-watch.org/weblog/2011/07/22/wipo-traditional-knowledge-committee-on-way-to-new-mandate/*[Accessed November 17, 2011].

^{41 &}quot;WIPO Traditional Knowledge Committee on Way to New Mandate", Intellectual Property Watch, July 22, 2011, available at http://www.ip -watch.org/weblog/2011/07/22/wipo-traditional-knowledge-committee-on-way-to-new-mandate/ [Accessed November 17, 2011].

In the same vein, proposals by Switzerland and the European Union to introduce the disclosure of source of genetic resources and traditional knowledge in patent applications under the Patent Cooperation Treaty (PCT)⁴⁸ would only be optional. The Swiss proposal would modify certain PCT regulations to "explicitly enable the national patent legislation" to require the declaration of the source of genetic resources and traditional knowledge in patent applications. Such modification would allow disclosure to take place at the national level or later during the international phase.⁴⁹ Although these proposals reflect a perceptible evolution in the positions of these countries if compared with the early phase of the discussion on this issue a decade ago, they are not ambitious enough from the viewpoint of developing countries which favour the WTO as the primary forum to address this matter for the reasons mentioned above.

This condensed overview of developments during the past decade shows that there has been an intense policy debate regarding the interface between the international intellectual property system and public policy objectives. In the case of public health, the policy debate has been vigorous and fruitful in bringing forth a change in the normative landscape as reflected in the Doha Declaration, though its record of implementation is mixed in terms of both outcomes and the ability to develop more practical and technical solutions. In the case of climate change, the policy debate has been unproductive and continues to witness a strong polarisation in positions. With regard to biodiversity, the policy debate has been constructive leading to greater awareness and recognition of challenges faced, although agreement on normative solutions remains elusive, particularly with regard to the introduction of a mandatory disclosure requirement in patent applications.

In general, the positions of most industrialised countries and the private sector in these discussions seem to have hardened significantly over the past decade. In the context of climate change discussions, they have not even agreed to mentioning intellectual property rights in the negotiating texts in fear of embarking on a "slippery slope" that would end up repeating the Doha precedent of "relaxing" global intellectual property rules to accommodate public policy objectives. However, the existence of fundamental differences between the pharmaceutical sector and the clean energy sector is increasingly recognised.⁵⁰ Recent empirical studies have also shown that patterns of patent ownership and licensing practices in clean energy mitigation technologies do not differ significantly from those in other fields of technologies.⁵¹ At the same time, concerns that intellectual property rights may have an adverse impact on technology transfer are also well established, in the context of both the TRIPs Agreement⁵² and environmental discussions.⁵³

In fact, the debate about intellectual property and access to environmentally sound technologies predates the one on patents and access to medicines. The issue had already received significant attention at the first Rio Summit in 1992. Chapter 34 of Agenda 21, one of the key policy documents adopted at the Summit, extensively elaborated on this matter. It even included a reference to the use of compulsory licensing.⁵⁴

- UN Environment Programme, European Patent Office and ICTSD, Patents and Clean Energy (Geneva: 2010).
- ⁵² TRIPs Agreement, art.8(2).

⁴⁸ The PCT is an international instrument concluded under WIPO in 1970, which makes it possible for inventors to seek patent protection for an invention simultaneously in a large number of countries by filing an "international" patent application. ⁴⁹ "Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals Submitted by Switzerland",

PCT/R/WG/9/5, available at http://www.wipo.int/edocs/mdocs/pct/en/pct r wg 9/pct r wg 9 5.doc [Accessed November 17, 2011].

⁵⁰ J. Barton, Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies (Geneva: ICTSD, 2007); F. Abbott, Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health (Geneva: ICTSD, 2009).

⁵³ Agenda 21, Ch.34, para.18, adopted in 1992, available at http://www.un-documents.net/a21-34.htm [Accessed November 17, 2011].

⁵⁴ Interestingly, while Ch.34 used to be mentioned in the relevant section of UNFCCC COP Decisions on Technology Transfer, it is not the case in the relevant section of the Cancun Decisions establishing the Technology Mechanism.

Similarly, the debate on intellectual property rights and biodiversity has been present since the inception of the CBD in 1992. It is ironic that the Nagoya Protocol contains virtually no mention of intellectual property rights,⁵⁵ while the text of the CBD itself included key provisions addressing them.⁵⁶ Subsequent soft law norms adopted within the CBD, such as the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilisation, also included a reference to encouraging disclosure in intellectual property rights applications.⁵⁷

In conclusion, the international intellectual property system increasingly recognises the need to positively "engage" with efforts to address public policy objectives. However, with the significant exception of public health, and maybe as a result of developments in this area, efforts and proposals to make the international intellectual property system more "supportive" of such objectives have not materialised. We might even be witnessing a "regression" in international discussions in the context of the biodiversity and climate change regimes if we compare them with earlier debates at the inception of the CBD and at the Rio summit in 1992.

The conclusion of an international instrument(s) for the protection of genetic resources, traditional knowledge and cultural expressions under WIPO in the two to three years to come could potentially represent an important development in the normative landscape of the international intellectual property system. However, its impact should be determined in light of the nature, reach and effectiveness of the provisions contained in such instruments. More importantly, if such instruments are not accompanied by changes in patent rules relating to international trade, the root causes behind the misappropriation of genetic resources and associated traditional knowledge are likely to remain unaddressed.

Public interest and development: Mainstreaming or dilution? A persistent ambiguity

Apart from public policy objectives, the other set of challenges facing the international intellectual property system during the past decade related to its ability to address broader public interest considerations and development concerns.

Here too changes at the level of the policy debate have been significant. The international intellectual property system has shown a willingness to embrace the "language" of public interest and development concerns at the level of the policy discourse. The WIPO Development Agenda (DA) was instrumental in fostering this change, and its historic significance has been amply highlighted. The 45 DA recommendations, adopted by consensus in 2007,⁵⁸ are soft norms representing an important development in the normative landscape of the international intellectual property system.⁵⁹

In this context, many of the "fetish" statements originally made by developing countries and civil society during the first half of the past decade are now part of the rhetoric commonly used in international institutions, such as the WTO and WIPO. Examples of such statements include those mentioning that

⁵⁵ Intellectual property rights are only mentioned in the Annex under the list of monetary and non-monetary benefits. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation, available at *http://www.cbd.int/abs/text/* [Accessed November 17, 2011].

⁵⁶ Intellectual Property rights are mentioned explicitly in paras 2, 3 and 5 of art.16 of the CBD, available at http://www.cbd.int/convention/articles /?a=cbd-16 [Accessed November 17, 2011].
⁵⁷ "Contracting Parties with users of genetic resources under their jurisdiction ... could consider, inter alia, the following measures: Measures to

²¹ "Contracting Parties with users of genetic resources under their jurisdiction ... could consider, inter alta, the following measures: Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights." Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, available at *http://www.cbd.int/decision/cop/?id=7198* [Accessed November 17, 2011].

⁵⁸ The 45 Adopted Recommendations under the WIPO Development Agenda are available at *http://www.wipo.int/ip-development/en/agenda* /recommendations.html [Accessed November 17, 2011].

⁵⁹ N. Netanel, *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford: Oxford University Press, 2008); Peter K. Yu, "A Tale of Two Development Agendas" (2009) 35 *Ohio Northern University Law Review* 465.

"intellectual property is not an end in itself", those calling for a balanced intellectual property regime, those questioning the one size fits all approach to intellectual property and those noting the need for intellectual property reform.

However, it is not entirely clear that when different stakeholders now make such statements, these statements retain the original meaning as used by developing countries and civil society. For instance, the assertion that "intellectual property is not an end itself" figured in the original DA proposal put forward by Argentina and Brazil in 2004, which stated:

"Intellectual property protection cannot be seen as an end in itself, nor can the harmonisation of intellectual property laws leading to higher protection standards in all countries, irrespective of their levels of development. The role of intellectual property and its impact on development must be carefully assessed on a case-by-case basis. IP [intellectual property] protection is a policy instrument the operation of which may, in actual practice, produce benefits as well as costs, which may vary in accordance with a country's level of development."⁶⁰

In contrast, some of the current uses of the assertion that "intellectual property is not an end itself" tend to be conducive to an emphasis mostly on the "positive" role of intellectual property in promoting innovation and wealth creation. For instance, the relevant part of WIPO's website devoted to "Intellectual Property for Development" currently states:

"IP for Development is an emphatic articulation of the notion that IP is not an end in itself but rather is a tool that could power countries' growth and development ... Implied in this are the notions of balance, accessibility and reward for creativity and innovation."⁶¹

Even with regard to a greater focus on the role of intellectual property in promoting innovation, this implied, from the viewpoint of developing countries, the need to address situations when intellectual property rules and practices hamper innovation as reflected in the findings of a growing scholarship that has emerged in recent years.⁶²

Similarly, while the term "flexibilities" advanced by developing countries and civil society tends to refer to the public interest flexibilities in national and international intellectual property instruments used to advance public policy objectives, the WIPO Secretariat described the term as "operating either downward or upward". For example, it stated that flexibilities:

"may permit measures that reduce or limit the rights conferred; or measures that raise the level of protection above the minimum standards established by the TRIPs Agreement."⁶³

As one observer has accurately noted, WIPO "has become a battleground for competing visions of the role of intellectual property in development made more confusing by the shared language that is often deployed on different sides of the debate (but with different implied meanings)".⁶⁴

The changing reference to the concept of "balance" in recent years is also illustrative of these ambiguities. In its traditional self-perception, the international intellectual property system considers itself—with its set of international rights, obligations and national implementation of exceptions and limitations—as "inherently" balanced. From this perspective, the mere mention of "balance" is superfluous. In fact, the

⁶⁰ "Proposal by Brazil and Argentina for the Establishment of a Development Agenda for WIPO", August 27, 2004, WO/GA/31/11, p.1, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=31737 [Accessed November 17, 2011].

⁶¹ "Intellectual Property for Development", available at http://www.wipo.int/ip-development/en/ [Accessed November 17, 2011].

⁶² J. Bessen and M. Meurer, Patent Failure, How Judges, Bureaucrats, and Lawyers Put Innovators at Risk (Princeton: Princeton University Press, 2008); A. Jaffe and J. Lerner, Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What to do About It (Princeton: Princeton University Press, 2006).

⁶³ Information on WIPO's website on public policy relating to flexibilities is available at http://www.wipo.int/ip-development/en/policy/flexibilities .html [Accessed November 17, 2011].
⁶⁴ C. May, "Afterword" in J. De Beer (ed.), Implementing the World Intellectual Property's Organisation's Development Agenda (Waterloo: Wilfrid)

[&]quot;C. May, "Afterword" in J. De Beer (ed.), Implementing the World Intellectual Property's Organisation's Development Agenda (Waterloo: Wilfrid Laurier University Press, 2009), p.170.

term does not even appear in any international instrument concluded under WIPO and its predecessors until the 1990s. Evoking the need to "achieve" a balanced intellectual property system could imply that the existing system lacked such balance, an anathema to many defenders of a traditional conception of intellectual property.

Interestingly, art.7 of the TRIPs Agreement and the preamble of the 1996 WIPO Internet treaties make a reference to the concept of "balance". However, while art.7 of TRIPs mentions that the protection of intellectual property rights should ultimately be "conducive to a balance of rights and obligations", the preamble of the WIPO Copyright Treaty (WCT) makes reference to:

"the need to *maintain* a balance between the rights of authors and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention."⁶⁵ (emphasis added)

Some view this mention of balance as an important development from the perspective of integrating public interest concerns in international intellectual property norms, as it is "the most explicit acknowledgement of the concept on its own terms found in a global copyright agreement".66 However, the reference in the WCT preamble to "maintaining" a balance that is already "reflected in the Berne Convention" illustrates the point mentioned above that the international intellectual property system forged under WIPO and its predecessors has traditionally considered its norms to be "appropriately" balanced. 67

In the context of the negotiations leading to the first phase of the World Summit on Information Society (WSIS) held in Geneva in 2003, developing countries refused to describe existing international intellectual property instruments as "balanced", particularly in view of the criticisms directed at the WIPO Internet Treaties and the growing awareness about the effects of technological protection measures.⁶⁸ In effect, the 2002 final report of the UK Commission on Intellectual Property Rights cautioned developing countries concerning adherence to the WCT.⁶⁹ Ultimately, para.42 of the 2003 Declaration of Principles states:

"intellectual property protection is important to encourage innovation and creativity in the Information Society; similarly, the wide dissemination, diffusion, and sharing of knowledge is important to encourage innovation and creativity."70

By putting on an equal footing the role of intellectual property in encouraging creativity, innovation and the wide diffusion of knowledge, the paragraph's wording implies that, in performing its function of encouraging creativity and innovation in the digital environment, the intellectual property system might not always be equated with the wide diffusion of knowledge, particularly if it is not balanced.

Throughout the past decade, the case has been so forcefully made about the "imbalance" in existing global intellectual property norms that the need to "pursue" a balanced intellectual property system has become a central feature of the mainstream intellectual property debate. A symbolic change reflecting this evolution was the adoption by WIPO in 2009 of a new mission statement that stated that the organisation was:

⁶⁵ The language in the preamble of the WIPO Performances and Phonograms Treaty (WPPT) is similar to the one in WCT, except for the reference to authors and to the Berne Convention.

⁶⁶ G. Dinwoodie, "The WIPO Copyright Treaty: A Transition to the Future of International Copyright Lawmaking?" (2010) 57 Case Western Law Review 754.

⁶⁷ It should also be recalled that TRIPs was the result of a compromises reached in the context of the multilateral trade framework. Articles 7 and 8 of TRIPs on objectives and principles originate in developing country proposals. UNCTAD-ICTSD, Resource Book on TRIPs and Development (Cambridge: Cambridge University Press, 2005), pp.123-124

A. Abdel Latif, "The Emergence of the A2K Movement: Reminiscences and Reflections of a Developing Country Delegate" in G. Krikorian and A. Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (New York: Zone Books, 2010), p.106.

²⁰World Summit on the Information Society, "Declaration of Principles: Building the Information Society: A global challenge in the New Millennium", WSIS-03/GENEVA/DOC/4-E, available at http://www.itu.int/wsis/docs/geneva/official/dop.html [Accessed November 17, 2011].

"dedicated to developing a *balanced* and accessible international intellectual property system, which rewards creativity, stimulates innovation and contributes to economic development while *safeguarding the public interest*."⁷¹ (emphasis added)

Such a statement is no doubt a positive development in terms of recognising that a balanced international intellectual property system is an objective yet to be achieved.

At the same time, the mainstreaming of the reference to "balance" and its wide use by a variety of stakeholders, whose interests and views on intellectual property discussions tend to significantly diverge, has become confusing, as perceptions about where the "balance" should lie between the rights of creators and inventors on the one hand and those of the broader public on the other may vary considerably.⁷² Consequently, the mere mention of "balanced" intellectual property regimes or norms has been somewhat emptied of its original significance. A question begs to be asked is: Does such mention still carry any added value or specific connotation unless it is accompanied by a more detailed elaboration of specific policies and measures?

Similarly, the need for intellectual property "reform" during the past decade has passed from being considered "taboo" and perceived as an assault against the intellectual property system to becoming a "priority" pursued by a range of countries and stakeholders. Intellectual property "reform" is the order of the day in several developed countries as exemplified by the patent reform in the United States with the adoption of the America Invents Act (AIA) and the copyright reform in the United Kingdom with the *Hargreaves Review*.⁷³ In developing countries, Chile witnessed an important copyright reform process which culminated in legislative changes that entered into force in 2010.⁷⁴ Discussions in this area have also been taking place for several years in Brazil.⁷⁵

At the international level, calls for reform have also been made. In November 2010, at the WIPO Standing Committee on Copyright and Related Rights (SCCR), Lawrence Lessig, the American copyright scholar, made proposals for reform of the international copyright system.⁷⁶ In February 2011, WIPO's Director General put forward a number of proposals in the context of "adapting" global copyright to the challenge of the digital environment, pointing out that the "either the copyright system adapts ... or it will perish".⁷⁷ On their part, developing countries and civil society organisations have tabled in 2009 and 2010 draft instruments for international minimum standards for limitations and exceptions for visually impaired persons and for libraries, disabled persons, education and research. These draft instruments are under active discussion at the SCCR.⁷⁸

⁷¹ "What Is WIPO?", available at http://www.wipo.int/about-wipo/en/ [Accessed November 17, 2011].

⁷² For instance, expressing their support to the "strong" intellectual provisions to be included in a EU-India Free Trade Agreement, the European research-based pharmaceutical companies called upon India to "develop a more robust, stable and predictable legal framework for the protection of intellectual property rights", adding that "[b]alanced provisions will stimulate inward investment and creation of an Indian research-based pharmaceutical industry". "European Research-based Pharma Fully Supports an Ambitious EU/India FTA", February 14, 2011, available at http://www.thepharmaletter.com/file/102053/european-research-based Pharma-fully-supports-an-ambitious-eurindia-fta.html [Accessed November 17, 2011].

 ⁷³ I. Hargreaves, *Digital Opportunity: A Review of Intellectual Property and Growth* (Newport: Intellectual Property Office, 2011), available at *http: //www.ipo.gov.uk/ipreview.htm* [Accessed November 17, 2011].
 ⁷⁴ D. Valenzuela and M. Véliz, "Reformas a la ley chilena de propiedad intelectual: el desafío de una regulación equilibrada", *Puentes*, July 2010,

¹⁴ D. Valenzuela and M. Véliz, "Reformas a la ley chilena de propiedad intelectual: el desafío de una regulación equilibrada", *Puentes*, July 2010, available at *http://ictsd.org/i/news/puentes/80829/* [Accessed November 17, 2011].

⁷⁵ P. Paranagua, "Brazil's Copyright Reform: Schizophrenia?", Intellectual Property Watch, February 8, 2011, available at http://www.ip-watch.org /weblog/2011/02/08/inside-views-brazils-copyright-reform-schizophrenia/ [Accessed November 17, 2011].

⁷⁶"Lessig Calls for WIPO to Lead Overhaul of Copyright System", Intellectual Property Watch, November 5, 2010, available at http://www.ip-watch.org/weblog/2010/11/05/lessig-calls-for-wipo-to-lead-overhaul-of-copyright-system/ [Accessed November 17, 2011].
⁷⁷ F. Gurry, "The Future of Copyright", speech delivered at the "Blue Sky Conference: Future Directions in Copyright Law", Queensland University

⁶ F. Gurry, "The Future of Copyright", speech delivered at the "Blue Sky Conference: Future Directions in Copyright Law", Queensland University of Technology, February 25, 2011, available at http://www.wipo.int/about-wipo/en/dgo/speeches/dg_blueskyconf_11.html [Accessed November 17, 2011].

^{2011].} ⁷⁸ "Proposal by Brazil, Ecuador and Paraguay, Relating to Limitations and Exceptions: Treaty Proposed by the World Blind Union (WBU)", May, 25 2009, SCCR/18/5; "Proposal by the African Group, Draft WIPO Treaty on Exceptions and Limitations for the Disabled, Educational and Research Institutions, Libraries", June 15, 2010, SCCR/20/11, available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=20200 [Accessed November 17, 2011].

In the patent area, the adoption by the United States of a "first to file" system could pave the way for global patent harmonisation.⁷⁹ As previously mentioned, the African Group and the members of the DAG have proposed the adoption of a work programme on patents and health at the SCP. At the same body, Brazil has put forward a proposal for a work programme on limitations and exceptions in patent law, which would, in its ultimate phase, consider "the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference to WIPO Members".⁸⁰

Yet again, like "balance", intellectual property "reform" has become a "catchall" expression covering a myriad of initiatives and proposals with varying significance and whose intended objectives and ultimate goals differ. While in most cases "reform" entails legislative changes, in some cases it involves also "technical" solutions which tend to receive less attention. In this connection, WIPO's Director General underlines that "infrastructure is as important a part of the solution as law". He thereby suggested the need for "an international music registry—a global repertoire database—as a needed 'step in the direction of establishing the infrastructure for global licensing".⁸¹

If several of the proposals mentioned above were to be concretised, they could represent potentially important changes in the international intellectual property landscape. However, the key issue will be to closely examine the specifics and their implications. For instance, what precise measures and provisions will future international instruments on limitations and exceptions contain? How effective and practical will they be in achieving their intended objective? And what will be their impact on the global landscape of access to knowledge? The experience of the Berne Appendix—and the largely unused, and to a certain extent unusable, system it put in place—is an important reminder of where previous efforts to reform the international copyright system for the benefit of users and developing countries ended.

It appears likely that an international instrument on limitations and exceptions for the visually impaired persons could be concluded in the near future. In effect, at the 22nd session of the SCCR, in June 2011, a joint "proposal on an international instrument on limitations and exceptions for persons with print disabilities" was tabled by a group of countries including developed and developing countries, among which were the sponsors of the original proposal in 2009.⁸² At the end of the same session, the SCCR asked the chair to prepare a text "which will constitute the basis for the future text-based work" with the aim to agree and finalise a proposal on an international instrument at the 23rd session of the SCCR in November 2011.⁸³ Disagreements remain about several aspects of such an instrument, in particular its legal nature, and whether it would be a treaty or soft norm recommendation.

If such an instrument is concluded, it would no doubt set a symbolic precedent, particularly given its humanitarian dimension. For the first time in recent years, an international copyright instrument would be concluded to address the needs of users rather than those of rights holders, thus putting a "foot in the door" of the international intellectual property system. Ultimately, however, such an instrument addresses the needs of only a relatively specific category of users. Will its adoption facilitate future norm-setting efforts to address the needs of libraries and archives as well as educational and research institutions, which are essential building blocks of access to knowledge? Or will the "door" of reform close after such an instrument is adopted?

⁷⁹ "US Patent Law Seen Opening Door to Global Harmonisation at WIPO", *Intellectual Property Watch*, September 25, 2011, available at http://www.ip-watch.org/weblog/2011/09/25/us-patent-law-seen-opening-door-to-global-harmonisation-at-wipo/ [Accessed November 17, 2011].

⁸¹ F. Gurry, "The Future of Copyright", speech delivered at the "Blue Sky Conference: Future Directions in Copyright Law", Queensland University of Technology, February 25, 2011, available at http://www.wipo.int/about-wipo/en/dgo/speeches/dg_blueskyconf_11.html [Accessed November 17, 2011].

^{2011].} ⁸² "Proposal on an International Instrument on Limitations and Exceptions for Persons with Print Disabilities, document presented by Argentina, Australia, Brazil, Chile, Colombia, Ecuador, the European Union and its Member States, Mexico, Norway, Paraguay, the Russian Federation, the United States of America and Uruguay", June 22, 2011, SCCR/22/15 REV. 1, available at *http://www.wipo.int/meetings/en/details.jsp?meeting_id* =22/69 [Accessed November 17, 2011]

^{=22169 [}Accessed November 17, 2011]. ⁸³ "Report on the Work of the Standing Committee on Copyright and Related Rights (SCCR)", July 26, 2011, WO/GA/40/6, available at http://www. wipo.int/meetings/en/doc_details.jsp?doc_id=174317 [Accessed November 17, 2011].

Finally, the actual implementation process of the 45 DA recommendations since 2008 unsurprisingly reveals tensions between the competing "paradigms" of intellectual property and development that were captured in the recommendations in order to reach consensus. On the one side are the original proposals advanced by developing countries and civil society, which highlighted the importance of flexibilities, the need to take into account differences in levels of development in technical assistance and norm setting, and the support for a robust public domain, to mention a few. On the other side is the traditional view held by industrialised countries, rights holders organisations and the WIPO Secretariat, that intellectual property is a tool for socio-economic development that can be used by all countries for wealth creation and where challenges facing developing countries can be addressed by "technical assistance" to improve their ability to "use" the system.⁸⁴ The DA recommendations did not entirely resolve tensions between these two competing "visions". It has been pointed out that such tensions can be a sign of "malleability" in the sense that the DA can be "shaped and formed to suit different stakeholders' interests in different context". However, it has also been highlighted that "without a shared understanding of what exactly the Development Agenda involves … there is a substantial risk that, with too much interpretation leeway, nothing will change".⁸⁵

As a consequence, discussions of the Committee on Development and Intellectual Property (CDIP), the main body overseeing the implementation of the DA recommendations, developing countries and industrialised countries have been engaged in a low level confrontation aiming at advancing their respective paradigms of intellectual property and development in the context of the "thematic project" approach. WIPO proposed such an approach in 2009 to structure the implementation of the DA recommendations and to initiate wider efforts to "mainstream" the agenda in all of WIPO's activities. The constitution of the DAG of like-minded developing countries in 2010 injected a renewed momentum in developing country engagement with the DA implementation process. In their guiding principles document, the DAG called for:

"an organisational transformation of WIPO from a technical, treaty-administering body servicing primarily intellectual property right-holders, to a truly representative agency of the United Nations (UN) assisting Member States in achieving their development goals through a balanced and calibrated use of intellectual property."⁸⁶

Assessing in a comprehensive manner, the implementation of the DA is certainly beyond the scope of this article. However, some preliminary remarks can be made regarding, for instance, the projects being implemented under the DA.⁸⁷ Many projects with an operational component involving specific activities relating to a better use of the intellectual property system in developing countries do not depart from the "traditional paradigm" of intellectual property and development, which prevailed before the establishment of the DA.⁸⁸ Projects pertaining to the "development oriented paradigm" advanced by developing countries

⁸⁴ See works written by WIPO Secretariat members: e.g. S.A Khan, Socio-economic Benefits of Intellectual Property Protection in Developing Countries (Geneva: WIPO, 2000); K. Idris, Intellectual Property—A Power Tool for Economic Growth (Geneva: WIPO, 2003).

⁸⁵ J. de Beer, "Defining WIPO's Development Agenda" in de Beer (ed.), Implementing the World Intellectual Property's Organisation's Development Agenda (Waterloo: Wilfrid Laurier University Press, 2009), p.10.

⁸⁶ "Information on the Development Agenda Group Guiding Principles", April 26, 2010, CDIP/5/9 Rev., available at *http://www.wipo.int/meetings* /*en/doc_details.jsp?doc_id=133099* [Accessed November 17, 2011]. On this date, the DAG included 18 countries as members: Algeria, Brazil, Cuba, Djibouti, Ecuador, Egypt, Guatemala, India, Indonesia, Iran, Malaysia, Pakistan, Philippines, South Africa, Sri Lanka, Sudan, Uruguay and Yemen.

⁸⁷ Information on the projects and their status of implementation is available at *http://www.wipo.int/ip-development/en/agenda/projects.html* [Accessed November 17, 2011].

⁸⁸ Information about the Project on Developing Tools for Access to Patent Information (CDIP/4/6), the Project on Intellectual Property and Product Branding for Business Development in Developing Countries and Least-Developed Countries (LDCs) (CDIP/5/5), and the Project on Capacity Building in the Use of Appropriate Technology-Specific Technical and Scientific Information as a Solution for Identified Development Challenges, (CDIP/5/6REV.) is available at http://www.wipo.int/ip-development/en/agenda/projects.html [Accessed November 17, 2011].

and civil society, which relate to a more robust public domain and the use of competition policy and flexibilities, until now have been mostly confined to the preparation of studies and awareness-raising activities.89

The few instances where developing countries have made proposals for projects, such as those relating to "technology transfer" and the discussions over "south-south cooperation", have been marred by controversy and disagreements. In the latter's case, such disagreement resulted in the suspension of the 7th session of the CDIP in May 2011.⁹⁰ Beyond these projects, the implementation of the DA needs to be examined in all other areas of the organisation's work, such as norm setting and technical assistance. In what concerns this last issue, the DA had mandated an external review of WIPO's technical assistance which has just been made available for consideration at the November 2011 session of the CDIP.⁹¹

On the brighter side, efforts have been successful in reaching agreement in 2010 on the coordination mechanisms and on the monitoring, assessing and reporting modalities, by virtue of which all WIPO bodies have to include in their annual report to the WIPO Assemblies, a description of their contribution to the implementation of the respective DA recommendations.92

It has been pointed out that if:

"the developing countries present agenda [is to] succeed[, it] will depend on whether less developed countries and their supporting governments and NGOs can mobilise in time before they lose the momentum."93

In this regard, it is worth pointing out that the most recent declaration, adopted by Heads of State and Government at the India-Brazil-South-Africa (IBSA) forum:

"emphasised ... the need for a balanced international intellectual property system that contextualises Intellectual Property Rights in the larger framework of socio-economic development and ... called for the full implementation of the Development Agenda of the World Intellectual Property Organization (WIPO) in all areas of its work."94

Ultimately, there is little doubt that the DA has changed the tone and orientation of discussions at WIPO. To a great extent, this has been captured in some of the current discussions on norm setting, particularly in the copyright area. The extent to which the "spirit", and not only its "letter", of the DA have permeated the operational activities carried out by the organisation requires a closer and more detailed examination.

Adaptation or reform?

During the past decade, the global intellectual property policy debate centred on whether the international intellectual property system should be reformed. The current decade is more likely to focus on how reform should take place. A key question in this debate is: Can the international intellectual property system be reformed in any significant way beyond the minimalist concessions and adjustments that its most powerful backers-that is, industrialised countries and their intellectual property-based industries-would be willing to make?

⁸⁹ Information about the Project on Intellectual Property and the Public Domain (CDIP/4/3/REV.) and the Project on Intellectual Property and Competition Policy (CDIP/4/4/REV.) is available at http://www.wipo.int/ip-development/en/agenda/projects.html [Accessed November 17, 2011]. 90 "WIPO Committee on Development Agenda Suspended, Discussions Bogged Down", Intellectual Property Watch, May 7, 2011, available at

http://www.ip-watch.org/weblog/2011/05/07/wipo-committee-on-development-agenda-suspended-discussions-bogged-down/ [Accessed October 26,

^{2011].} ⁹¹C. Deere and S. Roca, An External Review of WIPO Technical Assistance in the Area of Cooperation for Development (Geneva: 2011), CDIP/8/INF/1,

available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=182842 [Accessed October 26, 2011]. "Coordination Mechanisms and Monitoring, Assessing and Reporting Modalities", available at http://www.wipo.int/ip-development/en/agenda

[/]coordination mechanisms.html [Accessed October 26, 2011].

Yu, "A Tale of Two Development Agendas" (2009) 35 Ohio Northern University Law Review 465, p.573.

⁹⁴ India-Brazil-South Africa (IBSA) Dialogue Forum, "Tshwane Declaration", October 18, 2011, available at http://vascopresscom.blogspot.com /2011/10/tshwane-declaration-india-brazil-south.html#!/2011/10/tshwane declaration-india-brazil-south.html [Accessed November 17, 2011].

In effect, several of the most important proposals and initiatives that would epitomise changes taking place in the global intellectual property landscape from a public interest perspective would not undermine the prevailing interests of industrialised countries and their intellectual property-based industries in a fundamental manner. This would be the case of an international instrument for visually impaired persons. Although the instrument would represent an important precedent and would address a pressing humanitarian issue, it ultimately concerns the needs of a relatively specific group of users that do not affect the overall business interests and models of major rights holders such as publishers. In contrast, sales of educational books and textbooks to educational institutions (schools and colleges) and to libraries tend to represent a major share in the revenues by publishers, particularly in developing countries.⁹⁵

In several public health-related initiatives aiming to increase access to medicines or develop new treatments, licensing schemes tend to be restricted in their scope mostly to LDCs and exclude many middle-income countries. This was raised in the debate concerning the conclusion of the first license agreement in July 2011 between the MPP and a pharmaceutical company, Gilead Sciences, to improve access to HIV and Hepatitis B treatment in developing countries.⁹⁶ The MPP indicates that one of the key features of the licensing agreement "is the expansion in the number of countries included in the geographical scope of the license is a critical area that needs to be improved. Critics have pointed to "restrictive provisions" in the licensing agreement and in particular the restricted geographical scope of the license for tenofovir (TDF). They mention that:

"the benefit of the addition of 16 new countries in the TDF license ... represent less than a one percent increase in patient coverage, whereas the addition of middle-income countries excluded from the agreement would have represented a 12 percent increase in access, significantly expanding the market."⁹⁷

Similar issues have arisen regarding the recent WIPO initiative on neglected diseases, WIPO: Re Search, which consists of a consortium of public and private sector organisations sharing valuable intellectual property and expertise with the global health research community to promote development of new drugs, vaccines, and diagnostics to treat neglected tropical diseases, malaria, and tuberculosis. Membership in the initiative is open to all organisations that endorse the guiding principles that intellectual property licensed via WIPO Re: Search will be royalty-free for research and development on neglected tropical diseases in any country and for sale of neglected tropical disease medicines in, or to, LDCs.⁹⁸

Reacting to the initiative, Médecins Sans Frontières criticised the "timid" licensing terms, stating that:

"by agreeing to licensing terms that have an unacceptably limited geographic scope, WIPO is taking a step in the wrong direction and setting a bad precedent for other licensing arrangements."

⁹⁵ P. Albach and E. Hoschino, International Book Publishing: An Encyclopaedia (New York: Garland Publishing, 2005). pp.270–271.

⁹⁶ Medicines Patent Pool, "The Medicines Patent Pool Announces First Licensing Agreement with a Pharmaceutical Company", July 12, 2011, available at http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement [Accessed November 17, 2011].

 ⁹⁷ ITPC/IMAK, "The Implications of the Medicines Patent Pool and Gilead Licenses on Access to Treatment", July 25, 2011, available at *http://www.itpcglobal.org/index2.html* [Accessed November 17, 2011].
 ⁹⁸ WIPO, "Leading Pharmaceutical Companies & Research Institutions Offer IP and Expertise for Use in Treating Neglected Tropical Diseases as

²⁶ WIPO, "Leading Pharmaceutical Companies & Research Institutions Offer IP and Expertise for Use in Treating Neglected Tropical Diseases as Part of WIPO Re: Search", available at *http://www.wipo.int/pressroom/en/articles/2011/article_0026.html* [Accessed November 17, 2011].

It underscored that many patients affected by neglected tropical diseases are not in LDCs, citing the example of the Chagas disease. That disease affects 21 countries in the Americas, even though the Consortium will only provide royalty-free licenses for Haiti, where Chagas is not endemic. MSF called on WIPO "to expand the scope of this initiative to cover, as a minimum, all disease-endemic developing countries".⁹⁹

Beyond health, a similar issue arises in other initiatives promoting access to knowledge such as the Access to Research for Development and Innovation (ARDI) Program WIPO coordinated with partners in the publishing industry with the aim to increase the availability of scientific and technical information in developing countries. According to its eligibility criteria, only academic and research institutions and intellectual property offices in LDCs may apply for free access to the journals made available through the ARDI Program.¹⁰⁰

These different examples of "technical solutions" where private sector actors are involved show a strong reluctance on their part to expand access initiatives to middle-income countries in the context of growing perceptions among industrialised countries that these countries, in particular emerging economies, are becoming competitors in the global economy. However, these examples are reflecting a broader fault line between two approaches to reform in the international intellectual property system: one that advocates incremental reform representing an improvement over the status quo and another concerning the potential for such an "incremental" approach to detract, or even undermine, more far-reaching proposals that could better serve the goals of access to medicines and knowledge and the public interest.

For the MPP, the Gilead license is "a first step—a floor, not a ceiling".¹⁰¹ Commenting at the launch of WIPO: Re Search, the Kenyan Ambassador to the United Nations also considered it "the first step of a long journey".¹⁰² For civil society critics, these initiatives are "first steps" headed in the "wrong direction". It will be interesting to see how the dynamics between these two approaches to reform will play out in future years and what will be their broader implications.

In any case, clearly some of these initiatives involving the pharmaceutical and publishing industries are taking place amid growing concerns about the increased prospects concerning the use by developing countries of flexibilities, in particular compulsory licensing, as well as of limitations and exceptions. A decade after discussions first emerged about such use, one would have thought that the use of flexibilities, limitations and exceptions by developing countries for public policy objectives would become a normal, routine feature of the global intellectual property landscape. However, this is far from the case, particularly for middle-income developing countries which remain vulnerable to political and trade pressures (as Brazil noted in its statement to the SCP). In this regard, it remains unclear the extent to which some industrialised countries and some parts of the private sector genuinely believe that the use of flexibilities, limitations and exceptions is an integral part of a balanced intellectual property system, rather than an external element seeking to undermine it.

For instance, free trade agreements concluded by some industrialised countries with developing countries pay lip service to the Doha Declaration while also containing provisions that go beyond the minimum standards of the TRIPs Agreement. These TRIPs-plus provisions can potentially have a detrimental effect on access to medicines and delay the arrival of generic competition on the market. Industrialised countries and the private sector continue to advance restrictive interpretations of the Doha Declaration in international fora and in discussions with developing countries. Commenting on the lawsuit that multinational drug

⁹⁹ Médecins Sans Frontières, "Statement by Médecins Sans Frontières in Response to WIPO Announcement of Re: Search, Consortium for Neglected Tropical Diseases (NTDs), TB and Malaria", available at http://www.msfaccess.org/contem/tstatement-m%C3%A9decins-scans-fronti%C3%A8res

⁻response-wipo-announcement-research-consortium-neglected [Accessed November 17, 2011]. ¹⁰⁰WIPO, "The Access to Research for Development and Innovation (ARDI) program", available at http://www.wipo.int/ardi/en/[Accessed November 17, 2011].

¹⁰¹ Albach and Hoschino, International Book Publishing (2005). pp.270–271.

¹⁰² "When does not international boot manang (cross), proceedings, *Bridges Weekly Trade News Digest*, October 26, 2011, available at *http://ictsd.org* /i/news/bridgesweekly/116974/ [Accessed November 17, 2011].

companies launched in 1999 against the South African government, a senior executive of a pharmaceutical company stated at a 2009 WIPO conference: "We were legally right but ethically, socially and morally wrong."¹⁰³ The assertion is rather revealing a decade later given that legal scholarship in this area points out that the lawsuit was "without merit".¹⁰⁴ How can changes at the level of the international intellectual property system be meaningful if the system's most powerful backers do not fully embrace them and are willing to contribute to their implementation?

Conclusion: Moment of truth approaching

The Doha Declaration and the WIPO Development Agenda are the two key changes in the policy and normative landscapes of the international intellectual property system from the viewpoint of public interest and development concerns. Both initiatives were initially advanced by developing countries and civil society, reflecting their aspirations for change in the system.

In response, the international intellectual property system has shown a significant degree of openness, adapted its policy discourse, displayed a willingness to engage with public policy objectives, produced a number of practical initiatives aiming to improve access to knowledge and medicines, and provided the space for discussions on a certain number of norm-setting proposals that address public policy concerns, particularly in the copyright area. Such developments are encouraging and should be welcomed. However, they should not be judged on the headlines they carry but more on the specifics and details they contain and the extent to which they respond to the original objectives set forth by developing countries and civil society. At the same time, worrisome trends and initiatives leading to strengthening the enforcement of intellectual property rights through plurilateral agreements such as the Anti-Counterfeiting Trade Agreement (ACTA) could undermine developments.

Ultimately, in terms of outcomes, the moment of truth is fast approaching for the international intellectual property system: Can it evolve from a system serving predominantly the interests of inventors and authors and intellectual property-based industries of developed countries to a more inclusive system that addresses the needs of users and consumers everywhere and of developing countries? Are the changes that the system have been witnessing during the past decade conducive to "achieving the historic aspiration of developing countries for a paradigm shift in the international perspective of intellectual property"?¹⁰⁵

In seeking answers to these questions, historical precedent does not augur well. The history of the international intellectual property system in the face of demands by developing countries is essentially one of adaptation without change, or at least meaningful change. Past changes to the system have mostly resulted in the strengthening of intellectual property rules to the benefit of rights holders, and most attempts to reform the system to the benefit of users, such as consumers and developing countries, have either failed or been of limited effectiveness.¹⁰⁶

However, history does not necessarily need to repeat itself. A unique set of circumstances and factors have opened a window of opportunity for meaningful change to potentially occur. These circumstances and factors include the pervasive effect of new technologies, geopolitical change, the growing recognition that intellectual property policy should be evidence-based, and increased awareness and participation of

¹⁰³ Intervention by Mr Robert Sebbag, Vice President, Access to Medicines, Sanofi-Aventis, Paris, at the Conference on Intellectual Property and Public Policy Issues, July 13–14 2009, available at *http://www.wipo.int/meetings/en/2009/ip_gc_ge/mp3/14_am_sebbag.mp3* [Accessed November 17, 2011]. ¹⁰⁴ F. Abbott, "WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries", Background Paper for the Commission

¹⁰⁴ F. Abbott, "WTO TRIPs Agreement and Its Implications for Access to Medicines in Developing Countries", Background Paper for the Commission on Intellectual Property Rights, p.54, available at http://frederickabbott.com/uploads/sp2a_abbott_study.pdf [Accessed November 17, 2011]. ¹⁰⁵ "Information on the Development Agenda Group Guiding Principles", April 26, 2010, CDIP/5/9 Rev., available at http://www.wipo.int/meetings

Information on the Constraint Systems and Constraints and

^{2011,} available at http://www.ip-watch.org/weblog/2010/11/12/global-copyright-reform-a-view-from-the-south-in-response-to-lessig/[Accessed October 31, 2011].

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a wide range of stakeholders in intellectual property debates, to name a few. More than ever, developing countries and civil society¹⁰⁷ need to intensify their efforts and seize this opportunity if they wish to press for the paradigm shift to which they had aspired.

¹⁰⁷ Recent examples of civil society mobilisation include the Washington Declaration on Intellectual Property and Public Interest, available at *http:* //infojustice.org/washington-declaration [Accessed November 17, 2011].

From World Intellectual Property Organization (WIPO) to World Innovation Promotion Organization (WIPO)? Whither WIPO?

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Developing countries; Intellectual property; WIPO

Introduction

The roots of the World Intellectual Property Organization (WIPO) go back to 1883, when the need for international protection of intellectual property (IP) became evident after foreign exhibitors refused to participate in the International Exhibition of Inventions in Vienna in 1873 because they were afraid their ideas would be stolen and exploited commercially in other countries. Flowing from this need for IP protection, the Paris and Berne Conventions were formalised by a few industrialised countries to protect their patented inventions and copyrights in 1883 and 1886 respectively, leading to the setting up of the United International Bureaux for the Protection of Intellectual Property (BIRPI) in 1893, which later became WIPO in 1967 under the WIPO Convention. Thus, the principal rationale and mandate of WIPO, historically, has been to promote world-wide protection and enforcement of IP. Even after WIPO became a specialised agency of the United Nations in 1974, the mandate of WIPO continued to be largely uni-dimensional, focusing on the promotion and protection of IP. However, in the new millennium, WIPO seems to have come a long way-from a limited focus on IP protection and enforcement to a larger vision of promoting global creativity and innovation; from being a "rich men's club" dedicated to protecting inventions from "theft" by others to the "promotion of intellectual property for development" as a strategic goal; from propagating the absolutism that protection of IP is a worthwhile end in itself to the acceptance of a more nuanced view that IP protection needs to be calibrated according to the level of a country's socio-economic development. In a world where IP continues to be mainly the preserve of developed countries and where IP is increasingly seen as a critical currency of national economic growth and global power, how can this slow but sure shift in WIPO be explained? What more needs to be done to usher in a balanced global IP system? What trends can we envisage in the days to come? This article tries to address these aspects.

The need for balance in the international IP system

From the *bourgeoise* origins of IP in the late 19th century as an issue of concern only to the developed world, the imposition of minimum levels of IP protection and enforcement globally through the TRIPS Agreement of 1995 made IP a common man's issue that became relevant even to developing countries. With developing countries brought under the reluctant ambit of TRIPS, there was a growing feeling that the international IP system was skewed in favor of private right holders and lacked the necessary balance in accommodating the interests of users, consumers and the larger public interest. Consequently, in the

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15 years since TRIPS, the global discourse in IP has mostly highlighted the need for bringing about greater balance in the IP system between private rights and public interests to advance socio-economic development and to cater to the broader public interest. At the international level, this post-TRIPS developmental consciousness in IP was primarily crystallised and manifested in the Doha Declaration on Public Health in 2001 and followed up by the WIPO Development Agenda in 2007. At the national level, it is evidenced in ongoing IP reforms both in the developed and developing worlds and the chorus of public interest voices even within the developed countries for rebalancing the IP system to ensure that stronger IP regimes do not constrain access to technology, knowledge and ultimately human welfare.

Impact on WIPO's core mandate: Post-TRIPS normative paralysis?

Against this background, it is not a coincidence that there has been no new norm-setting in WIPOTRIPS to enhance the protection of IP in line with WIPO's core mandate. While a series of treaties and conventions had been successfully concluded in WIPO prior to TRIPS and concurrent to TRIPS, none of the norm-setting proposals introduced in WIPO after TRIPS to enhance IP protection has succeeded.1 Several proposals for enhancing IP protection were initiated post-TRIPS, but failed, owing primarily to opposition by developing countries. For instance, the proposal for the Substantive Patent Law Treaty (SPLT) was introduced in 2001 to globally harmonise definitions of novelty, prior art, grace period etc. In 2006, it had to be aborted, owing to opposition by developing countries, despite forceful efforts by the proponents. Three years later, a much less ambitious soft norm-setting initiative proposed in 2009 in the Patent Cooperation Treaty (PCT) Working Group, aimed at harmonising these definitions in practice through reliance on patentability reports produced by other Patent Offices, also failed for similar reasons. In the area of copyrights and related rights too, attempts to enhance protection met with similar failure. A draft Treaty for the Protection of Audio Visual Performances which was introduced in the mid-1990s, was aborted after a failed diplomatic conference in 2000 and is yet to be concluded, even after a decade. Another draft Treaty for the Protection of Broadcasting Organisations which was proposed towards the end of the last millennium, has been similarly stalemated for lack of agreement, for more than a decade now. It is also noteworthy that the mandate of the Advisory Committee on Enforcement, the intergovernmental body set up in 2002 to deal with enforcement matters in WIPO, specifically excluded norm-setting and was limited to technical assistance and coordination, with the result that there has been no norm-setting so far in IP enforcement-a core mandate of WIPO. Similarly, the fact that the Standing Committee on the Law of Patents (SCP), which is the sole intergovernmental forum in WIPO tasked with patent-related norm-setting-another core area of WIPO's mandate, could not even agree on a work programme for the Committee for four years, let alone norm-setting of any sort, testifies to the normative paralysis in WIPO after TRIPS.

The development discourse in WIPO and the WIPO Development Agenda

While traditional norm-setting initiatives to promote the protection of IP thus failed to fructify, the only substantive norm that was adopted post-TRIPS in WIPO was, ironically, a revolutionary soft norm that was antithetical to the conventional IP paradigm—the WIPO Development Agenda. The 45 Recommendations of the WIPO Development Agenda, grouped under six clusters, which were adopted in 2007, reflected the new wisdom of the times and were counter-intuitive to WIPO's one-dimensional

¹ This excludes procedural treaties for harmonising specific IP registration procedures, such as the Patent Law Treaty (2000) and the Singapore Treaty on the Law of Trademarks (2006), which were finalised during this period, as also the WIPO Internet Treaties—the WIPO Copyright Treaty (1996) and WIPO Performances and Phonograms Treaty (1996)—which were adopted around the same time as TRIPS.

and simplistic mandate of promoting the protection of IP. In its short life of four years, the WIPO Development Agenda has impacted various aspects of the functioning of an organization that is more than 115 years old. Its impacts can be broadly categorised under the following headings:

- 1. Conceptual paradigm shift;
- 2. Norm-setting;
- 3. Substantive work in various WIPO committees; and
- 4. Institutional changes.

1. Conceptual paradigm shift

The WIPO Development Agenda engendered a conceptual "head-stand" by radically altering the conventional IP paradigm in the following ways:

(a) From IP as an "end in itself" to IP as a "means to an end"

The Development Agenda pulled IP out of its ivory tower, as something inherently good and self-justified in itself, and placed it firmly in the larger context of development, thereby replacing the dogma "IP is good; and more IP is even better", which was circulated until then as conventional wisdom, with the paradigm-shifting notion that "IP is not an end in itself; it is only useful when it serves as a tool for socio-economic development".

(b) From "one-size" IP policies to tailor-made IP strategies

It repudiated the "one-size IP policy fits all" credo accompanying the belief that IP protection was inherently and automatically beneficial, and replaced it with an acknowledgement that IP was useful only when it was calibrated to evolve tailor-made, country-specific IP policies that could be dovetailed into national development plans.

(c) From IP protection to Innovation Promotion

Flowing from this, a more fundamental shift in WIPO's vision was introduced, replacing the limited and exclusive focus on promoting IP protection and enforcement with a broader vision of promoting, universalising and democratising innovation globally, so that developing countries could also become IP producers and real stakeholders in the global IP system, with a concrete stake in IP protection.

2. Norm-setting

The rejection of these long-prevalent belief systems that were accepted hitherto as "conventional wisdom" and the accompanying change in perspective ushered by the Development Agenda has had its most important impact in the area of norm-setting in WIPO. In a short span of four years, the Development Agenda has led to concrete measures in norm-setting that seek to rebalance the global IP regime and usher in an altered perspective in an organization that has promoted the conventional paradigm in norm-setting for more than 115 years. Some of the important changes in the area of norm-setting are highlighted below.

(a) A new class of IP Rights

A revolutionary, paradigm-altering norm-setting initiative currently underway in the Inter-Governmental Committee (IGC) in WIPO is the effort to establish an entirely new class of IP rights that in fact circumscribe IP rights as they currently exist. The accelerated pace of negotiations for a legal

instrument/instruments that protects the rights of communities and indigenous groups over their traditional knowledge, genetic resources and folklore fundamentally alters the concept of IP from a private, monopoly right accorded for a limited timeframe to one of a historical right enjoyed by a group of people for an indefinite period of time. It also makes the conventional private IP right subsidiary to the collective community right by mandating that prior informed consent be obtained from the Community before converting any aspect of it into a private right and by stipulating that any profit arising from such use be shared with the community under mutually acceptable terms. In effect, the norm-setting initiative underway in the IGC turns the conventional IP paradigm on its head.

(b) Scaling back of Copyrights

Another such unprecedented and path-breaking initiative currently underway in the WIPO Standing Committee on Copyrights and Related Rights (SCCR) is the first-ever multilateral norm-setting effort to globally harmonise exceptions and limitations to IP rights for humanitarian and public interest reasons. While all other norm-setting initiatives in WIPO so far have sought to protect, promote or enforce IP rights, this initiative seeks to do the reverse: it aims to formalise a global normative framework that scales back IP rights by introducing exceptions and limitations to copyrights in order to make copyrighted works accessible to visually impaired persons, persons with other disabilities, libraries, archives, research and education. Interestingly, in comparison with the agonisingly slow pace of post-TRIPS norm-setting negotiations which met with failure eventually, this initiative appears to enjoy broad political support by Member States and is moving at a faster pace, with the SCCR having agreed to achieving closure within a clearly-defined timeframe.

(c) Integration of the development dimension in substantive norm-setting

In the recently revived negotiations aimed at finalising the long-pending Treaty for the Protection of Audio Visual Performances, Member States have agreed to include a reference to the WIPO Development Agenda in the amended treaty text. The treaty text that would be submitted to a diplomatic conference for adoption will consequently incorporate the Development Agenda. Similar parallel negotiations to bring closure to the stalemated Treaty for the Protection of Broadcasting Organisations continue to be based on the 2007 mandate of the General Assembly, which limits the proposed protection to traditional, signal-based broadcasting without expanding the scope to include digital and web-based broadcasting signals, as demanded by several developing countries.

(d) Integration of the development dimension in procedural norm-setting

Developmental perspectives are being integrated even in procedural norm-setting initiatives currently underway in the SCT and the PCT Working Group. There are two pioneering instances where developing countries have successfully integrated the development dimension even in procedural rule-making in WIPO, as distinct from substantive norm-setting. Though not as paradigm-altering as those mentioned above, they testify to the extent to which the Development Agenda is becoming an integral part of norm-setting. For example, the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT), in its recently-held session on October 24–28, 2011, deliberated on how the Development Agenda recommendations, in particular "Cluster B" pertaining to norm-setting, had been mainstreamed in the consideration of the proposed international Treaty on Harmonising Industrial Design Registration Procedures. Similarly, in an unprecedented development, the PCT reform process initiated in 2009 explicitly undertakes to be a:

"member-driven process, taking into account Development Agenda recommendations and without leading to substantive patent law harmonisation or harmonisation of national search and examination procedures."

Consequently, the discourse on PCT reform includes, for the first time, developmental issues that were hitherto alien to earlier PCT reform processes, such as "sufficiency of disclosure", "patent quality", "technology transfer" and "technical assistance". This marks a distinct developmental departure from earlier PCT reform processes which were mostly technical and exclusively focused on streamlining processing of PCT applications and expediting grant of patents.

3. WIPO's substantive work

Apart from the above momentous changes in norm-setting, the Development Agenda has ushered in a more balanced perspective of IP in other substantive areas of WIPO's work being undertaken in various Standing Committees and WIPO bodies. Important developments in some key bodies are outlined below.

(a) Standing Committee on Law of Patents (SCP)

The deadlock on the SPLT initiative led to a realisation that norm-setting on patents would only progress if developmental aspects were duly incorporated. Accordingly, the Committee started on a fresh page and drew up a "non-exhaustive list" of various aspects of the international patent system that were of concern to Member States and tried to address these dimensions holistically. A majority of the 18 issues listed therein were development-oriented. Based on studies and discussions on several of these aspects, a work programme for the Committee was finally adopted by WIPO Member States in 2010. This new work programme reflects a balanced and holistic approach and includes issues that were considered "taboo" in the SCP for a long time, such as "Exceptions and Limitations to Patent Rights",² "Patents and Public Health", "Quality of Patents Including Opposition Systems" and "Transfer of Technology".

(b) PCT Working Group

Another watershed moment for the Development Agenda in 2010 came when the PCT Working Group agreed to an unprecedented decision to integrate the Development Agenda recommendations in the technical discussions on improvements to the PCT system, while also agreeing to review the extent to which the PCT had succeeded in its aim of disseminating technical information and facilitating access to technology for developing countries, including through facilitating licensing agreements. Discussions have also been initiated about reviving the defunct PCT Committee for Technical Assistance provided under art.51 of the PCT, in order to better enable the PCT system to coordinate technical assistance projects for developing countries. Given the fact that PCT filings constitute the principal source of WIPO's revenue and the PCT constitutes a core, technical area of WIPO's central mandate, the new developmental issues introduced in the PCT Working Group, therefore, offer a stark testimony of the extent to which the Development Agenda has made inroads even into "core" areas of WIPO's mandate. The inclusion of the PCT Working Group in the list of "relevant" WIPO bodies required to report to the General Assembly on the implementation of the Development Agenda, following a concerted campaign by developing countries, further attests to this.

²With the envisaged goal of elaborating a manual on Patent Exceptions and Limitations that could serve as a reference guide for developing countries.

(c) Advisory Committee on Enforcement (ACE)

Another "core" area of WIPO's mandate where the Development Agenda has made a substantial impact is in the Advisory Committee on Enforcement (ACE) dealing with enforcement of IP Rights. The substitution of the conventional term "enforcement of IP" with the development-friendly concept of "building respect for IP" reflects the fundamental paradigm shift in WIPO in this area. The conventional approach based on the limited perspective of criminal-judicial enforcement has been replaced by a more balanced and holistic approach aimed at fostering respect for IP that takes into account the socio-economic and developmental dimensions of complex challenges such as counterfeiting and piracy. WIPO's literature review identifying methodological inadequacies and gaps in the existing studies on counterfeiting and piracy and pointing out the need to improve data collection methods as well as the consideration of socio-economic, technical and developmental variables, including factors such as pricing policies, make WIPO's work in the ACE encouragingly progressive and positively aligned with Recommendation 45 of the Development Agenda pertaining to enforcement.

(d) Program and Budget Committee (PBC)

While WIPO's biennial budget was, for a long time, determined largely by the North in consultation with the Secretariat, the inception of the Development Agenda and demands for its credible implementation have led to greater involvement and a stronger voice for developing countries. This has resulted in additional sessions of the PBC and more intensive deliberations among Member States on the draft Program and Budget proposed by the Secretariat, as have greater transparency and dialogue between Member States and the Secretariat. This, in turn, has yielded a more Member-driven and development-friendly Program and Budget. For instance, the percentage of the budget dedicated to developmental activities in the current 2012–13 biennium budget is shown as having increased by 1.9 per cent as compared with the previous biennium. At the programmatic level, the inclusion of a separate Program on Innovation Promotion with a focus on helping developing countries evolve tailor-made national IP strategies to advance their socio-economic development and the establishment of nascent Technology and Innovation Support Centres (TISCs) in developing countries to facilitate home-grown innovation through access to knowledge are some of the concrete initiatives in the PBC that further the Development Agenda.

(e) Committee on WIPO Standards (CWS)

The recently-concluded 2011 WIPO General Assembly revalidated the explicit inclusion of technical assistance and capacity building activities in the mandate of the newly-created Committee on WIPO Standards (CWS) that has been tasked with technical standard-setting in the area of information and communication technologies (ICT) pertaining to IP. The mandate also includes the provision of funding assistance to facilitate greater participation of technical experts from least developed countries and developing countries in the technical standard-setting body. This is yet another validation of developmental considerations incrementally becoming an inherent part of even the most technical aspects of WIPO's substantive work.

4. Institutional mainstreaming of the Development Agenda

Apart from ushering in a development-oriented conceptual paradigm and imparting a development dimension to WIPO's norm-setting and substantive work, the WIPO Development Agenda has also mainstreamed development institutionally, in operational terms, in the following ways:

(a) Committee on Development and Intellectual Property

The establishment of a distinct intergovernmental committee in WIPO in 2007—the Committee on Development and Intellectual Property (CDIP)—to discuss the inter-linkages between IP and development and to oversee the implementation of the Development Agenda, was in itself an institutional milestone in acknowledging the inescapable interface between IP and development. While the current thematic project-based approach to implement the Development Agenda recommendations has allowed Member States to have greater voice and oversight of various technical assistance activities being undertaken by the Secretariat, the CDIP has, more importantly, provided the first intergovernmental forum in WIPO where development issues linked to IP can be discussed and explored in a legitimate and frank manner. To this extent, the CDIP's greatest contribution has been in serving as a potential platform for discussing those dimensions of the IP system that have not been part of the mainstream discourse on IP.

(b) Development—A strategic priority for WIPO

Development is one of WIPO's stated Strategic Goals and has been integrated in WIPO's Strategic Plan as well as the Medium Term Strategic Plan of the Director-General. Since 2010, the linkages with the Development Agenda are also indicated in WIPO's biennial Program and Budget and in evaluating the programmes in the Programme Performance Report under the new Results Based Management system. While these indicators need to be substantially fine-tuned, a beginning has nevertheless been made.

(c) Reporting on Development Agenda implementation by all relevant WIPO bodies

A landmark decision was taken by the WIPO General Assembly in September 2010, making it obligatory for all relevant WIPO bodies to report to the WIPO General Assembly on how they are mainstreaming the Development Agenda in their respective areas of work. Following the adoption of this decision last year, the first such set of reports have been submitted to the General Assembly in September 2011 by the SCP, the IGC, the SCCR, the CDIP, the SCT, the ACE and the PCT Working Group. This mechanism operationalises the Coordination Mechanism and Monitoring, Assessing and Reporting modalities of the Development Agenda and makes all relevant WIPO bodies accountable to integrating the Agenda meaningfully in their work. It not only formalises reporting and monitoring of the mainstreaming of the Development Agenda, but also institutionalises it in an irreversible manner. Institutionally, this is the most significant achievement for developing countries in terms of ensuring that the Development Agenda does not get boxed into the limited format of short-term technical assistance projects in the CDIP or be reduced to mere lofty principles of an aspirational nature. By making all WIPO bodies accountable to their performance in this area, it enables genuine and meaningful transformation through tangible and concrete changes in WIPO's processes, functions and decisions.

(d) A more objective and open approach

The Development Agenda has also opened the door to objective and empirical research on IP issues in WIPO and enabled a more diverse representation of views from a cross-section of stakeholders. The establishment of the Office of the Chief Economist in WIPO and the appointment of a well-regarded economist to the post has allowed for more objective and credible research, analysis and background documentation for intergovernmental consideration of varied IP issues. The tentative willingness, demonstrated by the Secretariat in recent times, to hear different perspectives and stakeholder groups including civil society, public interest groups and specific interest groups in lieu of WIPO's traditional allegiance to right-holder groups has also contributed to an environment of open debate and constructive engagement. While, in the short term, it may appear as if WIPO is moving away from its core mandate

and core constituency of IP right holders, in the medium and long term, this open approach will stand WIPO in good stead and enable it to move forward in IP norm-setting, by enhancing the credibility of data, analysis and conclusions proposed by the Secretariat, leading to less political and more substantive debates and an environment of objectivity, openness and trust among Member States.

(e) Governance

An indirect fall-out of the growing voice of developing countries in the post-Development Agenda period has been the initiation of a discussion on WIPO reforms and an acknowledgement that some changes are urgently needed. For instance, the increase in the duration and frequency of the PBC sessions to enable a more meaningful consideration of the draft Program and Budget as well as the decision to make it obligatory for the PBC to accord priority in considering the oversight recommendations of the Independent Advisory Oversight Committee are both significant steps towards greater transparency in WIPO's governance and management. Ongoing efforts to establish a transparent, predictable and equitable system of appointing chairpersons to various WIPO bodies is yet another step in the direction of making WIPO a level-playing field for all countries, as is the recent decision to open up the Office of the "External Auditor" of WIPO to all WIPO Member States, instead of reserving it exclusively for Switzerland, as host-country—an arrangement existing since the inception of WIPO. While there has been no consensus on the need to reform the Coordination Committee (CoCo) or set up a smaller, more functional body of Member States³ to enable more regular and sustained oversight by Member States agreeing to constitute a Working Group to explore feasible reforms to WIPO's existing governance structures, is a step forward in the right direction.

What more needs to be done? The unfinished agenda of the WIPO Development Agenda

While the Development Agenda has ushered in several positive changes as outlined above, they signal just the beginning of a long road ahead, before the Development Agenda can bring about the transformative impact that it embodies. In this sense, mainstreaming the Development Agenda will continue to be a "work in progress" in the years ahead and will require urgent improvements in some of the key areas outlined below.

(a) Perception of WIPO as a "service provider" rather than as a UN Agency

Owing to its historical origins, there is a continuing perception in some quarters that WIPO is essentially a technical service provider with a singular mandate of promoting IP that has nothing to do with development, and even less to do with the United Nations and its goals. There is also a feeling that since almost 90 per cent of WIPO's revenue comes from IP registrations of right-holders, WIPO's resources should be channelled back to right-holders through enhanced IP promotion and protection, instead of being spent on promoting development. Despite the unanimous adoption of the Development Agenda, this negative perspective continues, accompanied by a resistance to development-oriented IP programmes and activities, an unwillingness to apportion adequate funds in WIPO's budget for such activities, and an underlying fear that WIPO may become "another aid agency". The decision by the 2011 General Assembly to refine the definition of what exactly constitutes "development expenditure" will hopefully provide an accurate reflection of the percentage of WIPO's budget currently being spent on development and allay such concerns of developed countries.

³ Such as an Executive Board.

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(b) Continued resistance to meaningful mainstreaming of the Development Agenda

While the tenets of the Development Agenda appeared to have been accepted by the developed world under some duress and pressure from developing countries, it was perhaps viewed as a strategic "give" at the time of its adoption, in exchange for continuing in a "business as usual" mode with WIPO's traditional mandate of promotion and protection of IP, particularly in norm-setting. Hence, while there is endorsement of the Development Agenda in principle and on paper, any attempt to give meaningful effect to the Development Agenda recommendations in intergovernmental decisions, is usually met with fierce resistance from traditional constituencies. For example, the opposition of developed countries to bringing all core WIPO bodies such as the PBC under the ambit of the General Assembly's Coordination and Monitoring mechanism, whereby they are obliged to report on how they are mainstreaming the Development Agenda in their work, demonstrates the continued reluctance to move beyond paying lip-service to actual changes on the ground. Another example pertains to the ongoing discussions in other forums on global challenges such as environment, food security, energy security, health, etc. where the link with IP is duly recognised as a part of the challenge. However, in WIPO, which is the designated global forum for IP issues, there is continued opposition to discussing the linkage of IP with these global public policy concerns, in an intergovernmental format. A proposal by India to invite the Special Rapporteurs appointed by the UN Human Rights Council on IP and Public Health to present their report was rejected. Similarly, a proposal by the Development Agenda Group for including a standing agenda item on "IP and Development" reflecting, the very mandate of the CDIP, was summarily opposed. In the absence of a genuine change in worldview, developing countries will need to continue to wage a concerted battle to translate the Development Agenda in tangible terms. Much more will need to be done to bring in a genuine transformation in the collective mindset.

(c) Technical assistance—A "black box"

With WIPO's considerable portfolio of technical assistance activities not being reported to any intergovernmental body for deliberation and oversight, technical assistance continues to be something of a "black box". There is a strong impression that the considerable resources spent by WIPO on a multitude of training programmes, seminars and workshops all over the world continue to propagate conventional IP views while providing mere lip-service to the Development Agenda. The transformative potential of the Development Agenda will only bear fruit when WIPO's legislative advice, training programmes, seminars, conferences and workshops, including in the area of patent examination and enforcement, are informed by a balanced agenda and programme, with a diverse panel of speakers who present alternate points of view and acknowledge the lack of clarity where none exists, in lieu of dogmatic and unfounded assertions. Representation of varied ideological perspectives, such as the "Copy Left" movement (which opposes stronger Copy "Right"), as a part of the growing global discourse in IP would significantly enhance the credibility and outreach of WIPO programmes.

(d) Development-oriented program and budget

Rather than simply adding a "development" dimension to existing programmes as is largely the practice now, there is a need for more concrete developmental programmes with adequate funding. For instance, India's proposal for setting up TISCs in developing countries to link R&D institutions with the patent system and serve as domestic "innovation hubs" has been reduced to a technical assistance programme of providing a few computers with access to patent information. While this could be an initial step, much more needs to be done to substantively assist developing countries in fostering innovation, using WIPO's expertise. Similarly, the Secretariat needs to accord priority and make more serious efforts to meaningfully assist developing countries in evolving tailor-made IP strategies and national policies, through appropriate legislative advice.

(e) Need for WIPO reforms

In contrast to the far-reaching changes in WIPO mandated by the Development Agenda, WIPO's governance structure remains frozen in the 1967 pre-UN format. While the Development Agenda seeks a radical transformation in the organizational culture, working methods and outcomes, no changes have been made post-2003 to WIPO's organizational structure or working methods, with the last substantive reform having been effected more than a decade ago in 1998 when the PBC and the current Standing Committees were set up.⁴ Consequently, in the post-Development Agenda period, WIPO has been asked to deliver new results with the same old tools.

WIPO reforms: How will they provide impetus to Development Agenda mainstreaming?

While organizational reforms in WIPO and mainstreaming of the Development Agenda do not seem to be patently linked, there is indeed a direct correlation between the two. Given that most of WIPO's institutional structures and governance mechanisms are founded in WIPO's pro-North historical origins and evolution, organizational reforms in WIPO are urgently needed if the Development Agenda is to produce the envisioned organizational transformation. WIPO reforms would help mainstream the Development Agenda in the following specific ways:

- (a) At an organizational level, it will give WIPO updated and relevant tools to achieve the new results demanded by the Development Agenda.
- (b) It will provide a level playing field for all WIPO Member States and place them on an equal footing, thereby dispelling the notion of continuing control by developed countries of WIPO's work and processes.
- (c) It will improve predictability and transparency in processes (thereby improving communication), address the "trust deficit" between Member States and allow smoother conduct of work.
- (d) It will improve Member States' oversight and WIPO's governance.

What are the specific reforms needed?

Some of the key reforms urgently needed, are outlined below.

(a) Create a functioning Executive Body

As recommended by the WIPO Audit Committee, there is a need for a smaller and more functional governing body that meets more frequently than the current PBC or COCO. This would allow, among other things, more effective and regular oversight of the implementation of WIPO's Program and Budget; review of recommendations of Oversight bodies such as the Internal Audit and Oversight Division and the IAOC; staff recruitments and human resource issues; thus creating greater transparency and trust between Member States and WIPO Secretariat. If the establishment of a new executive body in WIPO is politically difficult at this stage, the COCO could be redesigned to function as an executive organ, as was

⁴ In 2003, only marginal changes were introduced. Examples of these changes are the move towards a unitary contribution system for Member States and the abolition of the WIPO Conference.

originally envisaged in the WIPO Convention. This is not a new idea. The Working Group on Constitutional Reform set up by the WIPO General Assembly, recognised in 2001 that the COCO as currently constituted with 83 Member States, was too big in size and too complicated in its membership structure, to perform its mandated executive function.⁵ The Working Group, therefore, recommended that:

- The Coordination Committee be abolished and a new body or committee be set up under the General Assembly (or, alternatively, its executive functions be shifted to the PBC);
- (ii) the number of members be reduced, while maintaining representation of various treaty unions administered by WIPO, in order to enable it to fulfil its executive functions effectively. Redesigning the COCO on the lines of option (ii) above, would substantially contribute to improving governance, equity and smooth functioning of the organization.

(b) Reorganise WIPO's regional groups

WIPO's 184 member States currently constitute seven groups.⁶ With only one cross-regional interest group (Group B) and other six regionally divided groups, WIPO's extant group structure is not equitably representative. In order to ensure that all groups in WIPO are placed on an equal footing, WIPO's groupings should be reorganised to make them truly regional in nature, and to align them with the five traditional regional groups in the United Nations—the African Group, the Asian Group, GRULAC, the Group of East European States and the Group of West European and Other States. In addition to these standard UN regional groupings, there should be space for cross-regional interest groups such as the Development Agenda Group to function, without according any special formal or "historical status" to just one Group. This would ensure that no negotiating group receives "second class" treatment and all are on par to facilitate a more balanced representation of interests, direct dialogue and open communication, speedy resolution of issues, consensual outcomes and smoother conduct of business.

(c) Extend the frequency and duration of PBC sessions

While standing committees meet twice a year for five days each even when there is no norm-setting underway, it is an anomaly that the only body discussing Program and Budget issues and other important medium and long-term organizational and governance issues meets only once a year formally and for only three days. With the inception of the Development Agenda, developing countries as well as others are demanding time and space for a real discussion about the Organization's priorities, policies and budgetary allocations. While the duration of the formal PBC sessions has been extended from three to five days, there is a need to have at least two formal sessions every year, to put the PBC on par with other substantive committees of WIPO.

(d) Rationalise the work of WIPO bodies

There is a need to review all WIPO bodies, their mandates and meeting schedules with a view to rationalising their work and analysing whether the existing bodies are addressing all relevant areas of WIPO's mandate in an optimal manner, in terms of allocated time and resources. Important aspects of the global IP system that are currently unaddressed such as post-grant aspects of the patent system including enterprise practices, global challenges and IP, impact of ICT on IP should also be included in the agenda of relevant intergovernmental bodies. This would help optimise resources and time, lead to better work dynamics and facilitate productive outcomes that are relevant to today's realities.

⁵ A third of the Member States of the Paris and Berne Unions need to be represented in the COCO.

⁶ The African Group, Asian Group, Group of Latin American and Caribbean Countries (GRULAC), Central Europe and Baltic States (CEBS), Central Asia, Central and East European Countries (CACEEC), China and Group B (a cross-regional group of developed countries).

(e) Establish a transparent mechanism for appointment of Chairs and Bureau

The present ad-hoc system based on back-room negotiations to nominate Chairs of various committees impairs WIPO's ability to conduct work in a smooth, transparent and predictable manner and contributes to the "trust deficit" as well as unnecessary waste of time and human resources. A system of automatic rotation of Chairs among WIPO Groups is urgently needed. Similarly, a designated bureau for every meeting is a necessity to improve predictability, transparency and equity.

(f) Establish a "cooling-off" period for recruitments

The current "revolving door" policy where delegates to WIPO and capital-based IP officials dealing with WIPO join the Secretariat is pernicious, and leads to harmful politicisation and polarisation. A mandatory "cooling off" period of three years should be introduced before delegates and capital-based IP officials can take up employment in the WIPO Secretariat. There is also a need for greater geographical balance in WIPO's staffing, especially in decision-making positions in WIPO's "core" areas such as patents, which have traditionally been the preserve of developed countries.

(g) Foundational reforms?

In addition to the functional reforms outlined above, it would be worthwhile to explore the following two foundational reforms:

(i) **WIPO's two distinct mandates**

WIPO's two distinct mandates in the area of (1) norm-setting and provision of technical assistance and (2) provision of global IP services, treaty administration, dispute resolution, etc. are currently amalgamated, in organizational and governance terms. Separation of these two core functions would facilitate more streamlined functioning, less interference of one in the other, reduce conflict of interest and facilitate greater confidence and transparency.

(ii) Review of WIPO treaties' management

WIPO has a complex set-up where treaties have legally separate Unions of States, with independent administrative organs and budgets. It would be useful to review and simplify the management of these treaties under a uniform system. This was a recommendation of the Working Group on Constitutional Reform in 2003.

Will development continue to be integrated in WIPO? What can we foresee for the future?

It would be inevitable for WIPO, and indeed other forums dealing with IP, to increasingly incorporate developmental considerations into the global discourse and decisions on IP, for the following reasons.

(a) IP is becoming a critical asset in a growing global "knowledge economy"

Innovation is increasingly becoming the key contributor to national growth and competitiveness. The fact that PCT applications grew by 5.7 per cent in 2010 from 2009 and continued to grow at 9.5 per cent in the first half of 2011 despite, the persisting global economic crisis, shows the growing importance of investments in IPRs and intangibles. Apart from the G-8, many of the G-20 countries have incorporated innovation in their national planning and development goals. With more and more developing countries and emerging economies aspiring to join this wave and become IP producers, rather than simply users

and consumers, evolving a holistic approach to IP and calibrating it to achieve larger developmental goals will become inevitable. While there will be due recognition of the need for boosting technological innovation and creativity through the IP system, exceptions and limitations will need to be made for public policy concerns, including respecting the sui generis rights of communities on their traditional knowledge, genetic resources and folklore. Mainstreaming development is, therefore, not only a strategic goal for WIPO, but a pragmatic and necessary component of the global IP regime, if IP is to play a credible role as one of the key contributors to a thriving global economy.

(b) Democratisation and globalisation of IP

Innovation is no longer concentrated in a few industrialised countries and is becoming multipolar and geographically diverse. In 2010, Asia overtook Europe and North America as the largest PCT filing region, with PCT international applications from China, the Republic of Korea and Japan growing by 55 per cent, 20.3 per cent and 8 per cent respectively, as compared with 2009. From 2002 to 2010, the average annual growth rate from these three countries was 15.1 per cent, as compared with 1.1 per cent for North America and 3.1 per cent for Western Europe. In the area of trademarks too, four Asian countries-India, China, Japan and the Republic of Korea-accounted for 37 per cent of total trademark applications, with India showing the highest five-year growth from 2005 to 2009 (13.5 per cent) and China recording the highest annual increase (20.8 per cent) in 2009. Even in industrial design filings, China accounted for 50% of total industrial design activity in 2009 and registered an increase of 12.3 per cent during 2008–2009. As innovation becomes increasingly diversified among countries at different levels of development, the global IP system will have no choice but to contextualise IP rights in the larger framework of socio-economic growth and allow the necessary policy space to tailor IP regimes to specific national circumstances and priorities. This universalisation and globalisation of innovation will hopefully usher in an enlightened perception of IP that automatically integrates development as a natural adjunct to IP and succeeds in replacing the current perception in many quarters that any reference to development or bringing in balance to the global IP system is "anti-IP". The World Intellectual Property Organization will hopefully follow the cue and rechristen itself as the World Innovation Promotion Organization, without having to change its acronym!

(c) IP and IT

The unprecedented growth and reach of the internet has facilitated further democratisation and universalisation of innovation by providing a global market, unfettered access to information, fostering free expression, entrepreneurship and individual creativity. Coupled with the geographical diversification of innovation, the internet could also incrementally pave the way for more open, collaborative and synergistic models of innovation between different innovation networks. More fundamentally, the internet has dramatically challenged conventional notions of how IP is produced, transmitted, consumed, protected and enforced. The transnational, borderless nature of the internet, whose strength lies in its very irreverence and transcendence of national borders, fundamentally challenges the sovereign and territorial basis on which the current IP system is founded. With the internet age and come up with innovative models to facilitate access to knowledge, technology and culture *via* the internet, on the one hand, while ensuring adequate remuneration to the right-holders, on the other—a balance, in other words, between consumers and producers, which is at the heart of the Development Agenda. Indeed, in the internet age, the greatest innovation will perhaps be in how innovation itself takes place.

(d) IP and global challenges

With an expanding world population and rapidly shrinking resources, the world will increasingly be challenged by common concerns such as food and energy security, environmental degradation, climate change and public health. The global community will increasingly look towards technological innovation, technology transfer and human creativity to come up with "out of the box" solutions and viable ways of addressing these challenges. IPRs will consequently be viewed as an integral part of the debate and a means of finding solutions. With developing countries mostly bearing the brunt of these problems and the inherent development implications in all these challenges, it will be inevitable for the global IP system to address them from a public policy perspective, rather than the traditional prism of private profit and monopoly right—an altered perspective which is, again, at the heart of the Development Agenda.

(e) "IP consciousness" of developing countries—Setting up of the Development Agenda Group

The extent to which the "Development Agenda" will sustain and enhance a development consciousness in WIPO will depend on the ability of developing countries to build on it and optimise its applicability and potential for change. None of the achievements of the Development Agenda elaborated in this article has come easy. They are the fruits of many arduous battles waged by developing countries, as was the case with the inception of the Development Agenda itself. Much will, therefore, depend on the awareness and importance attached to IP at the global level by developing countries, as will their commitment and competence to effect the necessary change. An encouraging development in this regard is the recent inception of a new cross-regional group of 20 like-minded developing countries under the umbrella of the Development Agenda Group (DAG) in WIPO. In its short life since its inception in April 2010, the DAG has played an instrumental role in effectively and forcefully pushing the agenda for development in all WIPO bodies. The setting up of DAG has enabled developing countries to pool their resources and expertise efficiently to achieve shared goals in IP and enhanced their collective voice and bargaining power in WIPO. Indeed, the DAG has today emerged as the natural negotiating counterpart and interlocutor to Group "B"—a similar grouping of developed countries that enjoys a privileged and questionable position as the only formal cross-regional interest grouping in WIPO. While some constituencies in the developed world may view the emergence of DAG negatively, from a broader perspective, it is a healthy and much-needed development that allows for direct dialogue between two opposing viewpoints and facilitates outcomes by enabling the exploration of an acceptable middle ground, thereby enhancing the credibility of WIPO's work and encouraging balanced and sustainable progress in IP. The current global economic climate and persisting recession may, however, lead to protectionist tendencies in the developed world, with a hardening of conventional positions on IP protection, promotion and enforcement, as is evident from the recently-concluded plurilateral Anti-Counterfeiting Trade Agreement (ACTA). This will not only make the Development Agenda even more relevant and important, but also require concerted action and engagement by developing countries to ensure the continued mainstreaming of the Development Agenda.

Conclusion

The Development Agenda would have lived up to its transformative potential if it continues to guide developing countries and WIPO Member States in transforming WIPO from the "World Intellectual Property Organization" to the "World Innovation Promotion Organization" by helping to create and sustain a favourable international climate for fostering innovation everywhere; helping expand the policy space available in this critical area; assisting countries in evolving optimal national policies for encouraging

domestic creativity and innovation; helping to transform developing countries from being importers of intellectual property to becoming producers and net exporters of intellectual property; assisting countries in developing "green technologies" and other cutting-edge technologies to meet their domestic challenges in the field of energy, health, climate change and food security; and, above all, a WIPO that would help developing countries to climb the technological ladder and enable them to share their successes with other developing countries in need, thereby helping to make the world a better place for everyone.

Intellectual Property Policy Making in the 21st Century

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🕮 Intellectual property; International trade

This article assesses the various dimensions and processes which influence the formulation of intellectual property (IP) policy making, taking into account the complex, multi-faceted nature of this field.

The creation and distribution of products, especially knowledge-based products, are subject to many different legal and regulatory requirements. At the macro level, IP affects a wide range of issues, such as international trade policy, foreign direct investment, innovation climates, competition rules and public health. At the micro level, intellectual property rights (IPRs) are strongly embedded in contemporary business models.

As will be described in the article, the underlying logic and architecture of the system of IPRs has always been subject to intense debates. Indeed, the policy making of IPRs has traditionally faced the challenge of striking a balance between the incentive to innovate, on the one hand, and the need to secure access to existing proprietary products, on the other hand.

This approach, which we choose to term the "social" ("general welfare") approach, is pivotal to the process of IP policy making. Nevertheless, we submit that the set of considerations and constraints of the policy making of IPRs have evolved to include additional political economic dimensions that are just as important as the social one. These include the so-called "industrial policy" dimension (which is based upon the perception that knowledge, information and different forms of literary and artistic creations are assets of strategic economic importance) and the "global" dimension, which places IP policy making in an international comparative context.

These dimensions reflect a new wave of debates in the field of IPRs, which encompass issues such as incentives to innovate, industrial development, trade policy, access to available technologies, and effective commercialisation in the age of knowledge-intensive industries. We therefore argue that contemporary policy making of IPRs should incorporate these dimensions in the actual decision-making process, both globally and domestically.

Accordingly, this article first analyses key developments and trends which characterise contemporary processes of IP policy making. Following this, it identifies and discusses the three major dimensions or elements—social (general welfare), industrial and global—affecting the process of IP policy making. Finally, it concludes with key recommendations for effectively integrating the various dimensions into contemporary policy and decision-making in the field of IPRs and related areas.

The Context-developments and trends in the process of IP policy making

The evolving IP context

The IP debates of the 21st century are characterised by a shift in the perception of IPRs, relative to the previous centuries. At least four elements are particularly worth mentioning.

First, the unit of analysis has shifted from the individual to the organisational unit (be it a company, a research institution or a university). Consequently, the relationships governing the field of IPRs have become more complex. Therefore, modern discussions should reflect this change in the unit of analysis.

Secondly, patents are no longer the only form of IPRs that are worth discussing, especially with regard to policy making issues. Copyrights, trademarks, geographical indications and other forms of sui generis protection (such as pharmaceutical data exclusivity) are associated with some of the most intriguing and heated debates in the 21st century. Their economic rationale, legal manifestation and social uses (and abuses) should be addressed more frequently in policy discussions.

Thirdly, the field of IPRs is becoming increasingly fragmented, as various perspectives (i.e. economic, legal, management, etc.) and different sector-specific issues are integrated into IP debates. Therefore, in order to have a comprehensive understanding of the IP field it is very important to promote interactions between different IP themes.

Finally, in contemporary debates the role of IPRs is shaped by many different factors. For instance, it is the disastrous state of poverty and disease in sub-Saharan Africa (and obviously the fact that we know about it) that brings about the heated debates about IP policies and access to medicines in least developed countries. The fact that IPRs are never the only factor—the "silver bullet"—and sometimes not even the most important factor should be taken into account in policy making.

New trends and processes in IP policy making

The contextual shift in the perception of IPRs has had a profound effect on the manner in which various countries formulate their IP policies. It is possible to identify a number of processes which characterise contemporary IP policy formation. These processes are not necessarily coordinated or suited to one another. Occasionally they may even conflict with each other.

The first process consists of the different inputs directed towards decision-makers responsible for the formation of IP policies. This refers to a "bottom-up" process, in which various actors, such as private companies, representative organisations (associations and federations), professional bodies, voluntary organisations, nongovernmental organisations, academic bodies and even public and governmental organisations, seek to influence IP policy making. All these bodies have interests, demands and expectations, with regard to both the manner in which the formulation of IP policy should be handled in a given country and the results of such policy.

The second process concerns the decentralisation of the formulation and execution of IP policies. While traditionally IP policy was formulated by a single governmental office (such as the department of justice, trade or industry in a given country), the formation of today's IP policy formation is a multifaceted process involving formal and informal interactions between various government and legislative branches. This process may lead to reduced coordination and sharing of information, as well as increased exposure to outside pressure and deviation from the stated purpose of policies. All of these are likely to lead to a situation in which IP policy making in a particular country will become slow, inefficient and, on occasion, even irrational.¹

¹ For a short discussion on this issue see M. Blakeney, *The Process of National IP Policy Making: Theory, Practice and Policy Lessons* (London: Stockholm Network, 2006).

The third process involves global influences on decision-making regarding IP policies. Three factors influence this process. First, treaties and international agreements, such as the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) and the various conventions of the World Intellectual Property Organisation (WIPO), lay down a minimal threshold which every signatory country must adopt by local legislation.² Clearly there are still differences (sometimes substantial ones) in the IP environments of different countries. However, it is also clear that international agreements and treaties do promote convergence in the protection of IPRs.

Secondly, since the 1990s, the IP field has become integrated with the broader trade policy of various countries, especially developed countries such as the United States, members of the European Union and Japan. Perhaps the most illustrative example of this phenomenon is the inclusion of the IP agenda in the TRIPS Agreement.³ Moreover, since 2000, IP themes have also been included in regional and bilateral trade agreements.⁴ The operational significance of this trend is that IP policy is also influenced by the trade relations between countries, especially during periods in which regional and bilateral trade agreements are being negotiated.

Finally, it is clear that the process of globalisation has created a situation in which the IP climate in a given country is no longer intended to only serve the needs of local entities, but also to serve the needs of foreign organisations and companies.

Dimensions in IP policy making—The social, industrial and international aspects

The complex nature of the IP field undoubtedly demands "multi-disciplinary" policy making, which incorporates many diverse factors. Having said that, for the purposes of simplification, it is possible to define three dimensions that characterise this field: the social (or general welfare) dimension, the industrial dimension and the international (or global) dimension.

In this section, we shall attempt to chart the relevant components of each of the above dimensions. It is clear that the list which follows is incomplete and that it is possible to take additional important components into account. We are not talking about "black and white" issues but rather a collection of components representing a broader spectrum of considerations which should be taken into account in IP policy making.

The social (general welfare) dimension

The social dimension can be described as the "classical" dimension, because most of the material in economic literature tends to deal with this aspect. It focuses on the net advantages and disadvantages to society from IP policy making in a particular field (the general welfare perspective).⁵

The social dimension is founded on the perception that IPRs are a type of "social contract" between the innovator and society—the innovator is granted a temporary monopoly (the IPR) on his invention or intellectual creation, and in exchange he agrees to place that invention or intellectual creation in the market for the benefit of society.⁶ IP policy making within this dimension essentially focuses on balancing two central components—incentives and accessibility.

² See M.P. Pugatch, *The International Political Economy of Intellectual Property Rights* (Cheltenham: Edward Elgar, 2004), Ch.6 in particular. ³ F.M. Abbott, "Protecting First World Assets in the Third World: Intellectual Property in the GATT Multilateral Framework" (1989) 22 *Vanderbilt Journal of Transnational Law* 689; J.H. Reichman, "Securing Compliance with the TRIPs Agreement after US v. India" [1998] 1 *Journal of International Economic Law* 581.

⁴ M.P. Pugatch, "The International Regulation of IPRs in a TRIPs and TRIPs plus World" (2005) 6 *Journal of World Investment and Trade* 430; OECD, Trade Directorate, *Regional Trade Agreements and the Multilateral Trading System* (Paris: 2002), TD/TC(2002)8/FINAL; World Bank, Development Prospects Group, *Trade Regionalism and Development* (Draft) (Washington: 2004), Ch.5, pp.1 and 4.

⁵ M.P. Pugatch, *The International Political Economy of Intellectual Property Rights* (Cheltenham: Edward Elgar, 2004), Ch.2.

⁶E. Penrose and F. Machlup, "The Patent Controversy in the Nineteenth Century" (1950) 10 Journal of Economic History 1.

Incentives

With regard to incentives, the following objectives may be emphasised:

(1) **Prevention (of free-riding) and protection**—

ensuring that rights owners can commercially exploit the products which they own during the period of exclusivity, with a view to maximising their profits.

Here it must be noted that the most important role of IPRs with regard to the incentives of innovators and creators is to prevent the problem of "free-riding". Knowledge and other forms of intellectual and artistic creations have the characteristics of public goods (i.e. non-rival and non-excludable). As such, in the absence of institutional arrangements, such as IPRs, the innovator/creator cannot prevent others from exploiting his invention free of charge.⁷ Consequently, this creates a disincentive for innovators, especially private entrepreneurs, to engage in inventive activity, since they will not always receive commercial returns for their work.

Thus, the underlying rationale for the creation of IPRs from this perspective is that they allow innovators and creators (both firms and individuals) to secure commercial returns for their work, and as such, increase their incentive to invest in future inventive and creative activities.

(2) Absence of discrimination—

ensuring non-discrimination between various bodies that deal with the development of IP-based products, including between local and foreign bodies and among large-, medium-, and small-sized businesses.

(3) Education—

educating society concerning the honouring and protecting rights afforded to creators of IP-based products.

(4) Enforcement and operational efficiency—

maintaining certainty and providing confidence to rights-holders that their IPRs are, in fact, being enforced. This aspect also relates to the efficiency and the purposefulness of the IP system. For example, an effective IP system can be measured by the time authorities take to examine and register IP rights (for example, patents), the degree of expertise of courts in matters related to IPRs, effective law enforcement activities (for example, the number of police dedicated to the fight against counterfeiting), sufficient levels of compensation awarded to rights-holders for the violation of their rights, and criminal penalties imposed on crimes concerning thefts of IPRs.

Accessibility and affordability

With regard to the issue of accessibility, emphasis is placed on the following elements:

⁷ K. Arrow, "Economic Welfare and the Allocation of Resources for Invention" in National Bureau of Economic Research (ed.), *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton, New Jersey: Princeton University Press, 1962); E.J. Stiglitz, "Knowledge as Global Public Good" in I. Kaul, I. Grunberg and M.A. Stern (eds), *Global Public Goods: International Cooperation in the 21st Century* (New York: Oxford University Press, 1999).

(1)Mitigating the effects of IPRs on public access to proprietary technologies and products-

for the social dimension, probably the most significant element with regard to accessibility is the need to ensure that IPRs do not prevent access to proprietary technologies in a manner that would be "socially unjustified" or "socially unbearable".

This is a highly complex task as, by definition, patents, copyrights, trademarks and other forms of IPRs create a temporary monopoly on the knowledge and creations they protect, allowing their owners to restrict, and even prevent, others from using that knowledge. The result, as Hindley put it, is that "the establishment of private property rights in these cases artificially creates the symptoms of scarcity".8

Consequently, the structural trade-off built into the IP system-that in order to increase the amount of available knowledge and creations in the future the efficient use of existing and available knowledge and creation is inhibited in the present—is its most problematic aspect.⁹

The tension between IPRs and access to available knowledge is the most visible in the area of pharmaceuticals, especially in third world countries (i.e. issues surrounding so-called access to patented medicines). Under patent protection a pharmaceutical company sets a relatively high price for its drug in order to recoup the considerable research and development (R&D) costs it has invested and to secure profits. In contrast, under generic competition a generic company is not required to recoup R&D costs, and therefore can set a price that is much lower than that of the original drug. By lowering the price of the original drug the generic company increases public access to that drug and is still able to secure profits. Although both the R&D-based company and the generic company seek profits, it is quite understandable why the behaviour of the former is perceived as "monopolistic" while the practices of the generic company are perceived as "benign".

Thus, in the context of the first dimension of IP policy making, policy makers constantly seek to check the boundaries of IP protection in order to make sure that social costs associated with such protection do not become intolerable.

Limitations on the scope of exclusivity-(2)

preventing cases in which the scope of exclusivity is so broad that it creates a barrier to innovative activities.

(3) Prevention of abuse of IPRs aimed at unfairly securing an additional monopoly in the market—

preventing situations in which a rights-holder may abuse the market power granted to him in order to achieve control in the market above and beyond his IPRs. Obviously, what constitutes an abuse of IPRs and in which circumstances such abuse can take place must be defined. This element generally relates to the manner in which competition and anti-trust rules deal with IPRs.10

(4) Absence of discrimination—

preventing a situation in which a rights-holder discriminates adversely against different population groups on the grounds of religion or race with regard to the sale or use of proprietary products.

⁸B.V. Hindley, The Economic Theory of Patents, Copyrights, and Registered Industrial Designs: Background Study to the Report on Intellectual and Industrial Property (Ottawa: Economic Council of Canada, 1971), p.1.

 ¹⁰ Pugatch, The International Political Economy of Intellectual Property Rights (2004), Ch.3.
 ¹⁰ F. Etro, The Economics of Competition Policy and Dominant Market Position (London: Stockholm Network, 2007).

(5) Accessibility in an emergency situation—

guaranteeing full public accessibility to a particular IP-based product in times of emergency, such as war or health crises, provided that the purpose is strictly benign, without intentional prejudice against the rights-holder (for example, in order to provide commercial advantages to other competitors).

The industrial policy dimension

This dimension is based upon the understanding that knowledge, information and creativity are economic assets of strategic significance. In this dimension IPRs are viewed as a pivotal instrument for exploiting these assets.

Accordingly, policy making within this dimension seeks to identify, evaluate and maximise the factors which promote both the creation and exploitation of IP assets.¹¹

IP creation

IP creation refers to the capacity of a given country to translate its scientific and innovative base into exploitable IP assets. It includes the following elements:

1. The volume of IP assets created in the country, both in absolute terms and in relation to other countries—

naturally, the choice of tools used for measuring IP assets is important here. For example, an acceptable measurement of the ability to create IP assets at the national level (and in comparison to other countries) is patent intensity—the number of patents generated per person in a given country (this can be further analysed according to efforts by residents or nationals).

2. The typology and characteristics of IP assets—

policy-makers seek to ascertain national strengths and weaknesses in the creation of IP assets. They ask questions such as: Is the creation of IP assets based on inventive activities (knowledge-based) or creative ability? In which areas are IP assets being created, and why? Can measures be undertaken at a national level to encourage IP creation in those areas in which there is a dearth of IP assets? The aim here is to attempt to assess the existing potential for IP creation in a given country in order to translate assets into economic and commercial instruments.

3. Identification of IP-intensive bodies—

here policy makers identify who is most active in creating IP assets, including the type of entities (small or large; private, public university, government, etc.) and the scope (only by small groups of companies or widespread). They also evaluate how they can support IP creation by entities having a viable yet unexploited potential.

IP exploitation

IP exploitation refers to the national ability to commercially exploit the IP assets created by a given country. Here, the following elements or indicators are often employed:

¹¹ M.P. Pugatch, Creation and Exploitation—Analysis of Sweden's Intellectual Property Performance (Sweden: TIMBRO, 2006).

1. The balance of trade arising from the exploitation of IP assets, i.e. the extent to which a given country is an exporter (or importer) of IP products—

policy makers examine whether the country experiences a net profit or loss in the trade of IP-related products. They also ask if the country enjoys an advantage in the manufacture and trade of these products relative to other countries.

For example, today the ability to rely on the export of knowledge-based products is increasingly critical to countries seeking to climb up the technological value chain. In line with this objective, the Organisation for Economic Development and Cooperation (OECD) regularly measures the income generated from knowledge-based products which involve IPRs, focusing on income from royalties and licence fees.¹² The table below illustrates which countries had a total net surplus or net deficit in royalties and licence fees in 2008.

US\$)				
Country	Exports	Imports	Net	
Austria	912.5865	1612.773	-700.187	
Belgium	1185.044	2137.181	-952.137	
Canada	3415.055	8774.741	-5359.69	
Czech Republic	55.41019	727.0577	-671.648	
Denmark	2641.557	1718.718	922.8384	
European Union 27	68552.66	93596.6	-25043.8	
Finland	1481.671	2026.88	-545.355	
France	10265.5	4911.561	5353.939	
Germany	8829.97	11948.58	-3118.61	
Greece	43.94478	709.5617	-665.617	
Hungary	802.2521	2019.16	-1216.91	
Ireland	1334.456	30172.48	-28838	
Italy	823.2321	1790.017	-966.785	
Japan	25687.17	18291.59	7395.582	
Luxembourg	336.324	541.8391	-205.515	
Netherlands	19636.14	14310.76	5325.521	

Figure 1: Intellectual property transactions—royalties and licence fees—2008¹³ (millions of US\$)

12 OECD, Statistics on International Trade in Service (Paris: 2005).

Norway

Poland

Portugal

Spain

Sweden

Switzerland

United Kingdom

Slovak Republic

¹³ Calculations and compilation based on OECD Statistics on International Trade in Service.

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670.3901

226.438

80.12598

163.9081

789.5411

4884.385

12292.89

13536.5

-48.4043

-1529.62

-416.45

-18.8787

-2440.4

2862.988

691.8252

3422.272

718.7943

1756.354

496.4295

182.7868

3229.941

2021.396

11601.07

10114.23

Country	Exports	Imports	Net
United States	93920	25781	68139

On the other hand, the trade balance from the exploitation of IP-based products also involves trade of products based on imitation. For example, in the pharmaceutical field, there are countries with very strong generic industries. The manufacture of generic medicines in these countries is not only aimed at serving the needs of the local market but, often more importantly, for export purposes. Clearly, IP policies aimed at promoting trade of products based on imitation will differ somewhat from those aimed at encouraging exploitation of original products.

2. The ability to translate IP-related assets into viable products in the market—

policy makers seek to identify the factors which both facilitate and hinder a given country's ability to translate IP-related assets (throughout all stages of R&D) to a marketable product. Here, various factors at the macro level are generally taken into account, such as: the base of available human capital; R&D infrastructure and technological capabilities; manufacturing capacity, funding sources (public and private) available to entities which develop IP-related products (particularly in the initial stages of a company and/or when the technology is at an embryonic stage); and the nature of national regulation (i.e. whether it helps such entities flourish or is overbearing and unhelpful). National policies relating to each of these factors can have far-reaching impact on the ability to exploit IP-related products in that country.

3. Maximising the benefits to the economy from IP-related assets through effective enforcement—

it is clear that efficient enforcement of IPRs in general, and counterfeiting in particular, constitutes a central tool for maximising the economic benefits arising from the exploitation of IP assets. From a national perspective, the higher the level of IP piracy in a given country, the greater the losses to its economy, both directly (e.g. from the direct loss of legitimate revenues derived from the exploitation of IP-based products) and indirectly (e.g. from the loss of income from taxes). Accordingly, within this dimension decision-makers place particular emphasis on policies which support the practical ability to contain the phenomenon of piracy.

The global dimension

This dimension places IP policy making in an international comparative context. The basic unit of comparison within this dimension is the state, with national IP policy judged in comparison with other countries and with the international arena in general.

The formulation of IP policies in the global context may focus on the following elements:

1. The extent to which the national policies of a given country improve or detract from the competitive advantage (and the balance of trade) of that country—

obviously, part of this assessment requires identifying which sectors in the country are engaged in the development of IP-based products and/or the copying of existing IP-based products.

- 2. The extent to which these IP policies strengthen or weaken the ability of the country to compete for foreign direct investment (FDI) vis-à-vis other countries.¹⁴
- 3. The extent to which these IP policies increase cooperation between foreign and local entities in the area of technology transfer.
- 4. The impact of linking trade policy in the IP field with trade policy in other areas—

i.e. whether it enhances or detracts from effective policy in either fields as well as from the potential to achieve favourable results for the economy.

5. The extent to which the IP policy of a given country is exposed to negative reactions (say, trade retaliation) on the part of trading partners-

one of the best known examples on this subject is the so called "Special 301" lists of the United States Trade Representative (USTR).¹⁵ Section 301 (commonly referred to as Special 301) of the Trade Act of 1974, particularly after its amendment by the Omnibus Trade and Competitiveness Act of 1988, enables the USTR to identify Priority Foreign Countries, which according to US criteria, provide inadequate protection for IPRs, thereby causing adverse impact to rights-holders. The 301 process may result in increased bilateral attention aimed at addressing the problem areas. It can eventually lead to a situation in which the US may take unilateral actions and possibly impose sanctions against countries found to be egregious violators of IP rights.

6. The extent to which the IP policy of a given country conforms to its international obligations-

for example the TRIPS Agreement, the various international treaties of the World Intellectual Property Organisation (WIPO),¹⁶ and preferential trade agreements among various countries and regions, such as the Trans-Pacific Partnership Agreement and the Anti-Counterfeiting Trade Agreement.

7. The extent to which the IP policies of a given country are influenced by the political as well as economic demand to belong to various international economic "clubs"-

here it is useful to note the key international "clubs" that have taken differing approaches regarding IPRs. For example, the OECD supports a high standard of IP protection in line with, and even beyond, existing multilateral agreements.¹⁷ In contrast, the United Nations Conference on Trade and Development (UNCTAD) promotes the use of "flexibilities" in existing agreements (such as TRIPS), or a reduced standard for IP protection in some cases, particularly for developing countries and their development partners.¹⁸

¹⁴ For a discussion on this issue see D. Lippoldt and W. Park, Technology Transfer and the Economic Implications of Strengthening of Intellectual Property Rights in Developing Countries, OECD Trade Policy Working Paper No.62, available at http://www.eecd.org/officialdocuments /displaydocumentpdf?cote=TAD/TC/WP(2007)19/FINAL&doclanguage=en [Accessed October 31, 2011]. ¹⁵United States Trade Representative's website, available at http://www.ustr.gov/Trade_Sectors/Intellectual_Property/Section_Index.html [Accessed

October 31, 2011]; US Department of Commerce, Office of the Chief Counsel for International Commerce, section 301 of the 1974 Trade Act available at http://www.osec.doc.gov/ogc/occic/301.html [Accessed October 31, 2011].

For the various international treaties under WIPO see http://www.wipo.int/treaties/en/[Accessed October 31, 2011].

¹⁷OECD, Recommendation of the Council Concerning a General Framework of Principles for International Co-operation in Science and Technology (Paris: 1988), available at http://webdominol.oecd.org/horizontal/oecdacts.nsf/Display/4557F1D8001991C9C1257088005816EB?OpenDocument

[[]Accessed October 31, 2011]. ¹⁸UNCTAD, "Stringent Intellectual Property Protection Hampers Technological Progress in the World's Poorest Countries", available at http://www .unctad.org/Templates/Webflyer.asp?docID=8593&intItemID=1530&lang=1 [Accessed October 31, 2011]

Conclusions—The changing nature of the IP policy making process

The formulation of IP policy has become one of the most complex and weighty issues facing policy makers today. Indeed, the IP field now encompasses legal, economic, business, political and ethical dimensions that affect the whole of society.

This article has identified a number of processes which characterise the policy making of IPRs in the 21st century. These include, among other things, the ever increasing inputs directed at IP policy makers from a wide range of stakeholders; the decentralisation of IP policy making (whereby policy making related to IPRs is distributed among multiple governmental departments and agencies) and the "loss of national sovereignty" in decision-making with regard to IP policy.

The article has also outlined three central dimensions which influence IP policy making. The social dimension understands IPRs from the general welfare perspective, focusing on the benefits and costs to society as a whole resulting from the formulation of IP policies. Within this dimension, emphasis is placed on the need to formulate IP policies that provide adequate incentives for the creation of future knowledge products, as well as guarantee sufficient access to existing ones.

The industrial policy dimension is based upon the understanding that knowledge, information and different forms of literary and artistic creations are assets of a strategic economic importance. Accordingly, within this dimension the focus is on the manner in which IP policies can help boost the creation and exploitation of these assets.

Finally, the global dimension places national IP policy making in an international comparative context. Emphasis is given to the global economic positioning and ambitions of different countries, as well as on the legal and political consequences of their actions.

The issues raised above constitute only a portion of the wide and complex array of considerations which are worthy of examination and adoption by decision-makers when they formulate and execute IP policy.

Of course, it is impractical to expect the individual policy maker to form the "perfect" policy tool-kit that answers all the challenges and opportunities associated with the IP field. Put forthrightly, the economic, commercial, political, social and moral aspects of IPRs are too complex for one person, and even for an entire directorate, to handle.

Indeed, combining the three approaches above requires stronger and better coordination among IP policy makers in a given country. A more efficient and informed IP policy making process is therefore needed, based on three major pillars.

First, while there is an obvious need to take all three of the perspectives discussed in this article into account, the policy maker must eventually prioritise one approach over the others.

Secondly, it is important to ensure that IP policy making in one area is harmonised with other policy areas, such as competition rules, and vice versa.

Finally, for each and every IP topic, there is a need to ensure throughout the entire policy making process that the strategic objectives identified by policy makers are actually reflected in resulting legislation, especially in its final phases. Too often we encounter a situation in which political compromises essentially nullify or even overturn the principal objectives of the legislation. Such coordination can help ensure that the strategic goals of IP policies are preserved and may be implemented.

The Politics of IP Maximalism

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Intellectual property; Politics; United States

In 2007, author Mark Helprin, perhaps most famous for his novel A Winter's Tale,¹ published an opinion piece in the New York Times titled, "A Great Idea Lives Forever. Shouldn't Its Copyright?"² In this short essay, Helprin expressed his frustration with the current protection of copyright and outlined his argument for a copyright maximalist position. He argued that while the constitution prohibits perpetual protection, authors should retain the rights to their works for as long as possible and that these rights should be inheritable almost in perpetuity. In essence, Helprin sketched out the key concepts of the copyright maximalist position.

The terms "intellectual property maximalist" and "intellectual property minimalist" have been used to denote different political positions and attitudes towards the current state of intellectual property (IP) law. It can be difficult to label scholars working on IP-related issues either "maximalists" or "minimalists" because these terms may change over time, as cycles of critique move in response to the status of a law. Furthermore, even the most pro-IP advocate may find a specific piece of legislation unappealing, even if that legislation expands protection. Conversely, many who may be deemed copyright minimalists understand the need for some layers of protection.

Generally speaking, however, labelling someone an IP maximalist is a relatively new method of claiming that they support strong or even further enhanced IP laws. By IP maximalist I mean several things.³ Primarily, IP maximalists do not believe that the current protective levels are sufficient and thus advocate for longer terms, broader protection and enhanced punishment for violations. Secondly, maximalists align themselves with the argument that providing economic incentives via an IP system is crucial to progress. They also take the view that without this system, nobody would create. Any reduction in the current level of protection therefore will lead to less creativity. Thirdly, maximalists, at the very least, want to preserve the status quo when it comes to IP protection and thus resist efforts to enhance access to creative work that may weaken current IP laws.

Much to Helprin's surprise, his opinion piece generated enormous negative backlash. Of course, by 2007 it should have come as no surprise that an editorial advocating for copyright maximalism would be met with disagreement. After all, the Sonny Bono Copyright Term Extension Act (CTEA) had culminated in a Supreme Court decision in *Eldred v Ashcroft*,⁴ where arguments against a 20-year retroactive extension were rejected. In the aftermath of the Court's support for extending the term of copyright, the Creative Commons movement, led by Lawrence Lessig, among others, gathered steam and grew internationally. 2007 was also almost a decade after Napster had transformed the face of the music industry, turning into pirates most of the world who engaged in illegal music downloading. It was also more than a decade after the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) was signed. But given

¹ M. Helprin, A Winter's Tale (New York: Mariner Books, 1995).

² M. Helprin, "A Great Idea Lives Forever. Shouldn't Its Copyright?", The New York Times, May 20, 2007, available at http://www.nytimes.com /2007/05/20/opinion/20helprin.html [Accessed October 26, 2011].

Goldstein would call them copyright optimists, not maximalists, in distinction to copyright pessimists. See P. Goldstein, Copyright's Highway: From Gutenberg to the Celestial Jukebox (Stanford: Stanford University Press, 2003), p.11. ⁴ 537 US 186 (2003).

the international resistance to the application of TRIPs to the global south, some of the least developed countries have been given even more time to align themselves with the current international legal norms. In other words, a global and vocal struggle over the scope of IP rights exists.⁵ Perhaps Helprin did not know he was entering an ongoing debate, one that could actually be charted back much further than this century. However, does not change the fact that the debate had long been raging before Helprin entered the fray.6

As a pro-author advocate, Helprin is somewhat unusual, in the sense that the scholarly literature on copyright, patents, trademarks, and other forms of what has come to be known as IP tends to be fairly critical of the current "balance" struck by both domestic and international laws. It is generally the case that academics writing on issues associated with IP offer a far more critical analysis of the state of contemporary law than can be found in policy making circles. Given the nature of scholarship is to challenge, it perhaps should come as no surprise that the literature is filled with scholarly critiques of the law and that few published works advocate enhanced and stronger protection, given that business interests have taken up this position.

Aside from Helprin's passionate argument, it is somewhat difficult to find book-length works that justify, embrace, or advocate for stronger IP rights. The now classic book by Paul Goldstein, Copyright's *Highway*, describes the tension between copyright optimists and pessimists as those seeking greater or less protection for copyrighted works.⁷ While I would not call Goldstein's work "maximalist", his argument is better described as a legal analysis of the technological challenges that have evolved over the past 30 years for copyright law. However, his work does begin with the assumption that IP as a system has legitimacy. Posner and Landes' economic treatment of IP law has been mentioned as a book that develops an economic justification for IP.8 Robert Merges' recently published Justifying Intellectual Property seems to fit the bill of general IP advocacy.9

There are of course numerous sources for the IP maximalist position worth considering for how they shape our understanding of the law. One avenue for the IP maximalist position could be the legal system itself. The courts have often worked to maximise protection even when the opportunity exists to limit the interpretation of the law. For example, the US Supreme Court could have agreed with Eric Eldred in his efforts to strike down the CTEA, but the decision did in effect support a maximalist position.¹⁰ Another example might be *Bridgeport v Dimension*, a ruling by the US Court of Appeals for the Sixth Circuit that made sampling impossible without licensing and thus eliminated even the possibility of fair use in music.¹¹ Obviously, courts offer a diversity of interpretations of the law, but the general outline of copyrights, patents, trademarks, and other forms of IP remain bound by the regulatory apparatus of the statutes involved and make no radical break from them.¹² As such, to the degree that the law remains maximalist, so too will the court's interpretation. These approaches are then reflected in the ways in which IP is taught via casebooks. While these books perhaps ask questions critical of the current system, as a general rule they

⁵R. Stoll, "Developing Countries' Compliance with the TRIPS Agreement", available at http://www.law.washington.edu/casrip/symposium/Number6 /Stoll.pdf [Accessed October 26, 2011].

⁶ The tenor and depth of the negative response shocked Helprin so much that he wrote a book in response: M. Helprin, Digital Barbarism: A Writer's Manifesto (New York: Harper, 2010).

Goldstein, Copyright's Highway (2003).

⁸W.M. Landes, The Economic Structure of Intellectual Property Law (Cambridge, MA: Belknap Press of Harvard University Press, 2003). ⁹ R.P. Merges, Justifying Intellectual Property (Cambridge, MA: Harvard University Press, 2011).

¹⁰ Eldred v. Ashcroft, 537 US 186 (2003).

¹¹ Bridgeport Music, Inc. v. Dimension Films, 383 F. 3d 390 (2004). This case is cited in Demers' work where she argues it has virtually killed music sampling unless the musician is wealthy or willing to do so illegally: J.T. Demers, Steal This Music: How Intellectual Property Law Affects Musical Creativity (Athens: University of Georgia Press, 2006), pp.95–97.

For example, while the American constitutional mandate requires that authors and inventors be given exclusive protection for a limited time, no judge is likely to write an opinion eliminating the term of copyright or reduce the time of protection below the statutory assignment. The legal system is bound by the code, meaning that outcomes must fall within a limited interpretive scope. While the world "limited" might provide room for interpretation, the operationalised Congressional mandate of life of the author plus 70 years is much clearer. Thus, to reduce protection for intellectual property (or increase it), one must see Congressional or Executive change

will not diverge radically from the status quo.¹³ Instead, they help establish IP law as beyond politics: while politics may have informed the creation of the law, the legal system is involved in a much more neutral form of interpretation.

A second set of non-critical IP literature includes texts that purport to educate authors, inventors, artists and others about their IP rights and how to support them.¹⁴ These texts are usually "how to" books—how to register a copyright, what a patent is, and so forth.¹⁵ They are not generally written with a theoretical claim or argument in mind, but rather to help the sole inventor or the non-professional author understand how to use the IP system to support their work. They also tend to be supportive of the logic behind IP and see it as a method for protecting authors and inventors.

A final source of IP maximalist arguments, the one from which most of what is written below will draw, comes in the form of government and industry reports, as well as from scholars and inventors seeking increased protection. Industry reports, especially those from the relevant IP actors, are perhaps the clearest advocacy statements for the maximalist position, because it is in the interest of these groups and their lobbyists to push the agenda as much as possible. However, to a disturbing degree, government reports and public comments about the role IP plays tend to reflect a maximalist position as well. Public speeches regarding IP rights are categorically uniform across ideological divides, suggesting that as an issue of public policy, the assumed starting point is that all forms of IP are good and that the government's role is to increase regulation of these property rights until the threat posed by those who "steal" IP is alleviated. Debate in the past 30 years has almost always been configured around the increase in protection justified by the threat of piracy and the need to further incentivise authors to create.

These efforts to shore up a maximalist position of IP advocacy are made in the face of a continuous and repeated critique of the expansion of copyrights, patents, trademarks, and other forms of IP over the past few decades that exists in the scholarly literature. The end result has been a field of struggle between competing IP interests over the structure and scope of the future of legal measures. While IP maximalists (or optimists as Goldstein calls them) tend to believe the government has not gone far enough, IP reductionists (or pessimists) believe it has gone too far. Goldstein, in his 2007 book, Intellectual Property: The Tough New Realities that Could Make or Break Your Business, sees the uncertainty created by the push and pull of these positions to be the "tough new reality" within which business must operate. Constant legal challenges, efforts to reform the law and expansion of rights are all part of an uncertain and continually changing terrain.¹⁶ While Goldstein is correct that there is uncertainty in the IP world, I tend to disagree with the assessment that it comes from those who seek to reduce the current status of IP.

Instead, I would argue the current instability comes from the expansion of rights. As the IP concept has achieved a more popular status, more people have turned to the courts to protect what they see as their rights, using the law to make their claims. One of the unintended consequences of expanding concepts of property rights is that not only the original actors seek to protect their self-interest, but the field upon which rights will be contested is widened and broader claims are thus allowable. More contestation over rights by new actors and thus more litigation have the impact of undermining the very efforts intended by the law. Once someone understands a previously unprotected thing as property, then a new struggle over ownership ensues by default. Expansion of rights also transforms previously non-criminal acts into criminal ones, requiring more enforcement, surveillance and control than previously warranted, again making the field more divisive.

¹³ Dratler, for example, is very pro-IP. However, even he has difficulties with the Digital Millennium Copyright Act: J. Dratler, Intellectual Property

Law: Commercial, Creative, and Industrial Property (New York: Law Journal Press, 1991). ¹⁴Goldstein's book about intellectual property and business is a single example: P. Goldstein, Intellectual Property: The Tough New Realities that Could Make or Break Your Business (New York: Portfolio, 2007). ¹⁵Justone example in this genre is M.E. Carter, Electronic Highway Robbery: An Artist's Guide to Copyrights in the Digital Era (Berkeley: Peachpit

Press, 1996). ¹⁶ Goldstein, Intellectual Property (2007). Each chapter concludes by mapping the change that has occurred in that area of law.

The IP terrain is perhaps so destabilised through the expansion of IP rights because there exists an ongoing struggle over the legitimacy of IP, which all sides understand will frame the future of our cultural creativity, economic assets and productivity. The information age has enhanced the levels of abstraction of property and hence established a new cross-cutting line of control by the state over the productive classes.¹⁷ The struggle being waged is one that will determine how the apparatus of state control over creativity, innovation and our information future evolves.

In this article, I seek to develop and analyse the politics of IP as developed in American public policy circles. Government publications and statements by public officials from the President down across the last 30 years indicate virtually no hint that a critical debate regarding the scope, length and depth of all types of IP has been underway or that there is a possible alternative to the IP maximalist frame of reference. Instead, enormous effort has been put into producing a stable system that will continue to expand the length of protection, the scope of protection and the consequences for violating the law. Despite decades of substantive critique and historical evidence that innovation is hardly at all tied to the existence of patent or copyright regimes, policy makers globally reproduce the same narrative about technological innovation, ingenuity and the rush to protect the creative spirit. These mythological assertions remain the foundation for IP law. Public speeches do not provide evidence, but assertions, regarding the economic importance of IP. However, they also help clarify the political positioning that has taken place to justify stronger IP laws globally. In the world of politics and public policy, the literature critical of copyright might as well not exist.

For the good of the country: Reagan to Obama on IP

On March 11, 2010 the White House published on its website the remarks by President Barack Obama at the Export-Import Bank's Annual Conference. The President was talking at the conference about general economic issues and his plans for helping the economy by facilitating international trade and travel. Key to this international agenda, it turns out, is the issue of IP. Obama had this to say about IP and its importance to the United States:

"What's more, we're going to aggressively protect our intellectual property. Our single greatest asset is the innovation and the ingenuity and creativity of the American people. It is essential to our prosperity and it will only become more so in this century. But it's only a competitive advantage if our companies know that someone else can't just steal that idea and duplicate it with cheaper inputs and labor. There's nothing wrong with other people using our technologies, we welcome it—we just want to make sure that it's licensed, and that American businesses are getting paid appropriately. That's why USTR [the United States Trade Representative] is using the full arsenal of tools available to crack down on practices that blatantly harm our businesses, and that includes negotiating proper protections and enforcing our existing agreements, and moving forward on new agreements, including the proposed Anti-Counterfeiting Trade Agreement."¹⁸

Obama's speech indicated that he would continue in the path set before him by his predecessors. The language used by Obama was not new—the American people are creative, our economic well being comes from IP, those who "steal" our IP harm our country, we will do everything possible to protect our IP, and we will provide for enhanced regulatory structures with new laws.

These same themes were present 24 years earlier, when President Ronald Reagan made a radio speech to the nation on free and fair trade in which he also discussed issues of international trade and IP. In Reagan's words,

¹⁷ M. Wark, A Hacker Manifesto (Cambridge: Harvard University Press, 2004), p.20.

¹⁸ B. Obama, "Remarks by the President at the Export-Import Bank's Annual Conference", March 11, 2010, available at http://www.whitehouse.gov /the-press-office/remarks-president texport-import-banks-annual-conference [Accessed October 26, 2011].

"Our country is ... victimised by the international theft of American creativity. Too many countries turn a blind eye when their citizens violate patent and copyright laws designed to protect intellectual property rights. If we permit the product of our best minds to be stolen, we will pay the price in ingenuity, vision, and creativity-the core of all human progress. Here again, we expect tangible changes to be made to straighten this matter out."19

There is not a significant difference between the language used by Obama and Reagan when it comes to how IP should be protected. Obama's concession that we would let others use our ideas if appropriately licensed is simply a more modern framing of the same issue and the one-sentence indication of Obama's awareness of the popularity of the open source movement, the creative commons, the GPL, and numerous other efforts to provide alternatives to IP.

George Herbert Walker Bush was also concerned with issues of IP and trade, negotiating the General Agreement on Tariffs and Trade (GATT), which was eventually transformed into TRIPs. Under his administration, he made numerous statements about strengthening IP through GATT.²⁰

Clinton was not out of step with his predecessors either. Along with continuing the GATT and TRIPS negotiations, Clinton encouraged Congress to pass the Digital Millennium Copyright Act (DMCA), which included international obligations under World Intellectual Property Organisation Internet Treaties. In his remarks to Congress regarding the passage of the DMCA, he said:

"American copyright-based industries that produce and promote creative and high-technology products contribute more than \$60 billion annually to the balance of US trade. This bill will extend intellectual protection into the digital era while preserving fair use and limiting infringement liability for providers of basic communication services. I look forward to signing this legislation into law, and I urge the Senate to ratify these treaties so that America can continue to lead the world in the information age."21

In a 1999 speech, Clinton helped justify the need for IP protection by commenting on the American spirit and its constant quest for creativity and innovation. For Clinton:

"[T]he American people have always been a bold and innovative bunch. We are always drawn to uncharted lands over the next horizon. Who will pack our bags and head out to the latest gold rush or tinker in our basements for years to invent a product no one else has ever imagined? That's what we do."22

Clinton's vision of the American innovator as isolated individual and pioneering leader is wholly consistent with the larger American myth of our underlying creativity as a nation-this is nation-building, a tactic employed by all Presidents to help paint the American innovative spirit as exceptional and innate in our heritage.

Under the Clinton administration, and based upon these general assertions of American innovation and the creative spirit, we witnessed a dramatic increase in the scope, duration and depth of IP coverage. Clinton's administration helped to create a new generation of criminals by outlawing and criminalising file sharing with the No Electronic Theft Act. It created liability for service providers who did not comply with the notice and take down procedures included as a concession to service providers in the DMCA. With the CTEA, the administration also extended the length of copyright protection, including retroactive

¹⁹ R. Reagan, "Radio Address to the Nation on Free and Fair Trade", September 13, 1986, available at http://www.presidency.ucsb.edu/ws/?pid =36412 (Accessed October 26, 2011). ²⁰ One such comment was made to the US Chamber of Commerce, where President Bush pledged to increase international IP protection via the

GATT: G.W. Bush, "Remarks at the Annual Meeting of the United States Chamber of Commerce", April 30, 1990, available at http://www.presidency

 ²¹W.J. Clinton, "Remarks on the National Economy", December 3, 1999, available at http://www.presidency.ucsb.edu/ws/?pid=15077 [Accessed October 26, 2011].
 ²²W.J. Clinton, "Remarks on the National Economy", December 3, 1999, available at http://www.presidency.ucsb.edu/ws/?pid=57019 [Accessed

October 26, 2011].

protection for those who had already died. While the general trajectory for US IP law has always been expansive, it was during the Clinton years that the regulatory apparatus constituting our modern IP world went from theory into being.

George W. Bush did not stray from the well-entrenched national narrative, though he helped create a terrorist-themed interpretation of the threat caused by IP piracy. During the signing ceremony for the Stop Counterfeiting in Manufactured Goods Act, Bush made the following comment about piracy and IP:

"Counterfeiting costs our country hundreds of billion dollars a year. It has got a lot of harmful effects in our economy. Counterfeiting hurts businesses. They lose the right to profit from their innovation. Counterfeiting hurts workers because counterfeiting undercuts honest competition, rewards illegal competitors. Counterfeiting hurts consumers because fake products expose our people to serious health and safety risks. Counterfeiting hurts the Government. We lose out on tax revenue. We have to use our resources of law enforcement to stop counterfeiting. Counterfeiting hurts national security because terrorist networks use counterfeit sales to, sometimes, finance their operations."23

To come full circle, then, Obama has also taken up the language of security to describe IP issues. The cybercrime battles of the century, according to Obama, will deal with IP issues. Obama noted:

"It's been estimated that last year alone cyber criminals stole intellectual property from businesses worldwide worth up to \$1 trillion. In short, America's economic prosperity in the 21st century will depend on cybersecurity."24

While it is not clear where the \$1 trillion figure came from, it would certainly suggest that the past 30 years of attention to the issue and regulation have done little to halt what we now see as a significant threat to our national security.

Despite the ideological differences claimed to exist between Democratic and Republican Presidents, the underlying discourse on IP has remained remarkably steady. The comments regarding IP seem to have come from the same script—a script that includes the following claims. First, America's biggest strength is its innovation and creativity. Secondly, countries outside the United States profit from stealing our ideas, and this hurts us economically. Thirdly, it is the government's job to establish strong rules that will protect American IP property abroad. Finally, the theft of IP has negative consequences not only to our economic bottom line but to public health-through the distribution of counterfeit goods with the ultimate result that terrorists and criminals profit at the expense of hard-working innovative Americans.

The standard rhetorical approach to IP by our most prominent elected leaders is anything but nuanced. They tend to gloss over the distinctions between different IP regimes and instead lump them all together. These Presidential statements function to help create something called "intellectual property" that must be protected from "theft". They do not suggest any distinction among copyrights, patents, trademarks, or other sui generis forms of protection. Instead, they lump all these different forms of rights under a "property in ideas" rubric. In fact, even after decades of attention paid to this area of law, it would seem the distinction among patent, copyright and trademark laws remains as it did in 1970 when Alan Latman said, "[M]ost people do not understand the differences between patents, trademarks, and copyrights. This applies to clients, other lawyers, and at times even judges."25 These individuals tend to assume that more protection is better. In order to capitalise on the language of security, much of the IP debate is now focused on the

²³ G.W. Bush, "Remarks on Signing the Stop Counterfeiting in Manufactured Goods Act", March 16, 2006, available at http://www.presidency.ucsb *edu/ws/?pid=65347* [Accessed October 26, 2011]. ²⁴ Bush, "Remarks on Signing the Stop Counterfeiting in Manufactured Goods Act", March 16, 2006, available at *http://www.presidency.ucsb.edu*

[/]ws/?pid=65347 [Accessed October 26, 2011]. ²⁵ Quoted in Goldstein, *Copyright's Highway* (2003), p.6.

material production of counterfeit goods despite the digitalisation of many products making the necessity of smuggling things across borders ever more obsolete. Furthermore, the focus has shifted to criminalising IP acts and enforcement both at home and abroad.

In part, focusing attention on counterfeit goods helps to clarify what is being stolen. While nobody is clear on what is stolen if you download an electronic file, it is far easier to understand theft in the tangible world. While it still may be the case that a person buying a knockoff designer handbag or a pirated copy of Microsoft Windows would not purchase the "real" product, from a policy perspective it is easier to target the producer of a product than a file sharer online. Much of the language produced by Presidents is aimed at the flow of a material product. Indeed, more recent debates on counterfeiting tend to conflate the intangible aspects of a product with their tangible flow across borders. This does not mean that those engaged in the illicit electronic circulation of IP have been forgotten, merely that the staging of the law is beginning with what is clearly aligned with what people already understand.

Removed from claims about the concept of IP publically envisioned by Presidential speeches is the vision of a government grant of a limited monopoly via a legal regime designed to balance the interests of the public in the free flow of ideas and progress with the self-interest of an individual author or inventor—or, in this case, the corporate owners of copyrights, patents, and trademarks. Calling it creative property at all implies a more permanent relationship to the intangible than what might otherwise exist if we were to use the language of limited monopolies. In many ways, the overwhelming success of the term "intellectual property" has already defined the boundaries for the future.

Furthermore, in these Presidential statements, there is absolutely no hint that too much IP protection might harm innovation as much as too little. The statements are unreflective about how innovation actually occurs. Instead, they reproduce the myth that America's best innovative work has happened because of the creative genius of an individual "working in his basement". These statements create the stark world where you are either a pirate or an innocent victim of piracy. They do not reflect the complicated process of creation and innovation. They do not talk about patent or copyright trolls and their predatory practices. They do not talk about access to life-saving medicines at significantly lower costs. They do not discuss the ways in which Web 2.0 technologies have changed creation and distribution of creative work and the very people who do it. In other words, these statements create the world as producing a problem that is easy to solve with more restrictive legislation and enforcement. In the process of making policy, the United States establishes a relatively hegemonic discourse on IP that has not waivered over time. It has done so despite decades of scholarship pointing out the flaws in the logic, the policy process, the clear ways in which the law singles out beneficiaries at the expense of the general public, the global south and new innovation itself.

Congressional perceptions on IP are similar to presidential claims. Taken together they mark a transformation in how the US government approaches IP issues. While earlier generations saw the enforcement of IP as primarily a private issue, sometimes subject to civil litigation, it has since been reconfigured into a criminal issue subject to federal oversight and an international economic issue requiring US administrative intervention around the world. The efforts by the US Government to become relevant to the issue and to support laws that go beyond the initial provision of a limited monopoly help to clarify how significant, though subtle and slow, the change in focus has been.

While in 1985, Robert W. Kastenmeier, the chair of the House Judiciary Committee's subcommittee on copyright, patent, and trademark, requested that changes in IP law should be accompanied by evidence that the public benefit would outweigh private benefit, no such claim, according to Paul Goldstein, had ever been made before, or since.²⁶ All told, the United States has passed over 25 laws expanding some aspect of IP protection since 1995, including recently the Prioritising Resources and Organisation of Intellectual Property (PRO-IP) Act of 2008, which established the first ever copyright "tsar" for the United

²⁶ Goldstein, Intellectual Property (2007).

States, a position that echoes the language of the drug wars.²⁷ Also considered in the 111th Congress was a series of laws that would expand protection to fashion design, the Innovative Design Protection and Prevention of Piracy Act, and the Combating Online Infringements and Counterfeits Act.²⁸

Congressional support for strong IP tends to be bipartisan and industry focused. Representative Bob Goodlatte, the Chairman of the House Subcommittee on the Courts, the Internet and Intellectual Property for the 112th Congress recently reproduced the same narrative about American innovation and the role IP plays in protecting it in his weekly statement published in the Lynchburg Times. He said:

"Specifically, we will promote policies to protect American intellectual property. America is the most innovative nation on earth, due in part to the strong intellectual property protections our Founder's included in the Constitution and Congress' commitment to keep those protections strong and current. In order to grow our national economy we must ensure this vital sector is protected and able to thrive."29

As a strong advocate of broad IP rights, Representative Goodlatte does not seem substantively different in ideological focus from his Democratic counterparts when it comes to IP. The irony of an anti-government, pro-deregulation representative being willing to pass legislation to prop up monopoly control of big industry should not be lost.

Compare Mr. Goodlatte's statements with those of his Democratic counterpart, Representative Howard Berman who was quoted in a press release from (Democratic) Senator Patrick Leahy:

"The theft of American Intellectual Property not only robs those in the creative chain of adequate compensation, but it also stunts potential for economic growth, cheats our communities out of good paying jobs, and threatens future American innovation, added Berman. Today I remain as committed to this fight as ever, and I look forward to working with my colleagues both Republicans and Democrats to protect American businesses, workers, and innovators."30

What is clear is that the leading Congressional representatives with an interest in IP align behind the same arguments as those seen on both sides of the ideological divide at the Presidential level.³¹

In tandem with the enhancement of domestic and international laws regarding all forms of IP, the US Government has reconfigured its bureaucracy to help fight piracy and further protect IP. In 1999 President Clinton made the United States Patent and Trademark Office (USPTO) an agency within the Department of Commerce and established an Under Secretary of Commerce for Intellectual Property who also serves as the director of the USPTO.³² Obama nominated David Kappos, former counsel for IBM, to serve as the

²⁷ For an updated list of copyright-related legislation introduced in the most recent Congress see "US Copyright Office-Legislative Developments (111th Congress)", available at http://www.copyright.gov/legislation/ [Accessed October 26, 2011]; Lawrence Lessig, Code: Version 2.0 (New York: Basic Books, 2006).

[&]quot;US Copyright Office-Legislative Developments (111th Congress)", available at http://www.copyright.gov/legislation/ [Accessed October 26, 20111

²⁹ B. Goodlatte, "Congressman Bob Goodlatte's Weekly Column: The Technology Sector Is Vital to Our Economic Recovery", The Lynchburg Times, June 21, 2011, available at lynchburgtimes.com/news/2011/06/21/congressman-bob-goodlatte%E2%80%99s-weekly-column-the-technology -sector-is-vital-to-our-economic-recovery/[Accessed October 26, 2011].

These democratic senators are joined by Republican House Judiciary Committee Chair Lamar Smith in making these statements. States News

Service, "Senate, House Judiciary Committee Leaders Focus on Fighting Online Infringement", April 4, 2011. ³¹ It should be noted that Berman is considered the "representative from Disney" for his staunch advocacy of strong copyright laws to help support his entertainment industry supporters. M. Masnick, "Will Howard Berman Step Down from Leading Copyright Subcommittee?", available at *http:/*

[/]www.techdirt.com/articles/20080123/16460153.shtml [Accessed October 26, 2011]. ³² US Department of Commerce, "Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office", available at http://www.osec.doc.gov/opog/dmp/doos/doo10 14.html [Accessed October 26, 2011].

Under Secretary of Commerce for IP. Prior to Kappos and his predecessors, Bruce Lehman headed the USPTO and was an instrumental voice in the creation of the DMCA as well as a strong advocate for enhanced IP rights.³³

Numerous agencies within the federal bureaucracy now have IP related subdivisions. According to a resource list compiled by the Department of State, they include the following. The USTR continues to issue a Special 301 report yearly, which puts offending countries on a priority watch list or a watch list depending upon how significant the piracy in that country is and how the country has worked to address it. In exceptional cases, countries that do not sufficiently protect IP will be considered priority foreign countries. The USTR requests public comments in the process of designating countries. The Department of Commerce includes the International Trade Administration which helps oversee the Special 301 process as well as issues related to TRIPs. It also hosts the Strategy Targeting Organised Piracy (STOP) initiative designed to help businesses protect their IP via the USPTO.³⁴

The US Department of Justice now includes a Computer Crime and Intellectual Property Section. The US Department of State has an Office of International Intellectual Property Enforcement. There is a collaborative International Intellectual Property Training Database sponsored by the Department of State. And the US Immigration and Customs Enforcement Division includes the National Intellectual Property Rights Coordination Center, a multi-agency entity focusing on IPR crime that includes the FBI.³⁵ There is of course the US Copyright Office, hosted by the US Library of Congress.

One of the most recent expansions of the scope of IP protection passed with bipartisan support in both houses, along with support from a broad range of special interests from Hollywood to unions, was the PRO-IP Act, which was formerly known as the Enforcement of Intellectual Property Rights Act.³⁶ George W. Bush signed the act into law in October 2008. This new law increased the civil penalties for copyright, patent, and trademark infringement and established an executive branch agency to oversee IP enforcement. It also created a new IP tsar (also known as the US Intellectual Property Enforcement Coordinator), who sought to develop a more comprehensive approach to IP. Chris Israel was the first appointee. A former Time-Warner public policy executive, Israel had worked for Bush in the Commerce Department before taking on its duties. Upon leaving his office, he began working for several pro-IP lobbying firms.³⁷

Obama became the first president to appoint an IP tsar to the White House. That position was taken by Victoria Espinel. As the first IP tsar, Espinel's initial statements about the new agency and its direction adhered to the already well-established government policy regarding IP. In 2010, she announced the new US IP Enforcement Strategy:

"I am pleased to announce that today we unveiled the administration's first Joint Strategic Plan to combat intellectual property theft. The US economy leads the world in innovation and creativity thanks to American inventors, artists and workers. Our ability to develop new technology, designs and artistic works supports jobs and allows us to export great new products and services around the

³³ He was inducted into the "IP Hall of Fame" in 2006. The IP Hall of Fame is funded by the IP Media group and inducts individuals based upon their support for strong IP laws. See "IP Hall of Fame—Bruce Lehman", available at http://www.iphalloffame.com/inductees/2006/Bruce_Lehman .aspx [Accessed October 26, 2011].

³⁴ The information in this section comes from the following resource provided by America.gov and developed in 2008: "List of Resources on Intellectual Property", available at http://www.america.gov/st/econ-english/2008/April/20080429235644eaifas0.1053299.html [Accessed October 26, 2011]. To view the STOP hotline, currently hosted on the USPTO website, see "Strategy for Targeting Organized Piracy (STOP)", available at http:// www.uspto.gov/ip/global/stop/fakes.jsp [Accessed October 26, 2011].

³³ "List of Resources on Intellectory", available at http://www.america.gov/st/econ-english/2008/April/20080429235644eaifas0.1053299 html [Accessed October 26, 2011].

³⁶D. Kravets, "Obama Appoints Scholar as New Copyright Czar", available at http://www.wired.com/threatlevel/2009/09/obama-taps-new-copyright -czar/ [Accessed October 26, 2011].

³⁷ Biography available at *http://www.netcaucus.org/biography/chris-israel.shtml* [Accessed October 26, 2011]. After his tenure with the Bush Administration, Israel co-founded PCT Governmental, a pro-IP lobbying firm that continues to work with major corporations interested in ensuring the laws favour their companies: *http://www.pctgr.com/welcome* [Accessed October 26, 2011]. He joined the American Continental Group in 2010, another lobbying firm where he continues to do pro-IP related lobbying. See *http://www.acg-consultants.com/our-team/chris-israel/*[Accessed October 26, 2011].

world. Our citizens need to feel confident that they can invest in new innovation and intellectual property, knowing it will be safe from theft. Ensuring that our ideas and ingenuity are protected helps us create jobs and increase our exports."³⁸

She goes on to say:

"Now, more than ever, we need to protect the ideas, artistry, and our reputation for quality, provide our businesses with the incentives to make each new product better, reduce crimes related to intellectual property infringement and keep dangerous counterfeits out of our supply chain to protect our citizens. Strong intellectual property enforcement will help us to accomplish that. The Obama Administration has always embraced the free flow of information, online collaboration, and fair use by average citizens, which are also helping to advance our society and economy every day—this strategy does not target legitimate and legal activity. The Administration is technology-neutral, using both proprietary and open source platforms on the web and all content on WhiteHouse.gov is public domain, making it an active participant in the online communities of the 21st Century."³⁹

Espinel demonstrates that the US is supportive of the maximalist position, that US policy requires the strictest of enforcement measures for piracy and the assurances that this type of property will be protected globally. It is also worth noting the small concession to the concept of the public domain and to open source platforms, along with the hint that net neutrality might be a considered option for this administration. Perhaps the first fissure in the long-standing policy approach can be seen in her statements. However, there is little other evidence that the Obama administration will act significantly differently from its predecessor over these issues.

In fact, there is evidence that Obama's administration will continue down the path of greater enforcement. The strategic plan issued by the White House on IP legislative recommendations in March 2011 focuses exclusively on increasing punishment for IP crimes, including longer sentences and increasing law enforcement flexibility to catch IP criminals. They specifically identify infringement by streaming as a possible felony and make more targeted recommendations regarding counterfeit goods.⁴⁰ In response to the White Paper, the President and CEO of the Computer & Communications Industry Association (CCIA), Ed Black, issued a statement asserting that the administration had been "hijacked" by "big content":

"The legitimate desire to address some serious counterfeiting abuses—such as medications or industrial components used in defense products—has been hijacked to create draconian proposals to alleviate the content industry of the burden of protecting its own interest using its own extensive resources... This is the latest indication of the extent to which the content industry has infiltrated this administration and managed to turn the Administration's IP agenda into a policy which protects old business models at the expense of consumers, citizens' rights and our most innovative job creating industries."⁴¹

CCIA's response to the Obama plan is telling on several fronts. First, it helps to identify the consistency in the efforts of government to expand IP protection. Second, it also begins to highlight the fissures between different copyright-based industries. The case can hardly be made that computer-related industry associations are not interested in copyright legislation. However, what CCIA suggests is that there is a growing recognition on the part of some that government regulation to protect "old business models" will increasingly put the administration at odds with their own citizens.

³⁸ "Secretary Locke Joins Vice President Biden for Intellectual Property Enforcement Strategy Event", available at http://www.commerce.gov/blog /2010/06/22/secretary-locke-joins-vice-president-biden-intellectual-property-enforcement-strategy [Accessed October 26, 2011].

³⁹ "Secretary Locke Joins Vice President Biden for Intellectual Property Enforcement Strategy Event", available at http://www.commerce.gov/blog /2010/06/22/secretary-locke-joins-vice-president-biden-intellectual-property-enforcement-strateg [Accessed October 26, 2011].

⁴⁰ Office of the President, "Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations", March 2011, available at http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf [Accessed October 27, 2011].
⁴¹ "US IP Czar Proposes Limits on Civil Rights and Liberties to Protect Big Content", available at http://www.ccianet.org/index.asp?sid=5&artid

^{=210&}amp;evtflg=False [Accessed October 26, 2011].

Obama's overarching strategy, however, seems to remain very much in favour of additional IP enforcement. Obama's USTR Ron Kirk was part of the launch of the IP Enforcement Strategy in 2010. In discussing his office's efforts to make the world safe for American IP, he said in a press release:

"USTR uses a full arsenal of trade policy tools to support and implement President Obama's commitment to aggressively protect American intellectual property rights around the world. We are actively engaged in bilateral and multilateral trade negotiations, dialogues, and cooperation that are particularly critical to advancing the effective enforcement and protection of intellectual property rights overseas. That engagement is backed by a strong commitment to ensuring that our trading partners deliver on their commitments."42

As can be seen by the numerous public statements and commentaries, the predominant approach to IP enforcement remains focused on securing these rights for business interests in foreign and domestic markets. The economic justification for strong IP protection is difficult to separate from claims about the harms of IP piracy.

Conclusion

The IP maximalist approach is the corporate future, where government works in tandem with corporate entities to facilitate the increased concentration of IP ownership under the guise of providing "free access to information" and an incentive to innovate. The hegemonic language of IP maximalism leaves no space for a more complex and nuanced approach to innovation or creativity. It also assumes that only the most maximalist protection will inspire art, music and literature. Increasingly, the maximalist position pits content owners against content users as well as against the technological infrastructure where content is primarily circulated—the internet. As with any political discourse, the IP maximalist project is based upon ideological assumptions, the articulation of victims and victimisers, winners and losers, and lots of assertions about the conditions under which innovation and creativity occur.

Interestingly, most scholarship on IP issues has a critical lens—it criticises a specific aspect of the law, embraces the logic that the law ought to balance competing interests, highlights the unequal outcomes of the law as it stands, offers a critical history of the evolution of the law, or makes arguments that types of IP should be abandoned all together. Goldstein identifies the emergence of the critical academic approach to the software battles of the 1980s where "the greatest casualty of the softwars was copyright itself, and not because the judicial decisions in any way injured copyright principle-they did not-but because the debate ignited a scepticism about the value of copyright that was unprecedented in the law's long history".⁴³ As Goldstein continues,

"other academics picked up this critical theme during the software battles of the 1980s, and have not dropped it since. No expansionist legislative initiative-from extending the term of copyright to shoring up the rights of movie and record companies-has failed to trigger a loud and critical academic response."44

However, despite these layers of criticism, government policy remains remarkably unconcerned about opposing points of view. Instead, as this article has sought to demonstrate, that policy reflects a coherent national narrative about the importance of American ingenuity and government efforts to protect it. As a

⁴² Office of the United States Trade Representative, "USTR Ron Kirk Joins Vice President Joe Biden to Announce the Joint Strategic Plan on Intellectual Property Enforcement", available at http://www.ustr.gov/about-us/press-office/press-releases/2010/june/ustr-ron-kirk-joins-vice-president -joe-biden-announce [Accessed October 26, 2011]. 43 Goldstein, Intellectual Property (2007), p.96.

⁴⁴ Goldstein, Intellectual Property (2007), p.96.

result, academics, activists and others concerned with the future of IP are lumped together with pirates, counterfeiters and those engaged in economic acts against the current system as the problems that must be stamped out.

If IP activists and scholars want to see a different future, it is important to figure out how to alter the policy trajectory of the IP maximalists. Critics of IP span the globe, represent many disciplines of thought, are activists seeking to alter the information economy. They also are artists, musicians, authors, and creators themselves. In contrast to claims by IP maximalists that government has not gone far enough to protect IP, critics of the current IP system see the failure of government in its going too far and creating too expansive a system, as opposed to not going far enough. Each side recognises the state as the arbiter of IP rules—either seeing the state as a vehicle for corporate interests against the public interest or, for the maximalists, seeing the state as failing to establish the necessary conditions for economic growth.

It is difficult to identify winners and losers here. After decades of debate, there seems to be not much new that can be said either for or against the protection of IP. All the arguments for and against the system have been played out, critiqued, and exhausted. We know the arguments and counter-arguments by heart. The same stories are told. What must be noted is that as long as those with self-interest in expanding rights are able to control the structure of the law, then all the criticisms in the world will not change the system. In the political economy of the information age, the user, the sick, the student, the global South, the music fan, the movie buff, the small business, and many more are those who either don't care about IP rights or who can't afford to protect what rights they might have anyway. This leaves the playing field open to interests who do have the wherewithal to establish strong rights. This is the politics of IP maximalism.

Having Faith in IP: Empirical Evidence of IP **Conversions**

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The puzzle of global IP politics

The field of global intellectual property (IP) politics is booming. Still seen as esoteric in the mid-1990s, the number of new publications is now rapidly growing. Tellingly, at the 2011 Annual Convention of the International Studies Association, as many as 23 papers presented looked at the global governance of IP.¹

In exploring power struggles underlying the global IP regime, political scientists have built on two of the legal experts' legacies.² The first is a propensity to define the dependent variable in terms of legal standards for IP protection. This focus is exemplified by the few studies that aim at explaining anything other than legal standards, such as preferences, behaviours, practices, principles or worldviews related to IP.³ Concentrating on a single dependant variable, however, is not necessarily a scientific sin. Arguably, a focus on only one dependent variable but eclecticism in the search for significant independent variables is a fruitful strategy to advance a research program.

The second of the IP lawyers' legacies is a strong tendency to picture IP debates as binary oppositions. Political stances are located on a unidimensional continuum opposing the advocates of stronger IP protection with the supporters of weaker protection. The reference point used to define the meaning of the terms "strong" and "weak" evolve as new narratives are constructed to explain the past and to encapsulate aspirations for the future.⁴ At present, the division between "strong" and "weak" seems to be embodied by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs), which several OECD countries and businesses see as weak and outdated while many developing countries and nongovernmental organisations (NGOs) consider overly strong and unfair. The reality of political debates is obviously more complex than simplistic dichotomies. For analytical purposes, however, binary oppositions are useful heuristic devices to apprehend empirical realities.

¹To be fair, political scientists are not the only ones researching the field of global IP politics. A number of legal scholars have pioneered the field, including James Boyle, Rosemary Coombe, Peter Drahos, Laurence Helfer and Peter Yu.

²For recent critical reviews of the literature on global IP politics, see S. Haunss and K. Shadlen, "Rethinking the Politics of Intellectual Property" in S. Haunss and K. Shadlen (eds), Politics of Intellectual Property: Contestation Over the Ownership, Use and Control of Knowledge and Information

⁽Cheltenham: Edward Elgar, 2009). See also C. May (ed.), The Political Economy of Intellectual Property Rights (Cheltenham: Edward Elgar, 2010). ³For a recent exception, see P. Drahos, The Global Governance of Knowledge: Patent Offices and Their Clients (Cambridge: Cambridge University Press, 2010). ⁴ D. Kahneman and A. Tversky, "Choices, Values, and Frames" (1984) 39 *American Psychologist* 341.

We accept and take on the above two legacies. With this article, we aim at explaining why some developing countries adopt US-style IP rules that go beyond those required by the TRIPs Agreement. For example, why does Guatemala authorise the patentability of plants although it does not have a viable biotechnology industry? Similarly, why has Cambodia criminalised the dissemination of technologies intended to circumvent copy protection while this measure solely benefits foreign copyright holders? How can we explain that these and some other developing countries have gone beyond their minimal obligations under the TRIPs Agreement and have adopted US-style rules?

With this article, we contribute to the disentanglement of this puzzling situation in two manners. First, we explore one off-neglected reason for the adoption of US-style rules, i.e. the socialisation of decision-makers in the adopting country through interactions with experts in US IP law. Secondly, we rely on a more systematic conceptualisation and measurement of variables than has been adopted in many previous studies. Overall, we bring forward strong quantitative evidence that socialisation is a significant force in the export and import of IP rules.

Socialisation as a causal mechanism

For our purposes, socialisation can be defined as the process of internalising the social norms of a given community. Explaining the level of IP protection in developing countries through socialisation implies that interests are not exogenously given but socially constructed. We hypothesise that developing countries adopt US-like IP standards because they came to believe that, after being socialised to US social norms, these standards are appropriate for their own country.

IP rules are especially vulnerable to socially constructed beliefs. Notwithstanding the rich literature on the economics of IP, methodological constraints—especially the inability to control for all factors that drive innovation—have prevented the establishment of an optimal depth and breadth of IP protection. This exceptional level of scientific uncertainty leaves room for unexamined assumptions and persistent myths to govern discourse and policy-making.⁵ Moreover, IP lawmakers are guided by their own political values when determining the appropriate balance between short- and long-term objectives, or private and collective interests. These economic uncertainties and political dilemmas lead policymakers to rely on socially constructed norms when designing IP systems.

If IP is a matter of belief, then different faiths compete to convert decision-makers and to become the official creed, sacralised by domestic and international law.⁶ An increasing number of scholars use the concept of "frame" to describe and locate these competing views.⁷ A frame is a socially constructed cognitive filter that enables individuals to select and interpret relevant information in order to understand and respond to external events. Research on IP frames has reached two main findings, both consistent with the broader frame literature. First, frames adopted by decision-makers are usually rooted in pre-established norms, such as human rights, private property or fair trade. The frame that "IP protection = increased trade and investment = economic growth", for example, attempts to reconcile IP with the

⁵C. Garmon, "Intellectual Property Rights: Protecting the Creation of New Knowledge across Cultural Boundaries" (2002) 45 *American Behavioral Scientist* 1145; E.R. Gold et al., "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" (2004) 18 *Public Affairs Quarterly* 299.

⁶ J. Boyle, "A Natural Experiment: Do We Want Faith-based IP Policy", *Financial Times*, November 22, 2004; E.R. Gold and J.-F. Morin, "From Agenda to Implementation: Working Outside the WIPO Box" in J. de Beer (ed.), *Implementing the World Intellectual Property Development Agenda* (Waterloo: Wilfred Laurier University Press, 2009).

⁷D.J. Halbert, *Resisting Intellectual Property* (London: Routledge, 2005); L.R. Helfer, "Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29 Yale Journal of International Law 1; A. Kapczynski, "The Access to Knowledge

Mobilisation and the New Politics of Intellectual Property" (2008) 117 *The Yale Law Journal* 804; J.-F. Morin, "The Life-Cycle of Transnational Issues: Lessons from the Access to Medicines Controversy" (2011) 25 *Global Society* 227; J.-F. Morin, "Rhetorical Discourses in International Patent Lawmaking: Property, Fairness, and Well-Being" (2008) *Asian Journal of WTO and International Health Law and Policy* 505; V. Muzaka, "Linkages, Contests and Overlaps in the Global Intellectual Property Rights Regime", *European Journal of International Health Communications* (forthcoming); J.S Odell and S.K. Sell, "Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health 2001" in J. S. Odell (ed.), *Negotiating Trade: Developing Countries in the WTO Cond NAFTA* (Cambridge: Cambridge University Press, 2006); S.K. Sell and A. Prakah, "Using Ideas Strategically: The Contest between Business and NGO Networks in Intellectual Property Rights" (2004) 48 *International Studies Quarterly* 143.

established paradigm of liberalism. Secondly, IP scholars have found that successful frames take advantage of political opportunity structures, such as a crisis or policy failure, to reach out to decision-makers. The frame that "counterfeiting = funding for terrorism = insecurity", for example, capitalised on the terrorist attacks of September 11.

While IP scholars have well documented the competing frames and the communities that hold them, the micro-processes through which a specific frame makes its way from original norm-entrepreneurs to lawmakers remain unclear. There are at least three different pathways of socialisation, each involving different intermediaries: governmental officials, non-state actors, and members of the local elite.

First, beliefs that are dominant in the United States could migrate to a developing country through direct contact between officials of both countries. In other policy domains, recent studies show that direct contact within intergovernmental organisations generates norm transfer.^{*} This is rather unlikely at either World Intellectual Property Organization (WIPO) or the World Trade Organization (WTO) as controversies are currently so intense at the multilateral level that they impede socialisation.⁹ Meaningful contact between US and developing countries officials are more likely to occur bilaterally. Training activities labelled as "technical assistance" or "capacity building" are especially well-suited for socialisation as they offer informal, confidential, insulated and technical settings.¹⁰ The WIPO Development Agenda has recently drawn attention to the policy implications of capacity building activities and many authors repeatedly warn against their potential adverse consequences.¹¹ Methodological limitations, however, have impeded a full assessment. Participant observation and archive analysis are out of reach because training sessions are usually confidential. Some studies rely on semi-structured interviews or surveys but with limited benefit as socialisation often leaves the "socialiser" and the "socialisee" unconscious of belief transfers. If both are convinced of the appropriateness of US-style IP norms for developing countries, the former would deny any malicious intention and the latter would refute being the passive victim of US capacity building. Given these methodological hurdles, the UK Commission on Intellectual Property Rights and others have renounced studying the impact of capacity building activities despite the frequent but still unproven claim that they are a major driver of socialisation.¹²

Secondly, non-state actors can serve as belief carriers. The vast majority of the above-mentioned framing literature follows the general trend of constructivism and focuses its attention on NGOs and their normative influence. The frames held by NGOs unquestionably have had a major impact on issues such as access to patented medicines and protection of traditional knowledge. Businesses, however, are engaged in

⁸D. Bearce and S. Bondanella, "Intergovernmental Organisations, Socialisation, and Member-State Interest Convergence" (2007) 61 International Organisation 703; X. Cao, "Network of Intergovernmental Organisations and Convergence in Domestic Economic Policies" (2009) 53 International Studies Quarterly 1095; B. Greenhill, "The Company You Keep: International Socialisation and the Diffusion of Human Rights Norms" 54 International Studies Quarterly 127; J.C. Pevehouse, "Democracy from the Outside-in? International Organisations and Democratisation" (2002) 56 International Organisation 515

M. Cheek, "The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime" (2001) 33 George Washington International Law Review 307; J.-F. Morin and A. Orsini, "Complexity Is What States Make of It: The Case of Genetic

Resources" (forthcoming). ¹⁰ J. Checkel, "International Institution and Socialisation in Europe: Introduction and Framework" (2005) 59 *International Organisation* 801; J. Checkel, "Why Comply? Social Learning and European Identity Change" (2001) 55 International Organisation 553. ¹¹ J. de Beer and C. Oguamanam, Intellectual Property Training and Education: A Development Perspective (Geneva: ICTSD, 2010); C. Deere

Birkbeck and R. Marchant, The Technical Assistance Principles of the WIPO Development Agenda and Their Practical Implementation (Geneva: ICTSD, 2010); Drahos, The Global Governance of Knowledge (2010); Drahos, The Global Governance of Knowledge (2010); P. Drahos, "Trust Me: Patent Offices in Developing Countries" (2008) 32 American Journal of Law and Medicine 151; M. Kostecki, Intellectual Property and Economic Development: What Technical Assistance to Redress the Balance of Favour of Developing Nations? (Geneva: ICTSD, 2006); M. Leesti and T. Pengelly, Assessing Technical Assistance Needs for Implementing the TRIPs Agreement in LDCs (Geneva: ICTSD, 2007); D. Matthews, "TRIPs Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreement" (2005) 27 EIPR 420; D. Matthews and V. Munoz-Tellez, "Bilateral Technical Assistance and TRIPs: The United States, Japan, and the European Communities in Comparative Perspective" (2006) 9 Journal of World Intellectual Property 629; C. May, "Learning to Love Patents: Capacity Building, Intellectual Property and the (Re)production of Governance Norms in the 'Developing World'" in E. Amann (ed.), Regulating Development: Evidence from Africa and Latin America (Cheltenham: Edward Elgar, 2006); S. Villanueva, Intellectual Property-Related Technical Assistance: The Philippine Experience (Geneva: ICTSD, 2005). ¹² Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (2002), p.160.

socialisation as well.¹³ Although their capacity to invest and relocate provides them with the ability to use coercion, they can also engage in socialisation by trying to convince foreign lawmakers to follow the US model. There is some evidence that foreign investors are actively engaged in "public education" against counterfeiting and piracy.¹⁴ Arguably, foreign investors also act, behind closed doors, to socialise government officers and legislators. If the domestic business community is disproportionally populated by foreign investors, as opposed to local industry, one can anticipate that socialisation will be even more pronounced.¹⁵ Unfortunately, evidence of the socialisation led by non-state actors other than NGOs remain fractional and anecdotal.

Thirdly, foreign students who populate the LL.M programs of US law schools could convey US norms once they return to their home countries and join the local elite. Indeed, several authors argue that foreign legal education is a powerful driver of legal transplant from one country to another.¹⁶ More than officials participating in *ad hoc* training and lawmakers exposed to foreign investors, foreign students are immersed in US culture while conducting their studies. During their stay, they likely acquire not only the causal beliefs at the heart of IP, but also the worldviews and normative principles underlying IP, such as individualism, rationalism, liberalism and modernism predominant in the United States.¹⁷ On return to their home country, they integrate into the local community of lawyers, with its exclusive expertise, its authoritative language, and its political influence, thereby introducing exogenous norms regarding IP originating in the United States.¹⁸ Surprisingly, the impact of education of its elites on a country's level of IP protection has never been studied systematically.

In a nutshell, socialisation is one of the causal mechanisms that offer much promise in explaining the adoption of US-style IP laws but is also one of the least understood. Many make assumptions but few bring strong empirical evidence to support their claims. Part of the problem is a tendency for the literature on IP politics to rely exclusively on qualitative analysis. For reasons presented above, socialisation is hard to document through direct observation, archive analyses, in-depth process-tracking, surveys, or interviews. To actually investigate the mechanics of socialisation, quantitative analysis drawing on a minimum of information for each country sounds a more promising strategy at this stage of the research program.

¹⁴ J.D. Aronson et al., *Protecting International Intellectual Property: A Report for the Pacific Council on International Policy* (Los Angeles: Pacific Council on International Policy, 1998); M. Yar, "The Rhetorics and Myths of Anti-Piracy Campaigns: Criminalisation, Moral Pedagogy and Capitalist Property Relations in the Classroom" (2008) 10 *New Media and Society* 605.

⁵D.R. Kelemen and E.C. Sibbitt, "The Globalisation of American Law" (2004) 58 International Organisation 103.

¹³D. Matthews, Globalising intellectual Property Rights: The TRIPS Agreement (London: Routledge, 2002); S. Oddi, "TRIPs—Natural Rights and a Polite Form of Economic Imperialism" (1996) 29 Vanderbilt Journal of Transnational Law 415; S.K. Sell, "The Origins of a Trade-Based Approach to Intellectual Property Protection: The Role of Industry Associations" (1995) 17 Science Communication 163; S.K. Sell and A. Prakash, "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights" (2004) 48 International Studies Quarterly 143; P. Steidlemeier, "The Moral Legitimacy of Intellectual Property Claims: American Business and Developing Country Perspectives" (1993) 12 Journal of Business Ethics 157. ¹⁴J.D. Aronson et al., Protecting International Intellectual Property: A Report for the Pacific Council on International Policy (Los Angeles: Pacific

¹⁶C. Atkinson, "Does Soft Power Matter? A Comparative Analysis of Student Exchange Programs 1980–2006" (2010) 6 Foreign Policy Analysis 1; R. Brand and W. Rist (eds), The Export of Legal Education: Its Promise and Impact in Transition Countries (Farnham: Ashgate, 2009); Y. Dezalay and B. Garth, "The Import and Export of Law and Legal Institutions: International Strategies in National Palace Wars" in D. Nelken and J. Feest (eds), Adapting Legal Cultures (Oxford: Hart, 2001); U. Mattei, "A Theory of Imperial Law: A Study on U.S. Hegemony and the Latin Resistance" (2003) 10 Indiana Journal of Global Legal Studies 383; D.M. Trubek and M. Galanter, "Scholars in Self-Estrangement: Some Reflections on the Crisis in Law and Development Studies in the United States" (1974) 4 Wisconsin Law Review 1062; W. Twinning, "Diffusion of Law: A Global Perspective" (2004) 49 Journal of Legal Pluralism 1; W. Wiegand, "The Reception of American Law in Europe" 39 American Journal of Comparative Law 229.

¹⁷K. Burch, "Intellectual Property Rights and the Culture of Global Liberalism" (1995) 17 Science Communication 214; P. Drahos, A Philosophy of Intellectual Property (Dartmouth: Ashgate, 1996); C. May, A Global Political Economy of Intellectual Property Right: A New Enclosure (London: Routledge, 2000); C. May and S. Sell, Intellectual Property Right: A Critical History (Boulder: Lynne Rienner, 2006).

¹⁸ A.M. Burley and W. Mattli, "Europe Before the Court: A Political Theory of Legal Integration" (1993) 47 International Organisation 41; J. Jordana and D. Levi-Faur, "The Diffusion of Regulatory Capitalism in Latin America: Sectoral and National Channels in the Making of a New Order" (2005) 598 The Annals of the American Academy of Political and Social Science 102; Kapczynski, "The Access to Knowledge Mobilisation and the New Politics of Intellectual Property" (2008) 117 Yale Law Journal 804; F. Kratochwil, Rules, Norms, and Decisions: On the Conditions of Practical and Legal Reasoning in International Relations and Domestic Affairs (Cambridge: Cambridge University Press, 1989); A. Newman, "Building Transnational Civil Liberties: Transgovernmental Entrepreneurs and the European Data Privacy Directive" (2008) 62 International Organisation 103; F. van Waarden and M. Drahos, "Courts and (Epistemic) Communities in the Convergence of Competition Policies" (2002) 9 Journal of European Public Policy 913.

Moreover, as Jeffery Chwieroth argues, "quantitative methods also offer the advantage of helping ideational researchers overcome objections by sceptics about the importance of social factors for a particular outcome".19

Accounting for context

Any robust understanding of how socialisation drives changes in the IP law of developing countries must take into consideration the role that other forces play in concurrently shaping this outcome. This is particularly critical where quantitative research methods are adopted, as failure to account for the full range of causal factors can produce spurious results. This section presents three mechanisms already identified in the literature as alternative explanations for why developing countries integrate US-style IP rules: coercion, contractualisation and domestic economics.

The impact of US coercion on developing countries was the first identified explanation of US-style IP rule adoption and remains the best documented. Coercion occurs when an actor uses its material capability to force another actor to do what that second actor would not otherwise voluntary do. The United States's best-known coercive instrument is the so-called "Special 301", a law requiring the United States Trade Representative (USTR) to publish, on a yearly basis, a Watch List and a Priority Watch List (PWL) of countries that "deny adequate and effective protection of intellectual property rights".²⁰ The impact of this measure on the strengthening of IP protection in developing countries has been supported empirically through both qualitative²¹ and quantitative studies.²²

A second explanation for the adoption of US-style IP norms in developing countries, contractualisation, is based on the assumption that developing countries adopt higher IP standards in exchange for better access to the US market. The two partners secure this quid pro quo bargain through a bilateral treaty.²³ The literature on these agreements is largely comparative. Most studies compare US bilateral treaties with the TRIPs Agreement, conclude that they could be characterised as TRIPs-Plus agreements, and infer from this finding that these treaties could have adverse social and economic effects on developing countries.²⁴ Other studies compare US bilateral agreements with US law to reveal their imbalances,²⁵ earlier

¹⁹ J. Chwieroth, "Neoliberal Economists and Capital Account Liberalisation in Emerging Markets" (2007) 61 International Organisation 443. ²⁰ 19 USC § 2411.

²¹ J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000), p.17; P. Drahos, "Developing Countries and International Intellectual Property Standard-Setting" (2002) 5 Journal of World Intellectual Property 765; S.K. Sell, Private Power, Public Law: The Globalisation of Intellectual Property Rights (Cambridge: Cambridge University Press, 2003).

K.A. Elliott and J.D. Richardson, "Determinants and Effectiveness of Aggressively Unilateral US Trade Actions" in R.C. Feenstra (ed.), The Effects of US Trade Protection and Promotion Policies (Chicago: University of Chicago Press, 1997); C. Özden and E. Reinhardt, "The Perversity of Preferences: GSP and Developing Country Trade Policies, 1976-2000" (2005) 78 Journal of Development Economics 1; K.C. Shadlen, A. Schrank and M.J. Kurtz, "The Political Economy of Intellectual Property Protection: The Case of Software" (2005) 49 International Studies Quarterly 45; K. Zeng, "Trade Structure and the Effectiveness of America's Aggressively Unilateral Trade Policy" (2002) 46 International Studies Quarterly 93.

K.C. Shadlen, "Exchanging Development for Market Access? Deep Integration and Industrial Policy under Multilateral and Regional-Bilateral Trade Agreements" (2005) 12 Review of International Political Economy 750.

²⁴ F. Abbott, Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of US Federal Law (Geneva: ICTSD-UNCTAD, 2006); C. Fink and P. Reichenmiller, Tightening TRIPs: The Intellectual Property Provisions of Recent US Free Trade Agreements (Washington: The World Bank, 2005); R. Mayne, Regionalism, Bilateralism, and TRIPS Plus Agreements: The Threat to Developing Countries (New York: PNUD, 2004); J.-F. Morin, "Tripping up TRIPs Debate: IP and Health" (2006) 1 International Journal of Intellectual Property Management 37; P. Roffe and C. Spennemann, "The Impact of FTAs on Public Health Policies and TRIPs Flexibilities" (2006) 1 International Journal of Intellectual Property Management 75; F. Rossi, "Free Trade Agreements and TRIPs-plus Measures" (2006) 1 International Journal of Intellectual Property Management 150; S.K. Sell, "TRIPs-Plus Free Trade Agreements and Access to Medicines" (2007) 28 Liverpool Law Review 41; K.C. Shadlen, "Exchanging Development for Market Access? Deep Integration and Industrial Policy under Multilateral and Regional-Bilateral Trade Agreements" (2005) 12 Review of International Political Economy 750.
 ²⁵ Abbott, Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of US Federal Law (2006)

treaties to track historical trends,²⁶ European agreements to locate differences in trade strategies,²⁷ or current multilateral negotiations to assess their capacity to serve as negotiating leverage.²⁸ Unfortunately, few studies have gone beyond textual analysis to investigate their actual impact on developing countries' laws and policies. The levels of implementation remain largely unknown, although some studies suggest that developing countries might negotiate international IP standards knowing very well that they will not fully implement them domestically.²⁹ Consequently, the causal relation between the rise of bilateralism and the increased level of protection in developed countries is widely assumed rather than firmly established.

A third factor shaping the trajectory of IP protection in developing countries is domestic economics. Ouantitative modelling has revealed that economic development generally exerts a curvilinear effect on the level of IP protection. While increases from the lowest levels of development tend to be associated with a lowering of IP protection, this effect weakens with greater development and then reverses direction such that increases in development are associated with increases in IP protection.³⁰ The theoretical explanation for this pattern, offered by Chen and Puttitanun, draws a link between economic growth and the quality of technological advances.³¹ Initial increases from a very low level of development will tend to involve technological advances that, more than anything else, make it easier for local firms to imitate or replicate the practices and products of foreign firms, thus encouraging local governments to relax IP rules that might otherwise protect the foreign firms and raise the costs of local ones. With further increases, however, come increasingly rapid advances in the type of technology that enables local firms to start innovating on their own. As advances in the second type of technology come to outstrip those in the first type, a tipping point is reached, such that increasing IP protection comes to serve the interests of local firms better than would unchanging or declining levels of protection. It bears mentioning that, for many developing countries, the relationship between economic development and IP protection will simply be monotonically positive in a study covering only the last 10 or 15 years; the level of development where the relationship with IP protection turns around is relatively quite low and many developing countries will already have passed this point by 1995, the study's earliest panel. In any event, any study estimating the forces behind the strengthening of IP law in developing countries must be sure to account for the influence of economic development within that country.

Data and methods

With the aim of testing the effects hypothesised in this study, we collected data on 49 developing countries for each year from 1995–2008, resulting in a sample of 686 country-years.³² Seeking to restrict the dataset to developing economies, we included only those countries that the World Bank ranked as low- or middle-income for more than half of the years covered.

²⁶ G.P. Krikorian and P. Szymkowiak, "Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine" (2007) 10 Journal of World Intellectual Property 388; R. Okediji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection" (2004) 125 University of Ottawa Law and Technology Journal 125; D. Vivas-Engui and M.J. Oliva, Biodiversity and Intellectual Property in North-South Free Trade Agreements (Geneva: ICTSD, 2010).

⁷M.K. El Said, "The European TRIPs-Plus Model and the Arab World: From Co-operation to Association—A New Era in the Global IPRs Regime?" (2007) 28 Liverpool Law Review 143; M.P. Pugatch, A Transatlantic Divide? The US and EU's Approach to the International Regulation of Intellectual Property Trade-Related Agreements (Brussels: ECIPE working paper, 2007).

J.-F. Morin, "Multilateralising TRIPs-Plus Agreements: Is the US Strategy a Failure?" (2009) 12 Journal of World Intellectual Property 175. ²⁹ A. Mertha and R. Pahre, "Patently Misleading: Partial Implementation and Bargaining Leverage in Sino-American Negotiation on Intellectual Property Rights" (2005) 59 International Organisation 695.

Y. Chen and T. Puttitanun, "Intellectual Property Rights and Innovation in Developing Countries" (2005) 78 Journal of Development Economics

^{474.} ³¹ Y. Chen and T. Puttitanun, "Intellectual Property Rights and Innovation in Developing Countries" (2005) 78 Journal of Development Economics

⁴⁷⁴. ³² The 49 developing countries were selected because of the availability in French, English or Spanish of updated information on their IP laws from a reliable governmental or intergovernmental organisation

In order to measure the relative adoption of US-style IP rules in any given country, we developed a new statistical index. Existing indexes are either limited to a specific IP right (e.g. patent or copyright) or include indicators, such as 20-year patent terms, largely irrelevant in the post-TRIPs period. The widely used Ginarte and Park index, for example, captures little meaningful variation after 1994 as it is based on indicators that thereafter became mandatory for WTO members.³³ Our index accounts for this shift in the IP landscape, assessing the level of adoption of certain IP rules that are not required by the TRIPs Agreement.³⁴

Our study operationalised the causal mechanism of IP socialisation using three indicators, each associated with an above-mentioned causal pathway. These are as follows:

- (1) the cumulative number of US-funded IP training events in which each country participated;
- (2) the stock of foreign direct investment as a percentage of GDP; and
- (3) the percentage of the population studying in the United States.

The effects of coercion, contractualisation and domestic economics were respectively controlled for by the variables of PWL designation, entry into US bilateral agreements and GDP per capita.

Where some delay in the effect of a variable was expected, that predictor was lagged accordingly in our estimations. This eliminated the observations from 1995, truncating the span of our study to the 1996–2008 period and reducing our sample to 637 country-years. Some variables were also transformed to adjust for non-linearity in their association with IP protection. These decisions are explained in the appendixes, which also contain for all variables descriptive statistics, data sources, the calculations for variable construction and transformations and missing values figures. The list of countries sampled is also provided.

Given the availability of panel data and our interest in explaining changes in IP law within countries, we chose to model the relationships hypothesised in this article using fixed effects regression. In addition to controlling for the influence of all predictors included in the model, this technique manages certain forms of unobserved heterogeneity quite well, eliminating bias arising from omitted variables, provided that they remain effectively fixed within countries. All models were estimated using robust standard errors to adjust for heteroskedasticity in the distribution of the error term.

Results and discussion

Our results strongly support the effect of socialisation on developing country adoption of US-style IP rules. Table 1 respectively sets out in its first three columns the bivariate effects of events sponsored by the United States, FDI per GDP and studying in the United States. Each of these three models shows the relationship between changes in a given socialisation factor and changes in IP law when no other variables are taken into account. In each instance, we see positive, highly significant relationships.

In order to rule out spuriousness, however, and isolate the independent effects of each factor, we must adjust for the influence of other causes as well. Column 4 sets out such a model, such that each socialisation factor is estimated together, while also holding constant the effects of GDP, PWL designation and bilateral agreements. Although the magnitude of each socialisation factor is substantially diminished from the bivariate estimates, each relationship remains positive and strongly significant. This is strong evidence of the positive effects of socialisation on the adoption of IP rules, supporting the still nascent theory relating to socialisation.

³³ J. Ginart and W. Park, "Determinants of Patent Rights: A Cross-National Study" (1997) 26 Research Policy 283.

³⁴ The actual implementation of these rules and their interpretation by executive and judicial authorities, which can either obstruct or favour a transplantation process, were not taken into consideration.

Table 1: Impact of	socialisation on	developing	countries'	IP laws ³⁵

Variables	1	2	3	4		
Capacity building events	0.023*** (0.002)			0.008*** (0.002)		
FDI stock		0.035*** (0.003)		0.015*** (0.003)		
US Study			0.785*** (0.134)	0.241* (0.108)		

These results raise some major policy implications. Evidence that socialisation is a significant carrier of US-style IP rules points to the need for developing countries to remain critical of assistance financed by other governments and to provide public fora in which IP issues are discussed by domestic stakeholders. Attention need also be paid to the other modes of norm transmission: study in the United States and foreign investors. While the advantages of studying in the United States and other countries are certainly significant, encouraging domestic scholarship and support of national academic institutions may act to at least question and assess the appropriateness of imported norms. Similarly, greater involvement by local investors and entrepreneurs can act to balance and critically assess the adoption of US norms promulgated by foreign investors.

In essence, this article constitutes an empirical basis for developing country delegates to ask, in Geneva-based international organisations, for the establishment of policies to make sure that technical assistance activities are demand-driven, transparent, neutral, and accountable. Technical assistance would have to be designed to better capture the reality of developing country creative and innovation systems and focus on long term capacity, policy independence and informed decision-makers. As Finnemore and Sikkink observe, "making successful law and policy requires an understanding of the pervasive influence of social norms of behaviour".³⁶

Appendix 1: Sample of developing countries

Albania, Algeria, Argentina, Armenia, Bolivia, Botswana, Brazil, Bulgaria, Cambodia, Chile, China, Colombia, Costa Rica, Croatia, Dominican Republic, Egypt, El Salvador, Guatemala, Honduras, Hungary, India, Indonesia, Jamaica, Jordan, Kazakhstan, Kyrgyzstan, Laos, Lebanon, Malaysia, Mexico, Morocco, Nicaragua, Paraguay, Peru, Philippines, Poland, Romania, Russia, Senegal, Slovak Republic, South Africa, Thailand, Tunisia, Turkey, Turkmenistan, Ukraine, Venezuela, Vietnam, and Zambia.

Appendix 2: Variable definitions and data sources

Variable	Definition	Source
Index	The index comprises 8 indicators, each ranging theoretically from a minimum value of 0 to a maximum value of 1. In each case, higher scores indicate closer alignment with US-style rules. Scores across indicators are added, such that each indicator receives equal weight and the index ranges theoretically from a minimum value of 0 to a maximum value of 8.	al government websites.
	 Patentability of plants: If no, 0; if yes, 1. Copyright term of 70 years or more after death: If no, 0; if yes, 1. Prohibition of the dissemination of technology used to circumvent measures that control access to copyrighted works: If no, 0; if yes, 1. 	

³⁵ * significant at <0.05, ** significant at <0.01, *** significant at <0.001.

³⁶ M. Finnemore and K. Sikkink, "International Norm Dynamics and Political Change" (1998) 52 International Organisation 893.

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Variable	Definition	Source
	 (4) Ratification of UPOV91: If no, 0; if yes, 1. (5) Ratification of WIPO Internet Copyright Treaty: If no, 0; if yes, 1. (6) Ratification of the Brussels Convention on Satellite Signal: If no, 0; if yes, 1. (7) Ratification of the Patent Law treaty: If no, 0; if yes, 1. (8) Ratification of the PCT: If no, 0; if yes, 1. 	
PWL Designation	Countries designated in the Special 301 Report from the year before as being (a) on the Priority Watch List; (b) a Priority Foreign Country (including potential PFCs); or (c) subject to section 306 monitoring receive a 1. All others receive a 0.	
Bilateral us	"Bilateral agreements" refer to international agreements that (1) are considered as treaties under international law; (2) include significant TRIPs-Plus provisions; (3) have a bilateral or regional scope; (4) concluded after 1994; (5) signed by the United States. Where, in a given country-year, a bilateral agreement has been signed that is not in force, they receive a 1 on the signature flag. The signature indicator identifies years in which a country has signed (whether in that year or an earlier one) a bilateral agreement with the United States, but the agreement is not yet in force. We lagged this measure by one year in our regressions. The "in force" indicator identifies years in which a bilateral agreement signed with the United States is in force in the country.	USTR
GDP	Log (In) of gross domestic product per capita	World Bank
Capacity building events	The total number of IP training events, whether sponsored by the US government or private actors, that the country has participated in since January 1995. The motivation for rendering the variable as a stock was to reflect the long-term nature of this investment.	
FDI stock	Total stock of foreign direct investment in a given country in a given year, as a percentage of the country's GDP that year.	UNCTAD
US Study	The percentage of the country's population studying in the United States. This variable was lagged by one year and transformed into its natural logarithm.	Institute for Inter- national Educa- tion

Appendix 3: Descriptive statistics

In the following table, the first column provides the overall rate of valid values for each variable. Only the 637 cases from 1996–2008 period were used to calculate these values, as the observations from 1995 were all excluded due to the one-year lags adopted. The following 14 columns display the average value for each given variable in each year for which data was collected. The arithmetic mean is reported for continuous variables, while a percentage is reported for dichotomous variables. Entry into a US bilateral agreement is represented by a single dichotomous variable flagging countries in which either the signature or the in force indicator would read 1. The averages are raw, reflecting neither the lagging nor the mathematical transformations adopted in modelling.

Variable	% cases valid	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Index	100	0.61	0.67	0.73	0.86	1.02	1.18	1.35	1.69	1.92	2.04	2.22	2.55	2.65	2.82
GDP/Pop.	100	2134	2235	2330	2289	2223	2292	2301	2298	2596	3054	3510	3931	4693	5498
PWL	100	6%	10%	16%	20%	24%	22%	29%	27%	22%	24%	27%	24%	24%	16%
US BA	100	0%	0%	0%	0%	0%	0%	2%	2%	4%	6%	18%	20%	20%	20%
US Study	100	0.013	0.013	0.013	0.013	0.014	0.015	0.016	0.017	0.017	0.016	0.015	0.014	0.014	0.013
FDI	99.4	14.9	16.8	19.4	24.2	27.0	28.8	29.7	32.0	33.2	33.5	33.5	36.0	39.5	35.4

Variable	% cases valid	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Events	100	0.0	1.5	12.5	15.9	18.9	23.7	29.8	34.5	40.1	43.6	46.8	50.8	58.0	64.2	

The Rise and Fall of "Prior Consent" in Brazil

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In Applications; Brazil; Patents; Pharmaceuticals

In 2001 Brazil introduced a novel mechanism for examining pharmaceutical patent applications, the system of "prior consent". Accordingly, all pharmaceutical patent applications that are approved by the National Institute for Industrial Property (INPI) must be sent to the Ministry of Health (MS) for review. Pharmaceutical patents can only be granted after the MS's health surveillance agency (ANVISA) issues its prior consent.¹ Thus, since 2001 Brazil has experimented with sharing the role of pharmaceutical patent examination among two state institutions, the patent office (INPI) and the health surveillance agency (ANVISA).

Brazil's prior consent rule has received significant attention by analysts. Some applaud prior consent for what it attempts to achieve and regard it as a model for possible emulation by other developing countries.² Some criticise it and regard it as something to be avoided.³ Yet, despite the attention that prior consent has received, few analysts have examined, in detail, the Brazilian experience of involving health officials in the examination of patents.⁴ What such an examination reveals is that the prior consent system in Brazil has generated exceptional levels of tensions, not just internationally⁵ but domestically, and has been burdened by intense—and growing—conflict. In fact, as of late 2011 prior consent appears, for all practical purposes, to be dead.

In this brief article I examine the rise and fall of this pioneering, and TRIPS-compatible policy instrument. I explain how prior consent operated and the sources of conflict, and I document the pattern of non-cooperation between the two main protagonists, INPI and ANVISA. In doing so I explain that the core of the conflict regarded alternative—and irreconcilable—approaches to examining patent applications on *incremental* pharmaceutical innovations (e.g. alternative molecular forms of known drugs, new formulations and additional uses). In illustrating how the INPI-ANVISA conflict has been resolved, both de facto and de jure, largely in favour of the patent office, the case study draws attention to the isolation within the state of the actors responsible for such examination and the ambivalent interests of key industrial actors.⁶

¹ The Portuguese term for "prior consent" is anuência prévia.

² M. Basso, "Intervention of Health Authorities in Patent Examination: The Brazilian Practice of the Prior Consent" (2006) 1 International Journal of Intellectual Property Management 54; C. Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective (Geneva: WHO-ICTSD-UNCTAD, 2007); C. Deere, The Implementation Game: The TRIPs Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford: Oxford University Press, 2008); P. Drahos, The Global Governance of Knowledge: Patent Offices and Their Clients (Cambridge: Cambridge University Press, 2010).

³ M.T. de Souza, "Should Brazil Allow Patents on Second Medical Uses?" (2008) 93*Revista da ABPI* 53; V.Y.M. Kunisawa, "Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil" (2009) 12 *Journal of World Intellectual Property* 297; E.C. Rosman, "O Limite Normativo de Agencia Nacional de Vigiliancia Sanitaria—ANVISA" (2004) 71 *Revista da ABPI* 32.

⁴ The most detailed analysis that I have seen was written as an MA thesis in public health in Brazil: H.S. Silva, *Avaliação da análise dos pedidos de patentes farmacêuticas feita pela Anvisa no cumprimento do mandato legal da anuência prévia* (Rio de Janeiro: National School of Public Health, 2008). The author of the study works in ANVISA.

⁵By "internationally" I mean annual criticisms of prior consent included in the US Trade Representative's Special 301 report.

⁶ This article draws heavily upon material published in K.C. Shadlen, "The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil" (2011) 39 *Politics and Society* 143.

INPI, ANVISA, and pharmaceutical patents

Brazil's TRIPs-compliant patent law (Lei de Proprieadade Industrial, LPI), which was passed in May 1996 and came into effect in May 1997, made pharmaceutical products and processes eligible for patents. As indicated, since 2001 all pharmaceutical patent applications have needed the approval of both INPI and ANVISA before they can be granted. Though this requirement was formally introduced in 1999 by "provisional measure", it was not put into operation until 2001 when the Brazilian Congress approved a new law reforming the 1996 LPI. At that time ANVISA created a special division to execute its new task, the Coordenação de Propriedade Intelectual (COOPI), which was housed in the same building as INPI in Rio de Janeiro.⁷

It is worth noting, at the outset, that the terms of the law are ambiguous. The LPI reform simply inserted a single clause, art.229-C, that states, "The concession of patents for pharmaceutical products and processes depends on the prior consent of the National Agency for Sanitary Vigilance [ANVISA]." Thus, while it is clear that ANVISA's "prior consent" is required for pharmaceutical patents to be granted, the terms on which ANVISA is supposed to exercise this role and grant or deny its prior consent are left unstated. Moreover, the lack of legislative debate, with regard to either the initial 1999 provisional measure and its subsequent renewals or to the 2001 LPI reform, provide little record of legislative intent. The little information we have to go on is the letter that the Executive submitted to Congress in making the original change. That letter simply says, in the spirit of "two heads are better than one", the purpose of involving ANVISA was to improve the examination of pharmaceutical patents.⁸

From ANVISA's perspective this lack of detail was not problematic, but to the contrary pregnant with meaning. After all, since TRIPS and Brazil's LPI both stipulate the criteria on which patents must be granted or denied (novelty, inventive step, and utility), the logical interpretation was that ANVISA's role must be to verify that pharmaceutical patents satisfied these standard patentability criteria.⁹ Thus, Brazil ended up with a dual examination system in the area of pharmaceutical patents that looks something like this:

- INPI receives and examines a patent application;
- if INPI determines that the patent should not be granted, then it is rejected;
- if INPI judges that the patent should be granted, then it is passed to ANVISA where it undergoes a second assessment;
- ANVISA examines the application and INPI's decision, often requesting additional material from the patent office and the applicants;
- ANVISA may deny or grant its prior consent to the patent, but even when it grants prior consent it may do so only after requiring that the applicant narrow some of the patent's claims:
- ANVISA's report is returned to INPI, which can formally grant the patent only if ANVISA has given its prior consent.

These arrangements have generated intense conflict between the two bodies involved in examining pharmaceutical patents in Brazil, INPI and ANVISA. While INPI appears to have welcomed ANVISA's assistance at first,¹⁰ by the middle of the decade the relationship between the two organisations became

⁷ For the sake of simplicity, except for where it is essential to make a specific distinction between the health surveillance agency itself and the agency's intellectual property division, I refer to ANVISA.

Basso and Kunisawa also discuss the background of prior consent: M. Basso, "Intervention of Health Authorities in Patent Examination: The Brazilian Practice of the Prior Consent" (2006) 1 International Journal of Intellectual Property Management 54; Kunisawa, "Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil" (2009) 12 Journal of World Intellectual Property 297.

 ¹⁰ de Souza, "Should Brazil Allow Patents on Second Medical Uses?" (2008) 93*Revista da ABPI* 53, 62.

increasingly acrimonious.¹¹ By the end of the decade, INPI ceased to acknowledge ANVISA's role in patent examination and sought—through administrative, judicial, and legislative channels—to marginalise ANVISA from the process.

INPI's approach to the division of labour between the two bodies was that ANVISA, as the country's health surveillance agency, should deal with health—and only health. Thus the patent office tended to take seriously ANVISA's interventions when they were made on grounds related to health but not when they appeared to be based on intellectual property criteria.¹²ANVISA, in turn, became increasingly out-spoken in its criticisms of INPI—both INPI's approach to pharmaceutical patent applications per se and INPI's approach to the process of dual-examination of such applications. It introduced measures to assert (or reinforce) its own authority over that of the patent office.¹³

To be sure, part of the conflict between the two agencies can be understood in terms of standard intra-bureaucratic rivalry, with the patent office resenting the incursion of health authorities on its territory. ANVISA's support and assistance may have been welcome at the outset—when INPI was understaffed and overwhelmed by the tidal wave of applications it received in a new and complex area such as pharmaceuticals. However, ANVISA's role came to be regarded as a nuisance once INPI acquired more capabilities for examining pharmaceutical patents (technology, resources and examiners). And as INPI was furthering its integration into the global circuit of patent offices and seeking to obtain recognition as an International Search Authority under the Patent Cooperation Treaty, the fact that its judgments and decisions in a key area such as pharmaceuticals would be reviewed by another agency in the Brazilian state was intolerable.

Yet the conflict between INPI and ANVISA goes far beyond a fight over turf. If that were all that was at stake, the conflict might be resolved by simply absorbing COOPI into INPI. Yet ANVISA's patent examiners could not work within INPI, because COOPI's approach to examining pharmaceutical patents would not be acceptable there. Indeed, what is driving the conflict over prior consent are substantive differences over how to examine pharmaceutical patent applications. While INPI's examination guidelines facilitate patenting of incremental changes to molecules and new uses of existing drugs, for example, COOPI's approach is significantly more stringent and restrictive. Silva provides a detailed analysis of the prior consent process in its early years,¹⁴ examining every patent application received by ANVISA from 2001 to 2006 and, critically, the reports made by COOPI examiners after their preliminary examination. The data show that in the cases where COOPI had substantive concerns about a patent application approved by INPI, 45.6 per cent of the concerns regarded degree of novelty, degree of inventiveness, or whether the innovation amounts to a therapeutic use, while another 36.4 per cent of the concerns regarded insufficient description of the invention. In short, the two agencies have divergent—and irreconcilable—perspectives on what sorts of incremental innovations merit patent protection.

Let's consider INPI's and ANVISA's approaches in more detail. In a sense, the conflict between the two agencies is indicative of a broader conflict between two objectives: encouraging and promoting incremental innovation through the patent system, and minimising periods of market exclusivity and preventing the effective extension of patent terms.

¹¹ Public debates featuring the President of INPI (Jorge Ávila) and the head of COOPI (Luis Carlos Lima) became a regular affair in Brazil. For a taste, see *http://www.inovacao.rei.unicamp.br/report/noticias/index.php?cod=468* [Accessed October 31, 2011]; *http://camara-dos-deputados.jusbrasil.com.br/noticias/1988139/inpi-e-anvisa-divergem-sobre-patentes-de-segundo-uso* [Accessed October 31, 2011].

 ¹² "Carta Aberta ao Jornal Estado de São Paulo", available at http://www.inpi.gov.br/menu-superior/imprensa/informacoesparaimprensa/carta-aberta
 -ao-jornal-estado-de-sao-paulo [Accessed October 31, 2011].
 ¹³ "Perguntas e respostas sobre a prévia anuência da ANVISA e a RDC 45/08", available at http://www.anvisa.gov.br/medicamentos/intelectual

¹⁵ "Perguntas e respostas sobre a prévia anuência da ANVISA e a RDC 45/08", available at http://www.anvisa.gov.br/medicamentos/intelectual /perguntas.htm [Accessed November 29, 2011]. These measures were, according to ANVISA's top patent official, a response to "INPI's boycott" of the prior accorder surface.

the prior consent system. ¹⁴ H.S. Silva, Avaliação da análise dos pedidos de patentes farmacêuticas feita pela Anvisa no cumprimento do mandato legal da anuência prévia (2008).

INPI's examination guidelines apply patentability criteria in such a way as to lead examiners to approve many applications on incremental innovations such as polymorphs and second uses. The logic informing this approach is that doing so can reward local actors' adaptive innovative efforts. INPI and its parent Ministry, the Ministry of Development, Industry, and Foreign Trade (MDIC), maintain that encouraging and rewarding *incremental* innovation is the key job of a patent system in a developing country where firms operate far from the technological frontier.¹⁵ Patent office officials insist that this approach matches—and responds to—the innovative capabilities of local industry. The reasoning is captured well by INPI President Jorge Ávila's testimony to Congress:

"The [Brazilian] firms that have developed innovative capacities demonstrate the need to retain the patentability of incremental innovations, because it is not possible for a new actor in the scenario of innovation to immediately become a radical innovator. The entryway to the system of innovation is incremental innovation."

COOPI's examination, in contrast, is informed by a more critical perspective on incremental innovation, with guidelines that are designed to effectively restrict the scope of patentability. To be sure, most patents approved by INPI are also approved by ANVISA, many on the same terms and some with claims narrowed. Yet, as the previous discussion suggests, certain types of pharmaceutical patent applications are examined more critically by ANVISA. ANVISA maintains that most polymorphs are obvious from the original molecules and therefore lack inventiveness, for example, and that second uses lack novelty.¹⁶ Fearful of patents that would effectively extend periods of patent protection and armed with strictly-operationalised patentability criteria, ANVISA thus attempted to use its position in the patent examination process to deny (or at least limit) the granting of patents on incremental innovations in Brazil.

With INPI protective of both its authority to examine patents and its approach to patent examination, it stopped cooperating with ANVISA and the system essentially broke down by the late 2000s. To illustrate the breakdown it is worth considering two dimensions of inter-agency cooperation that need to be achieved for the prior consent system to operate effectively.¹⁷ The first regards collaboration and communication in the course of patent examination. As indicated, upon making preliminary reports, ANVISA's examiners frequently demanded additional information and clarifying materials from the applicants. Yet INPI routinely refused to pass ANVISA's preliminary reports and requests for clarifying materials to applicants, thus inhibiting ANVISA's subsequent evaluation of the applications. At times, the system functioned, with ANVISA requesting more information and INPI dutifully obtaining this information from the applicant or INPI simply rejecting the application on procedural or substantive grounds without referring it back to the applicant. But often ANVISA's requests would simply be ignored. The pattern was not one of INPI uniformly refusing to intermediate between ANVISA and applicants, but rather unpredictability and unreliability of INPI's intermediation. ANVISA asking for more materials *may* have lead to INPI obtaining the materials or even rejecting the application, but it just as well may not have. INPI, not ANVISA, decided the cases where the system would function or not function.

A more striking form on non-cooperation is evident with regard to applications where the two bodies reach different conclusions, i.e. INPI approves and ANVISA denies. This has occurred roughly 130 times, but fewer than 10 of these applications that ANVISA rejected were subsequently rejected by INPI. In the

¹⁵ I provide further discussion of the logic of INPI's approach, and its relationship more generally to the country's innovation-based economic development strategy, in Shadlen, "The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil" (2011) 39 *Politics and Society* 143. Note that there is also a practical motivation to a less rigorous examination system, and that is simply the huge backlog of applications which INPI has.

¹⁶ According to ANVISA, treating second uses as inventions, which is what is needed to justify a patent, implies that something can be invented multiple times. In Congress, responding to INPI President Jorge Avila's defence of second use patents, COOPI's Luis Carlos Lima exclaimed, "he invents a molecule and, when he thinks he has a new use, he invents it again. The day he manages to explain that to me, perhaps we'll no longer have so much disagreement on this topic".

¹⁷ The pattern of conflict I describe in the subsequent paragraphs is strikingly different from the "formal collaborative relationship" between INPI and ANVISA lauded by Deere, *The Implementation Game* (2008), p.213.

case of the others, INPI cannot go ahead and grant the patents, as art.229-C of the reformed LPI prohibits doing so without ANVISA's approval, but INPI did not reject them either. According to INPI, its mandate is to examine patents and it is uniquely vested with that mandate; so once its examiners have approved a patent there is no reason why INPI should change its verdict on account of the health surveillance agency's evaluation. As a result, INPI does nothing at all, essentially "freezing" the applications. It is important to note that holding the applications in a state of non-decision, neither granted nor rejected, is more than an act of petulance on the part of the patent office. INPI wants to grant these patents, and if they were to be rejected then they could never be granted. But doing nothing essentially buys time and amounts to a bet on the eventual abolition of the prior consent requirement: once ANVISA's role is formally removed, then not-yet-rejected patent applications may still be granted.¹⁸

Notwithstanding INPI's largely successful efforts to marginalise ANVISA's input, however, the patent office still found itself restrained, because, at the end of the day, pharmaceutical patents could not be granted without ANVISA's permission. In other words, INPI could make it difficult for ANVISA to examine applications and INPI could try to ignore ANVISA's rulings, but INPI could not grant patents independently so long as the law requiring ANVISA's prior consent was in force. What INPI really needed to do, in order to examine pharmaceutical patents on the terms it desired, was to eliminate ANVISA from the process.

To that end INPI lodged a formal complaint to the office of the Brazilian Attorney-General (PGF), maintaining that, as the national patent office, it was solely—and uniquely—vested with the authority to examine patent applications according to the terms of the LPI.¹⁹ Moreover, INPI officials argued, not only was the patent office the only actor that could grant patents, but it would be violating its own mission and failing to discharge its own responsibilities were it to deny patents based on another agency's examination. Again, patent examination should be done by the patent office, not health officials; ANVISA should dedicate itself to health affairs. INPI, reiterating its posture of "completely rejecting"²⁰ANVISA's role in pharmaceutical patent examination, sought a ruling that would allow it to proceed without the interference of the health agency.²¹

In October 2009, the PGF published a report that supported INPI's position almost in its entirety.²² The PGF declared that INPI—and only INPI—had the authority to examine patents on grounds of novelty, inventive step, and utility (i.e. to apply patentability criteria). While ANVISA could continue to evaluate pharmaceutical patent applications, in doing so it must only make health-based assessments of these applications; it could only deny "prior consent" to applications when it judges that granting the patents would pose health risks.

The PGF's report was attacked by public health activists, who were alarmed by INPI's examination guidelines and thus regarded ANVISA's participation in the formal examination process as crucial for preventing the granting of patents on incremental innovations that lack novelty or are insufficiently inventive. Civil society groups launched an on-line petition against the PGF's position,²³ and ANVISA formally requested that the PGF's report be rejected. Yet, despite these criticisms and demands, in January

²³ The petition is available at *http://www.petitiononline.com/gtpi2/petition.html* [Accessed October 31, 2011].

¹⁸ Note that the state of non-decision also provides effective protection because of third parties' fear of retroactive damages in the case of the patent ultimately being granted. Since the Brazilian patent law guarantees a minimum of 10 years of patent protection from the time of the grant, these delays would effectively extend patent terms.

¹⁹ Procuradoria-Geral Federal, "Atribuições INPI & ANVISA", Parecer 210/PGF/AE/2009.

²⁰ The quotation comes from INPI's request to the Attorney General: Procuradoria-Geral Federal, "Atribuições INPI & ANVISA", Parecer 210/PGF/AE/2009, pp.1–2.

²¹ At the same time as the conflict between INPI and ANVISA was being waged within the Executive, it was also being fought in Congress. In 2008, a Deputy from the opposition Brazilian Social Democratic Party (PSDB) introduced an initiative (PL 3709/08) in Congress that would restrict ANVISA's role to pipeline patent applications. Meanwhile, deputies sympathetic to ANVISA, from the Workers Party, submitted legislation that would handcuff INPI by declaring polymorphs and second uses unpatentable subject matter in Brazil. Though neither of these bills was approved and converted into law, both were the subject of extensive debate and testimony in Brasilia. The congressional hearings on these two bills provide useful insights into the positions of state and societal actors.

²² Procuradoria-Geral Federal, "Atribuições INPI & ANVISA", Parecer 210/PGF/AE/2009.

2011 the Solicitor General (AGU) in the government of Brazil's new President, Dilma Rousseff, upheld the PGF's ruling.²⁴ Confirmation on the part of the AGU effectively converts the PGF's report from a recommendation into a mandate that, once signed by the President, would bind all actors in the Executive branch.

What is the upshot of these rulings? What is the status of prior consent? At the time of writing (October 2011), the participation of health authorities in patent examination, though formally part of Brazilian law in the sense that art.229-C remains on the books, is effectively eliminated. ANVISA is no longer able to intervene in the examination process as it had done (or attempted to have done) in the past. It cannot request information from applicants about novelty and inventiveness; it cannot issue reports on patent applications that consider whether or not the claimed inventions satisfy patentability criteria. It cannot, in short, examine patents. Instead, ANVISA can only base its decision to grant or withhold prior consent on the basis of "health risks", an instruction that is exceptionally difficult to follow since it is rarely if ever possible to assess "health risks" on the basis of the sort of information included in patent applications. Thus, while the 2001 reform to the LPI still formally remains in places, on paper, ANVISA is no longer able to execute the role assigned to it, at least as its role has been redefined.²⁵ Indeed, following the AGU's ruling and the decision of ANVISA's directorate to accept the new arrangements, the director of COOPI resigned from his position in protest.²⁶

Understanding prior consent's demise

Although the final word on prior consent has yet to be written (the President's signature to formally adopt the AGU's ruling remains pending), in the absence of an unlikely Executive decision to reverse the AGU's ruling or an equally unlikely legislative decision to reform the LPI, it is difficult to see how the system can be restored to its previous state. To be sure, ANVISA and INPI officials continue to try to agree on a way forward, but these discussions (to the best of my understanding) are more about establishing a new working relationship within the guidelines imposed by the AGU than about restoring ANVISA's role in patent examination.

A wide range of political dynamics contributed to this outcome. In the remainder of this article I focus on the key factors that, I argue, made prior consent so difficult to implement and maintain. Specifically I draw attention to ANVISA's inability to mobilise sufficient support for its role in patent examination, both from within the state and from key societal actors.

The inconsistent and somewhat confusing reaction within the rest of the Brazilian Executive to the conflict between INPI and ANVISA is revealing. In December 2008, the government's Inter-Ministerial Group on Intellectual Property (GIPI) declared a "consensus" position against issuing patents on most incremental pharmaceutical innovations. In doing so, it was supporting ANVISA's approach toward patent examination. Yet the "consensus" turned out to be inconsequential; GIPI's position was not a directive that binds any actors but rather a statement of opinion. The GIPI itself is an intra-governmental forum for discussion and not a policymaking body; it lacks the ability to enforce its consensus. Indeed, INPI dismissed the GIPI's resolution, declaring that it would not alter its examination practices without a change in the LPI itself. Of course, the MDIC, INPI's parent ministry, could certainly force INPI to change its practices,

²⁴ Lígia Formenti, "AGU restringe poder da Anvisa na concessão de patente de medicamento", O Estado de São Paulo, January 24, 2011, available at http://www.estadao.com.br/noticias/impresso,agu-restringe-poder-da-anvisa-na-concessao-de-patente-de-medicamento,670238,0.htm [Accessed October 31, 2011].

²⁵ Were it to do so, it may very well be in violation of TRIPS, which establishes the criteria by which patents must be granted or denied. While novelty, inventive step, and utility are ambiguous terms that can be operationalised differently from one country to the next, it is hard to see how "health risk" can fit into those three criteria.
²⁶ W. New, "Top Official Discusses Resignation from Brazil's ANVISA Over Patent Policy", *Intellectual Property Watch*, August 11, 2011, available

²⁶ W. New, "Top Official Discusses Resignation from Brazil's ANVISA Over Patent Policy", Intellectual Property Watch, August 11, 2011, available at http://www.ip-watch.org/weblog/2011/08/11/top-official-discusses-resignation-from-brazil%E2%80%99s-anvisa-over-patent-policy/ [Accessed October 31, 2011].

and if the MDIC would not bring INPI into line, the *Casa Civil* could do so. If the President of Brazil wanted INPI to abide by the GIPI's ruling—if she wanted prior consent to function—the behaviour of the patent office could be altered. Yet this did not happen.

To understand the government's reluctance to reign in INPI, it is important to emphasise how much Brazilian government agencies across the board have been re-geared to promote innovation. A principal objective of economic development policy in Brazil is to increase innovation, with patents used as an indicator of progress. The centrepiece of the new approach is the 2004 Innovation Law, which among other things facilitates patenting of publicly funded research and aims to increase university-industry linkages via licensing. The institutions strengthened by the new innovation policy—and the influential individuals attached to them—are emphatically in favour of incremental innovations and supportive of INPI's posture vis-à-vis pharmaceutical patents. ANVISA's concerns about the injurious effects of extended periods of exclusivity collide with the government's overriding enthusiasm for incremental innovation. With actors throughout the state bureaucracy seemingly united in their commitment to encouraging incremental innovation as a means to enhance the Brazilian economy's international competitiveness, there is an instinctive aversion to policies and practices that appear to go against the grain. To be opposed to incremental innovation—of any sort—simply does not resonate within a government dedicated to increasing innovation. As one prominent official said, it would be "suicidal" for a country such as Brazil to adopt a restrictive (i.e. ANVISA-like) position toward patents on incremental innovations.²⁷

ANVISA's-and, more accurately, COOPI's-isolation must also be understood in the context of the Ministry of Health itself. Although the MS itself is a large and powerful ministry in the Brazilian Executive and ANVISA is an important actor within the MS, the patent examination team (COOPI) is a tiny and marginal part of ANVISA. While INPI is acting "normally" and doing what patent offices do-granting patents, and in doing so gaining presence and recognition in the international patent community-participation in patent examination is not the sort of thing that health ministries ordinarily do. COOPI's atypical role-even one written into the reformed LPI-is far from the organisational remit of most Ministries of Health and health surveillance agencies, and this makes it difficult to protect and defend. MS officials and ANVISA officials are not socialised into thinking about patents, it is not something in their professional toolkit; while they may support the outcome of reducing "trivial" patents and minimising the extensions of patent terms, they are on unfamiliar and uncomfortable ground fighting on behalf of these goals. The MS and ANVISA already have their hands full working on health policy and health surveillance; they appear to have trouble getting worked up about the arcane business of patent examination. While expecting COOPI to assess patents according to "health risks" may make little sense and appear infeasible from an intellectual property perspective, from the perspective of health officials this appears to be an entirely logical way forward, for the reasons explained above. What this means, ultimately, is that while COOPI may have sympathisers within the government, it does not appear to have many advocates it can count on to fight its corner.28

Outside of government, ANVISA received the most solid and active support from health-oriented civil society groups. Prominent organisations such as the Brazilian Interdisciplinary AIDS Association (ABIA) and the Working Group of Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) were steadfast in their support for ANVISA's role in patent examination and their anger with INPI's practices. These actors played critical roles in defending and supporting prior consent.

Yet the benefits of the support received from civil society were not enough to compensate for the lack of support (or, at least, active and visible support) ANVISA received from another key actor in Brazilian society, namely the local pharmo-chemical and pharmaceutical sectors. The Brazilian pharmaceutical

²⁷ Confidential interview in São Paolo, November 2009.

²⁸ Within the Brazilian Government, the most outspoken—and, at times, sole—supporter of COOPI's role in patent examination has been the National AIDS Program.

industry supported prior consent when the measure was announced in 1999 and introduced in 2001; yet as the decade progressed and the conflict over prior consent became more heated and more public, the local sector's support for the system became increasingly hard to detect. In some forums some firms and associations come out in support of ANVISA, while in other forums firms and associations appear aligned with INPI (and its supporters in the transnational pharmaceutical sector). My interviews with officials from associations representing Brazilian pharmaceutical and pharmo-chemical firms reveal a growing unease with prior consent. The unease, if not always manifest in terms of outright opposition, is expressed in the form of unwillingness to actively and publicly mobilise in support of ANVISA's participation in patent examination.

ANVISA's inability to retain local industry's active support is rooted in the latter's growing capabilities for incremental innovation, and subsequently its interests in obtaining patent protection for such innovations. While radical pharmaceutical innovation (i.e. discovery or design of new molecular entities) remains largely out of the reach of Brazilian firms, local actors are acquiring increased capabilities to innovate incrementally. Data on pharmaceutical patent applications filed by Brazilians show a marked increase, an increase significantly sharper than global trends, particularly with regard to incremental innovations. The data suggest that local firms do not just harbour aspirations for incremental innovations, but many of them already possess such capabilities.²⁹

Because a strong bias against patents on incremental innovations would lead to many of Brazilian firms' own applications being rejected, many of these firms have reservations about ANVISA's role in patent examination. No one defends frivolous patents or favours unwarranted extensions of existing patents; in countless public forums, newspaper columns, hearings in Congress and virtually every venue conceivable, the condemnation of patents on trivial modifications that extend terms of exclusion is articulated by local and transnational firms alike. Yet these principled aversions contribute little to determining actors' actual political positions, precisely because they are shared by nearly everyone. In practice few if any actors regard their own innovations as "trivial".

The question is if actors want, as a matter of policy, the bias to be in favour or against the granting of patents on incremental innovations in pharmaceuticals. A bias in favour will disadvantage local firms relative to foreign firms, for notwithstanding Brazilian actors' increased capabilities for incremental innovation they are still far behind the leading, transnational firms in this regard. Yet a systematic bias against granting patents on incremental pharmaceutical innovations will disadvantage local firms in an absolute sense, since incremental innovations are just about the only innovations most can expect to achieve. The empirical question is: Which set of risks and opportunities mobilise local industry politically? My analysis of the political activities of firms and trade associations in the Brazilian pharmaceutical sector suggests that fear of absolute losses incurred by ANVISA's overly restrictive approach to patenting incremental innovations prevails.³⁰

To be clear, the position of the pharmaceutical sector in Brazil is not one of unity: many individuals and firms within the sector remain adamantly opposed to INPI's practices and supportive of ANVISA's approach, and many other individuals and firms are opposed to ANVISA's approach and supportive of INPI's practices. The emergence of new capabilities in the sector has not created a sector with uniform interests in support of one side or the other, but rather created internal divisions that, in turn, paralyse the

²⁹ Shadlen, "The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil" (2011) 39 Politics and Society 143, pp.158–160.

³⁰Cassier and Correa also point to the opposition of local pharmaceutical firms and scientific researchers to legislative initiatives that limit opportunities for pharmaceutical patenting: M. Cassier and M. Correa, "Intellectual Property and Public Health: Copying of HIV/AIDS Drugs by Brazilian Public and Private Pharmaceutical Laboratories" (2007) 1*RECIIS Electronical Journal in Communication, Information and Innovation in Health* 83.

sector as a political actor. In fact, at one point the trade association of pharmo-chemical producers adopted, after considerable internal debate and with some members abstaining and dissenting, a statement in support of ANVISA, only to then decide not to publicise it.³¹

One actor of local industry that has most consistently supported prior consent is the association of "generics" producers.³² These firms are hurt most directly by the extension of patent terms and their own business strategies are less based on incremental innovations. That said, the divisions are not clear and changes are afoot in this sector, as the firms in this sector have become increasingly fused with transnational and Brazilian firms that retain strong (or at least growing) interests in patenting incremental innovations.

Finally, it is worth noting how the two factors discussed here—ANVISA's isolation within the government and the erosion of industry's support-have reinforced each other. In 2007 a group of legislators proposed reforming the LPI to declare some types of incremental innovations (e.g. polymorphs and second uses) non-patentable in Brazil. From industry's perspective, of course, such an outright prohibition is more alarming than ANVISA's rigorous scrutiny of each application (at least there is a possibility of a patent in the latter scenario). ANVISA's original response to this legislative proposal was lukewarm, arguing that if legislators were concerned about non-deserving patents being issued it was not necessary to reform the LPI to alter the scope of patentability, but simply to enforce the existing law-including the prior consent provision-to assure that ANVISA could examine patents properly. Yet with INPI "boycotting" the system and GIPI unable to back up its "consensus", ANVISA since came to support the more radical (and, from industry's perspective, draconian) legislation. Thus, ANVISA's conflict with INPI and its inability to secure support from above radicalised the agency, which further alienated some of its initial supporters in the pharmaceutical industry.

Conclusion

Notwithstanding the considerable degree of harmonisation of national patent systems that has been introduced by TRIPS, it is widely recognised that one area where countries retain significant autonomy-and thus retain important levers of policy discretion-regards the administrative practices of national patent offices.³³ In particular, how countries go about operationalising and applying the key patentability criteria of "novelty" and "inventive step", through both patent office guidelines and examination procedures, remains an important source of cross-national variation in patent politics.

In this article I reviewed the experience of one country's efforts to take advantage of this remaining opportunity for policy innovation, focusing on the case of prior consent in Brazil. I showed how the system worked-and failed to work-and I documented the demise of the system through a series of decisions made at the highest level of the Brazilian political system. In doing so I showed how the conflict over prior consent was, ultimately, a conflict between two alternative approaches to and assessments of incremental innovations in pharmaceuticals. To explain why one approach-that favoured by INPI-prevailed and why the prior consent system thus appears to have collapsed, I focused on the isolation of the relevant actors within the state and the changing preferences (and political mobilisation) of the local pharmaceutical sector.

By way of conclusion, and to underscore the significance of these two causal factors, it is worth considering an alternative explanation for the outcome I have presented in this article-external pressures. Given that national-level changes in patent policy-not just in Brazil but throughout the developing

³¹ I learned about this statement and the events related to its "adoption" in personal communication with a member of the board of directors of the pharmo-chemical association. Yet the former director of COOPI evidently was not aware of the "support." See New, "Top Official Discusses Resignation from Brazil's ANVISA Over Patent Policy", Intellectual Property Watch, August 11, 2011, available at http://www.ip-watch.org/weblog/2011/08/11 /top-official-discusses-resignation-from-brazil%E2%80%99s-anvisa-over-patent-policy/[Accessed October 31, 2011].

In Brazil the term "generics" refers not simply to drugs that lack patents but specifically to drugs that have demonstrated bioequivalence to the reference drug. The formal "generics" sector was launched with a 1999 law that established the regulatory framework. ³³ Correa, *Guidelines for the Examination of Pharmaceutical Patents* (2007); Drahos, *The Global Governance of Knowledge* (2010)

world—have followed changes to international rules on intellectual property,³⁴ it seems reasonable to expect external pressures to be relevant here as well. To be sure, even though prior consent appears to be acceptable under TRIPS, Brazil has nevertheless come under considerable pressure on account of this measure. Transnational pharmaceutical firms that operate in Brazil are vehement in their criticism of prior consent, the Washington-based Pharmaceutical Research and Manufacturers of America incessantly complains about ANVISA's intervention, and the United States Trade Representative regularly echoes these complaints in its annual Special 301 reports. Yet the same actors have expressed strong opposition patent examination-with different effects. For example, Brazil has been subject to extensive external pressures not to use compulsory licenses, but the government's commitment has remained robust. Although Brazil has issued a compulsory license on only one occasion, it has repeatedly used threats to do so as a bargaining chip to extract price reductions from patent-holding firms. The point of this brief comparison is not to suggest that international pressures are irrelevant, but rather to drive home the point that we must consider how international pressures interact with changing domestic constellations of interests. In the case of compulsory licenses, the policy does not undermine or offend the activities of significant segments of the Brazilian state; nor does it threaten the material interests of important societal actors .

³⁴ Deere, The Implementation Game (2008).

When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to **Medicines in Developing Countries**

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JIDS; Developing countries; Human rights; Non-governmental organisations; Patents; Pharmaceuticals; Public health

Introduction

Over the past decade, the debate about the relationship between access to medicines and human rights has, to a large extent, come to define politics of intellectual property. This article describes how non-governmental organisations (NGOs) seeking to draw attention to the potentially adverse effects of patents for pharmaceutical products for public health, particularly for people living with Human Immunodeficiency Virus/Acquired Immune-Deficiency Syndrome (HIV/AIDS), not only reshaped the international debate about the relationship between intellectual property rights and access to medicines by framing it as a human rights issue, but have also utilised the concrete human rights principles enshrined in national constitutional law as a practical tool in their campaigns, often to far-reaching effect.1

Framing

A significant amount of attention has already been paid to the extent that NGOs will increase their gains if they "frame" or "reframe" intellectual property-related debates by using the emotive language of human rights to underpin substantive arguments.

Odell and Sell suggest that in much the same way as powerful transnational firms, and their governments had framed intellectual property protection as a trade issue during negotiations leading to the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)—using the emotive language of "piracy" and "theft" to describe alleged violations of intellectual property rights in developing countries—critics of TRIPS have attempted subsequently to reframe the debate as a public health issue, arguing that strong intellectual property protection could be detrimental to access to medicines (and hence an infringement of human rights).²

Reflecting on the negotiating history of the TRIPS Agreement, Braithwaite and Drahos even argue that had the property-theft-piracy frame of industry and developed country governments been contested at the time of the negotiations, the TRIPS Agreement might not have taken the final form it did and may have been more sympathetic to the development-orientated concerns of the developing world.³

¹ This article draws on research findings from a project funded by the UK Economic and Social Research Council (ESRC) on NGOs, Intellectual Property Rights and Multilateral Institutions (ESRC Grant No.RES-155-25-0038), published in a longer version in Duncan Matthews, Intellectual

Property, Human Rights and Development: The Role of NGOs and Social Movements (Cheltenham: Edward Elgar, 2011). ² John S. Odell and Susan K. Sell, "Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health, 2001" in John S. Odell (ed.), Negotiating Trade: Developing Countries in the WTO and NAFTA (Cambridge: Cambridge University Press, 2006), p.87. ³ John Braithwaite and Peter Drahos, Global Business Regulation (Cambridge: Cambridge University Press, 2000), p.571–576.

Used in this way, framing becomes a tactic utilised by rights-holders and developed country governments to demonstrate that intellectual property rights should be upheld because it is wrong to steal or, alternatively, to demonstrate that intellectual property rights should be applied in a manner that takes account of the need to avoid preventable deaths.⁴ However, these subjective frames of reference imply different policy responses; the more NGOs do to win this subjective contest and establish the dominant frame, the greater that NGOs' negotiated gains, with the framing strategy increasing the NGOs' credibility.5

For Lang,⁶ the diffusion of human rights language into the work of NGOs must be accompanied by degree of elaboration if it is to provide meaningful guidance to trade policy-makers.⁷ Seen in this way, reframing the debate on the impact of intellectual property rights for development in terms of human rights performs a number of potentially important functions. Such reframing, however, does not provide substantial policy guidance, is not a source of new policy ideas, and does not provide a means of choosing between competing ideas. Instead, Lang argues that, to the extent that the human rights movement can mobilise actors and groups presently marginalised and provide effective tools to augment their political influence, framing the issue as one of human rights may help NGOs to achieve real change. In this way, human rights add legitimacy, new constituencies and (to a certain extent) further resources to those groups pressuring for change.8

Similarly, Deere has described how framing has been deployed as a strategic tool to influence international discourse on intellectual property issues and the outcomes of international negotiations.⁹ For Deere NGOs, international organisations and academics working to reframe intellectual property debates to better facilitate discussion of their public interest priorities.¹⁰

Kapczynski also highlights the role of "frame mobilisation" in instigating, promoting, and legitimating collective action, creating areas of overlapping agreement within the coalition and establishing a language of common disagreement between itself and opposing groups.¹¹ For Kapczynski, this explains how actors interpret their interests, build alliances, and persuade others to support their cause.¹²

Reflecting back on the TRIPS negotiations, Drahos has suggested that, in retrospect, drawing on public health and human rights expertise, trade negotiators interested in opposing United States (US) and European Union (EU) pharmaceutical hegemony during the TRIPS negotiations should have built a counter-frame around the principles of timely access to medicines, equity in access, and the cost-effectiveness of medicines.13 However, Drahos has also cautioned against viewing framing as a master mechanism and has argued that it needs the support of other strategies if it is to bring genuine structural gains in intellectual property regimes.14

⁴ Odell and Sell, "Reframing the Issue" in Odell (ed.), Negotiating Trade, p.88.

⁵ Odell and Sell, "Reframing the Issue" in Odell (ed.), Negotiating Trade, p.89

⁶ Andrew Lang, "The Role of the Human Rights Movement in Trade Policy-Making: Human Rights as a Trigger for Social Learning" (2007) 5 New Zealand Journal of Public and International Law 147, 147.

e.g. Frederick M. Abbott, "The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPs" in Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi (eds), Human Rights and International Trade (Oxford: Oxford University Press, 2005), p.294.

⁸Lang, 'The Role of the Human Rights Movement in Trade Policy-Making'' (2007) 5 New Zealand Journal of Public and International Law 147. 147.

⁹Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford and New York: Oxford University Press, 2008), p.169.

Deere, The Implementation Game (2008), p.172.

¹¹ Amy Kapczynski, "The Access to Knowledge Mobilization and the New Politics of Intellectual Property" (2008) 117 Yale Law Journal 804, 804.

¹² Kapczynski, "The Access to Knowledge Mobilization and the New Politics of Intellectual Property" (2008) 117 Yale Law Journal 804, 883. ¹³ Peter Drahos, "Does Dialogue Make a Difference? Structural Change and the Limits of Framing" (2008) 117 Yale Law Journal Pocket Part 268, 269–270. ¹⁴ Drahos, "Does Dialogue Make a Difference?" (2008) 117 *Yale Law Journal* Pocket Part 268, 272.

Taking into account framing strategies in this way, this article examines how human rights have permeated the debate about the relationship between intellectual property rights and access to medicines. It then pursues this theme further by highlighting the extent that human rights law (as opposed to human rights rhetoric) has been used as a practical tool by NGOs in developing countries, often with significant results.

Framing intellectual property rights and access to medicines as a human rights issue

A human rights-based approach to the debate on the relationship between intellectual property rights and access to medicines first came to prominence when international NGOs began to frame the issue by using the emotive language of human rights to underpin substantive arguments that public health, the right to health and the right to life were at risk due to the patent provisions of the TRIPS Agreement. In the run-up to the Doha Declaration on the TRIPS Agreement and Public Health of November 2001,¹⁵ international NGOs began to campaign for access to medicines by calling for the full utilisation of flexibilities contained in the TRIPS Agreement. Using human rights to frame the debate, these NGOs ultimately added moral authority to the access to medicines campaign, which in turn contributed to a greater emphasis on the importance of using in-built flexibilities in the TRIPS Agreement and the need to permanently amend the TRIPS Agreement provisions on compulsory licensing, making explicit the link between the protection of pharmaceutical patents with key principled ideas and rhetoric of human rights discourse.¹⁶

This strategy proved relatively successful because the public, the media and politicians were able to engage in a relatively straightforward way with the notion that the provision of anti-retroviral drugs (ARVs) to treat people living with HIV/AIDS in the developing world was being hindered by the TRIPS Agreement. This contributed to the ability of NGOs to make explicit the link between the HIV/AIDS crisis and intellectual property rights, an issue that had resonance in both the developed and developing worlds.¹⁷

That resonance was articulated through the framing of the issue so that intellectual property began to be seen not only or primarily as a trade issue, but also as one relevant to health and human rights,¹⁸ rooted in the dignity of the other in relation to the self.¹⁹ By framing the TRIPS Agreement in terms of health and human rights, activists were able to resort to accountability politics, gaining moral leverage to pressure governments and international organisations previously committed to upholding such rights.²⁰

In many respects, the reframing strategies of NGOs in the access to medicines campaign mimicked and acted as a counterweight to the framing that corporate activists had employed to such great effect when linking intellectual property to trade in the run-up to that agreement.²¹ In the run-up to the TRIPS Agreement, corporate interests had portrayed intellectual property not only as a critical public policy tool for encouraging disclosure of inventions and encouraging investment in research and development (R&D), but also as an inalienable private property right. Corporate interests had also equated copying with "piracy" and "theft", even when this practice was entirely legal.²²

¹⁹ James Orbinski, An Imperfect Offering: Dispatches from the Medical Frontline (London: Rider Books, 2008), p.373.

²⁰ de Mello e Souza, The Power of the Weak (2005), p.159; Mark F. Schultz and David B. Walker, "The New International Intellectual Property Agenda" in Are Intellectual Property Rights Human Rights? (Washington: The Federalist Society for Law and Public Policy Studies, 2006), p.8. ²¹ Duncan Matthews, Globalising Intellectual Property Rights: The TRIPs Agreement (London: Routledge, 2002), p.21; de Mello e Souza, The

International Political Economy 467, 485; Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (The Hague: Kluwer Law International, 2001), p.2, quoted in de Mello e Souza, The Power of the Weak (2005), p.8.

¹⁵ Duncan Matthews, "The WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?" (2004) 7 *Journal of International Economic Law* 73, 73.

¹⁶ See also André de Mello e Souza, *The Power of the Weak: Advocacy Networks, Ideational Change and the Global Politics of Pharmaceutical Patent Rights*, unpublished doctoral thesis (Stanford University, 2005), p.25.

¹⁷ de Mello e Souza, *The Power of the Weak* (2005), p.28.

¹⁸ de Mello e Souza, *The Power of the Weak* (2005), p.10.

Power of the Weak (2005), p.25. ²²Susan K. Sell and Christopher May, "Moments in Law: Contestation and Settlement in the History of Intellectual Property" (2001) 8 Review of https://doi.org/10.1016/j.1016-1.0016-10016-100-1.0016-1.0016-1.0016-1.0016-1.0016-1.0016-1.0016-1.0016-

By replicating the strategies adopted by corporate interests in negotiation of the TRIPS Agreement, the reframing strategies of NGOs weakened the public sense of legitimacy about the achievements of the TRIPS Agreement, especially in the HIV/AIDS context.²³ While, in the 1980s, TRIPS advocates had framed the agreement as an alternative to tolerating piracy of private property, the access to medicines campaign compared TRIPS to a different reference point-saving the lives of poor people suffering from HIV/AIDS.24

The framing strategy also facilitated contestation, with the traditional model of patents as a driver for new drug development challenged by reframing the debate using the language of "human rights" and "the right to health" as a threat to public health and access to medicines. Through the mobilisation of moral outrage, that strategy also helped to generate a widespread sense that the TRIPS Agreement in its current form could not be justified.²⁵

NGOs were able to raise awareness that access to medicines was a trade issue, mobilising the press in developed countries and bringing the issue to the attention of the public as a means of pressurising politicians in these countries.²⁶ In part this task was made easier by developed country guilt about the post-colonial legacy, particularly in sub-Saharan Africa.

By raising awareness about the link between access to medicines and intellectual property rights issues to an extent hitherto not acknowledged, NGOs created pressure on governments in both the developed and developing worlds that counterbalanced the role played by industry, opening up the debate on intellectual property rights and development policy. This helped facilitate a more open discussion on the impact of the TRIPS Agreement on public health and access to medicines.

In addition to the international access to medicines campaign, NGOs in a number of prominent developing countries have gone much further than framing the discourse on intellectual property rights in terms of the language of human rights. In large, middle-income developing countries such as South Africa, Brazil and India, NGOs have actually used human rights law in substantive terms hitherto not considered by those emphasising framing strategies. NGOs in these countries have used rights enshrined in national constitutions before national courts as tools with which to challenge the scope and application of intellectual property law in a very real and tangible way.

Framing intellectual property rights and access to medicines as a human rights issue in South Africa

AIDS is the leading cause of mortality in South Africa. In 2001, approximately 200,000 people were dying of AIDS or AIDS-related illness each year.²⁷ By 2008 there were an estimated 5.7 million adults living with HIV/AIDS in South Africa, about 18 per cent of all people between the ages of 15 and 49.28

The wider socio-economic costs of HIV/AIDS for South Africa have also had catastrophic implications. HIV/AIDS leads to a loss of household income due to illness or death of a household member and time spent on caring. In economic terms, it is the poor who are the worst affected by HIV/AIDS since, in situations of minimal income, these additional costs cannot be absorbed easily by the family and thus

²³ Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights (Cambridge: Cambridge University Press, 2003), p.182.

²⁴ Odell and Sell, "Reframing the Issue" in Odell (ed.), Negotiating Trade, p.93

²⁵ Lang, "The Role of the Human Rights Movement in Trade Policy-Making" (2007) 5 New Zealand Journal of Public and International Law 147,

^{147. &}lt;sup>26</sup> Daniel W. Drezner, *Gauging the Power of Global Civil Society: Intellectual Property and Public Health* (2005), p.15, available at http://danieldrezner .com/research/gauginggcs.pdf [Accessed November 18, 2011].

Jacqui Boulle and Tenu Avafia, Treatment Action Campaign (TAC) Evaluation (2005), p.14, available at http://www.tac.org.za/Documents //FinalTACEvaluation-AfaviaAndBoulle-20050701.pdf [Accessed November 18, 2011]. ²⁸ UNAIDS, Report on the Global AIDS Epidemic (Geneva: 2008).

result in increasing poverty and deteriorating food security.²⁹ It is often women who bear the increased responsibilities of caring for ill household members and for orphaned children, in addition to their other domestic and economic responsibilities.³⁰

The socio-economic costs of HIV/AIDS are exacerbated by AIDS denialism, social stigmatisation, fear of violence and other social realities such as exclusion. Despite the horrendous loss of human life and the socio-economic costs of HIV/AIDS for South Africa, the government's response to the HIV/AIDS crisis was initially controversially slow. South African President Thabo Mbeki, for instance, questioned whether AIDS was caused by HIV and said that it was not certain that ARV drugs were safe and effective. He denied knowing anyone who had died of AIDS, despite so many South Africans succumbing to the virus. This institutional AIDS denialism had terrible implications for the provision of ARVs for people living with HIV/AIDS in South Africa.³¹

The focus for NGO activism to challenge the government's inaction came on December 10, 1998—Human Rights Day—when a group of about 15 people protested on the steps of St George's Cathedral in Cape Town, demanding ARVs for people living with HIV/AIDS.³² By the end of the day a new NGO, the Treatment Action Campaign (TAC), had been created, and over 1,000 people had signed up as supporters.

TAC's formation was grounded in a distinctly post-apartheid period of South Africa's history when human rights issues were particularly to the fore and, by linking the right to health to human rights principles, TAC shared historical continuities with the late 1980s and early 1990s anti-apartheid and gay rights activism. The objectives of TAC were set out in cl.4 of its constitution. These included campaigning for equitable access to affordable treatment for all people with HIV/AIDS and challenging, by means of litigation, lobbying, advocacy, and all forms of legitimate social mobilisation, any barrier or obstacle that limits access to treatment for HIV/AIDS.³³ To achieve these objectives, TAC's campaigns framed access to ARVs for people living with HIV/AIDS as a human right,³⁴ using to great effect the language and principles of human rights enshrined in the South African Constitution.

TAC's strategy of utilising the human rights principles enshrined in South Africa's constitution³⁵ and framing issues in the language of human rights and constitutional obligations³⁶ is consistent with the personal experiences of Zackie Achmat, its chairperson. Achmat was active in the United Democratic Front (UDF) during the later apartheid years in South Africa and used non-violent methods of political activism that included strikes and demonstrations. While never ceding the legitimacy of the apartheid government, UDF activists used human rights law to challenge every aspect of racist and arbitrary rule.³⁷ Informed by experience, TAC has developed its human rights approach from an initial framing of the issues to litigation based on human rights principles enshrined in the South African Constitution, working closely with lawyers based in the Law and Treatment Access Unit of the AIDS Law Project (ALP) to achieve its objectives.

²⁹ Boulle and Avafia, Treatment Action Campaign (TAC) Evaluation (2005), p.14.

³⁰Swedish International Development Cooperation Agency, AIDS: The Challenge of This Century—Prevention, Care and Impact Mitigation (2001).
³¹While other large developing countries like Brazil had begun offering large-scale public health treatment programmes as early as the 1990s, the South African cabinet only announced a national treatment plan in 2003 after years of ever-increasing mortality rates and NGO activism.

³² Boulle and Avafia, Treatment Action Campaign (TAC) Evaluation (2005), p.15.

³³Constitution of the Treatment Action Campaign, available at http://www.tac.org.za/Documents/Constitution/Constitution13Dec04.PDF [Accessed November 18, 2011]. See also Pieter Fourie, The Political Management of HIV and AIDS in South Africa: One Burden Too Many? (New York: Palgrave Macmillan, 2006), p.130.

³⁴ Boulle and Avafia, *Treatment Action Campaign (TAC) Evaluation* (2005), p.23; Debora J. Halbert, *Resisting Intellectual Property* (New York: Routledge, 2005), p.108; Mandisa Mbali, *The Treatment Action Campaign and the History of Rights-Based, Patient-Driven HIV/AIDS Activism in South Africa*, Research Report No.29 (University of Kwazulu-Natal Centre for Civil Society, 2005), p.2, available at *http://www.ukzn.ac.za/ccs/files /RReport_29.pdf* [Accessed November 17, 2011].

³⁵ See also Alex de Waal, AIDS and Power: Why There Is No Political Crisis—Yet (London: Zed Books, 2006), p.36.

³⁶ Fourie, The Political Management of HIV and AIDS in South Africa (2006), p.163.

³⁷ de Waal, *AIDS and Power* (2006), p.36.

As with TAC, the ALP's human rights approach grew out the experiences of the anti-apartheid struggle. Mark Heywood, the project head of the ALP for example, was involved in the anti-apartheid movement for a decade and was also a member of the UDF. Originally based at the University of Witwatersrand in Johannesburg, the ALP believes that the progressive realisation of a set of human rights principles is fundamental to achieving sustainable progress in tackling the HIV/AIDS pandemic. It uses a variety of legal approaches to put these human rights principles into practice in order to protect, promote and advance the rights of people living with HIV/AIDS, and to change the socio-economic and other conditions that lead to the spread of HIV/AIDS and its disproportionate impact on the poor.³⁸

The most effective ARV for the prevention of mother-to-child-transmission (MTCT) of HIV is nevirapine, the patent for which is owned by the German pharmaceutical company Boehringer Ingelheim (BI).³⁹ In 2001 BI had offered to donate nevirapine to South Africa at no cost. The South African government had nonetheless declined this offer and refused to adopt a full-scale nevirapine treatment program for HIV-infected pregnant women on the grounds that the ARV's efficacy and side-effects had not been adequately studied by the government's pilot programs. The Ministry of Health also contended that treatment would not prevent infected mothers from transmitting the virus through breast feeding and that it did not have sufficient resources to provide the counselling and monitoring required by treatment programs.⁴⁰

As a result, in July 2002, TAC brought a legal action before the Pretoria High Court in *Minister of Health v. Treatment Action Campaign.*⁴¹ The complaint concerned the refusal of the South African government to make nevirapine available in the public health sector and not setting out a timeframe for a national programme to prevent MTCT of HIV.

The applicants (TAC, Dr Haroon Saloojee and the Children's Rights Centre, together with the Institute for Democracy in South Africa, first amicus curiae, the Community Law Centre, second amicus curiae, and the Cotlands Baby Sanctuary, third amicus curiae) contended that restrictions on the availability of nevirapine were unreasonable when measured against the human rights principles of the South African Constitution. The Constitution commands the state and all its organs to give effect to the rights guaranteed in the Bill of Rights, in particular ss.27(1), 27(2) and 28(1).⁴²

Finding in favour of the applicants, the South African Constitutional Court held that ss.27(1) and (2) of the Constitution require the government to devise and implement within its available resources a comprehensive and co-ordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat MTCT of HIV. The Court also confirmed that the State is obliged to ensure that children are accorded the protection contemplated by s.28(1)(c) of the Constitution. The South African government was ordered to remove the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of MTCT of HIV without delay.

By seeking recourse to the human rights principles enshrined in the South African Constitution, TAC and its allies had succeeded not only in improving access to nevirapine but also in creating an alternative moral framework for understanding the relationship between patent, access to medicines and human life. This changed the discourse not only in South Africa but on patents and access to medicines internationally. The rights of people living with HIV/AIDS to have access to ARVs came to be more widely seen as an inalienable human right distinct from the temporary property right associated with intellectual property.

³⁸ AIDS Law Project, 18-Month Review: January 2006 to June 2007 (Johannesburg and Cape Town: AIDS Law Project, 2007), p.4, available at http://www.alp.org.za/pdf/Publications/ALP%20Annual%20Reviews/ALP_2006-2007_Review.pdf [Accessed November 18, 2011].
³⁹ Nevirapine is a non-nucleoside reverse transcriptase inhibitor for use against mother-to-child transmission of HIV which has been shown to reduce

²⁵ Nevirapine is a non-nucleoside reverse transcriptase inhibitor for use against mother-to-child transmission of HIV which has been shown to reduce MTCT of HIV in approximately 50 per cent of cases.
⁴⁰ de Mello e Souza, *The Power of the Weak* (2005), p.247.

⁴¹ Case CCT 8/02, Constitutional Court of South Africa, July 5, 2002, 10 BCLR 1033 CC, available at http://www.saflii.org/za/cases/ZACC/2002

^{/15.}html [Accessed November 18, 2011].
⁴² Constitution of the Republic of South Africa, 1996, available at http://www.info.gov.za/documents/constitution/1996/a108-96.pdf [Accessed November 18, 2011].

Thus, the debate over the implications of intellectual property rights for access to medicines were no longer simply framed in terms of the prevention of piracy and counterfeiting and the benefits of the patent system as a stimulus for innovation, but were also about balancing that system with the fundamental human rights to life and to health care.

Framing intellectual property rights and access to medicines as a human rights issue in Brazil

The recent history of democratic struggle in Brazil, which culminated in the end of military rule in 1985, had significant implications in terms of how NGOs have embraced and utilised principles of human rights in articulating their concerns. When military dictatorship came to an end in Brazil in the 1980s, there followed a profound period of national self-reflection. Public policy objectives were gradually restructured around a new social agenda for the country. This social agenda was underpinned by a new democratic constitution, firmly grounded in human rights principles that should be upheld at all costs to avoid a repeat of abuses experienced during the era of military dictatorship.

This belief in the primacy of human rights, particularly the right to health enshrined in the Brazilian Constitution, impacted subsequently on the decision of NGOs to mobilise in support of the Brazilian government in its attempts to achieve a balance between the patents for pharmaceutical products and the right to health through the compulsory licensing provisions of federal law. Those provisions were subject to a US complaint to the WTO and in turn led to sustained and detailed engagement with issues relating to patents, public health and access to medicines on the part of the Brazilian NGO community.

The period from 1985 to 1989 saw a rapid growth in the number of NGOs in Brazil acting for and on behalf of people living with HIV/AIDS. In particular, these NGOs made explicit the link between the protection provision of ARVs and the fundamental human rights of people living with HIV/AIDS. This link had profound resonance in a Brazilian society still recovering from the painful legacy of 21 years of military rule.

Articulate and well-educated people living within the gay community took the lead in these NGOs, advocating that the government make the provision of ARVs for people living with HIV/AIDS a priority.⁴³ Prominent amongst these new NGOs was Grupo de Apoio à Prevenção à AIDS (GAPA—AIDS Prevention Action Group), founded in Sño Paulo in 1985, the Associação Brasileira Interdisciplinar de AIDS (ABIA—Brazilian Interdisciplinary AIDS Association) and Grupo pela Valorização, Integridade e Dignidade do Doente de AIDS (Grupo pela VIDDA—Group for Life), founded in Rio de Janeiro in May 1989. This was followed, in 1995, by the founding of the Brazilian Network of People Living with HIV-AIDS (RNP+), which today has a membership in excess of 2,500 people. In total there are now more than 600 different NGOs working on issues related to HIV/AIDS in Brazil under the umbrella of the State Forum of AIDS NGOs.⁴⁴

These Brazilian NGOs are responsible for a number of significant initiatives that advocate improved access to ARVs. In the early 1990s, for instance, the Grupo pela VIDDA and GAPA sued the federal and state governments to assure access to medication for HIV/AIDS patients in hospitals.⁴⁵

A key strategy of the NGOs campaigning for improved access to ARVs in Brazil was art.196 of the 1988 Constituição da República Federativa do Brasil (Constitution of the Federal Republic of Brazil) which enshrined the right to health in federal law. Article 196 provides:

⁴³ Shawn Smallman, The AIDS Pandemic in Latin America (Chapel Hill: The University of North Carolina Press, 2007), p.80.

⁴⁴ Ezio Távora dos Santos Filho, "Real Challenges for Real Actors: The Role of Advocacy and Activism in the Fight Against AIDS in Brazil" [2000] Sexual Health Exchange, Issue 4, available at http://www.kit.nl/ils/exchange_content/html/2000_4_real_challenges_asp? [Accessed November 18, 2011]

^{2011].} ⁴⁵ Távora dos Santos Filho, "Real Challenges for Real Actors", [2000] Sexual Health Exchange, Issue 4, available at http://www.kit.nl/ils/exchange content/html/2000 4 real challenges asp? [Accessed November 18, 2011].

"Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery."

Using strategies that had worked to such good effect in opposition to the previous military regime, these HIV/AIDS NGOs began to use human rights principles to frame the health policy on the right to health care as a right for all.⁴⁶ The right to health enshrined in art.196 of the Brazilian Constitution quickly became the focus of attention for NGOs representing people living with HIV/AIDS seeking to articulate the universal right of access to ARVs.

To fulfil the constitutional right under art.196, the Sistema Único de Saúde (SUS-Unique Health System) was set up to provide healthcare to approximately 123 million Brazilians (74 per cent of the total population) who cannot afford private health care plans.⁴⁷ SUS is regulated by Laws 8.080/90 and 8.142/90. These laws also established the three founding principles of the SUS.⁴⁸ First, it should be universal, meaning that no citizen could be excluded from SUS coverage. Secondly, it should be characterised by equality of access with no discrimination regarding the public health services and products provided to users. Thirdly, it should provide full health care coverage, from the most basic to the most complex health care needs.

These three principles of universality, equality and integrated health care define the Brazilian state's promotion of health as a fundamental social right. Although the Brazilian constitution does not mention specifically access to medicines as part of the right to health, it is generally acknowledged that the right to access to medicines is derived from this implementing legislation.⁴⁹ Specifically, art.6(I)(d) of Law 8.080/90 provides that SUS "must be responsible for promoting full medical assistance, which includes pharmaceutical assistance".

In line with this obligation, in 1990 the federal government began free delivery of azidothymidine (AZT), one of the first ARVs, to the citizens of Brazil. Initially, the Brazilian federal government purchased AZT from Burroughs-Wellcome Company (now GlaxoSmithKline), the multinational pharmaceutical company that had undertaken research and development work and had subsequently been granted patents on the drug.

As the number of people living with HIV/AIDS increased and demands for treatment became more pressing, the federal government struggled to provide free ARV treatment to its citizens. The high prices of patented pharmaceutical products then started to come to the fore. Given the costs associated with purchasing large consignments of these patented pharmaceutical products at the market price, in 1993 the federal government began to purchase ARVs manufactured by Brazilian pharmaceutical companies which produced cheaper, equally effective, generic versions of AZT and other patented medicines.

'e.g. Monica Steffen Guise Rosina, Daniel Wang and Thana Cristina de Campos, "Access to Medicines: Pharmaceutical Patents and the Right to Health" in Lea Shaver (ed.) Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development (New Haven: Information Society Project, Yale Law School, 2008), p.170.

⁴⁶ See also Jane Galvão, "Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health" (2005) 95 American Journal of Public Health 1110, 1112. ⁴⁷ Jillian Clare Cohen and Kristiana M. Lybecker, "AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health" (2005)

²⁸ World Economy 211, 216.

The delivery of public health services is shared equally by the different levels of government: federal, state, municipal and the national health system (Sistema Único da Saúde-SUS). In practice, the delivery and management of health services is increasingly being decentralised to the state and municipal levels, reflecting the government's sensitivity to the population's preference for more local governance. The federal level of government defines the policies and regulations, grants technical and financial support for the states and municipal governments and provides some service delivery. These governments in turn contribute the remainder of the health budget and share responsibility for health service delivery. Cohen and Lybecker "AIDS Policy and Pharmaceutical Patents" (2005) 28 World Economy 211, 214.

By November 1996, this policy of universal access to ARVs at no cost to patients had become a legislative right for all Brazilian citizens as a result of Federal Law 9.313/96. This guaranteed that the SUS had a federal responsibility to provide ARV treatment to all Brazilian citizens and made it mandatory for the SUS to provide ARV treatment to all citizens living with HIV/AIDS.⁵⁰ As a result, Brazil became one of the few countries in the world with a policy of universal free access to ARV treatment.

While 1996 saw the adoption of Federal Law 9.313/96 and marked the beginning of a policy of universal access to ARVs in Brazil, it also marked the point at which awareness grew about the relationship between intellectual property rights, public health and access to medicines. This occurred with the adoption of Industrial Property Law 9.279/96, which introduced patent protection for an area of technology—pharmaceutical products—not previously patentable in Brazil.

Until May 15, 1997, when Law 9.279/96 came into force, Brazilian pharmaceutical manufacturers were permitted to legally reverse-engineer and manufacture cheaper, generic versions of pharmaceutical products that were subject to patent protection elsewhere in the world. This practice was permitted prior to 1997 under previous legislation, Industrial Property Law 5.772/71 which came into force on December 21, 1971. As a result, during the 1970s, many private firms, such as Aché, Farmasa, Libbs, Sintofarma and public sector manufacturers, such as Fiocruz in Rio de Janeiro and FURP in São Paulo, were able to supply generic pharmaceutical products in this way.⁵¹

In the pre-TRIPS era, this was permissible under international law because countries were not required to grant patents to all areas of technology, such as pharmaceuticals. This changed with art.27.1 of the TRIPS Agreement which required all WTO Members, after the expiration of transitional periods, to make available patents in all fields of technology (including pharmaceutical products).

Only a year after the TRIPS Agreement had come into force and well in advance of the applicable transitional period coming to an end, Law 9.279/96 was introduced in Brazil to provide for the protection of pharmaceutical products by patent law.⁵² In fact, the legislation was introduced despite concerns that patent protection for pharmaceutical products would increase the financial burden on the SUS, given its obligation to purchase ARVs and provide these drugs free of charge to all citizens living with HIV/AIDS. Nevertheless, Law 9.279/96 also sought to achieve a balance between the patents accorded to pharmaceutical products and the right to health, in particular the need to ensure the adequate provision of ARVs to people living with HIV/AIDS in Brazil.

The mechanism used to achieve this balance was compulsory licensing. Law 9.279/96 allowed the government to issue a compulsory licence where a patent holder exercises patent rights in an abusive manner, or by means of an abuse of economic power proven by an administrative or court decision. Other instances were also specified where compulsory licences may be issued, particularly under arts 68 and 71.

Under art.68, the holder of a patent in Brazil was required to "work" the subject matter of a patent, either by producing the patented good in the country, or by allowing the patented process to be used in Brazil. If this requirement was not met within three years of the issuance of the patent, the government could issue a compulsory licence allowing others to utilise the patent against the patent holder's wishes. Article 68 also stated that if a patent owner chooses to utilise the patent though importation rather than the local working of the patent, then others besides the patent holder would be allowed to import the patented process.

⁵⁰ See also Galvão, "Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health" (2005) 95 American Journal of Public Health 1110, 1112; Rosina, Wang and de Campos, "Access to Medicines: Pharmaceutical Patents and the Right to Health" in Shaver (ed.) Access to Knowledge in Brazil (2008), p.189.

⁵¹Cohen and Lybecker, "AIDS Policy and Pharmaceutical Patents" (2005) 28 World Economy 211, 215.

⁵² See also Rosina, Wang and de Campos, "Access to Medicines" in Shaver (ed.) Access to Knowledge in Brazil (2008), p.183.

Under art.71, compulsory licences could also be issued by the federal government in cases of national emergency or public interest.⁵³ A Presidential Decree on Compulsory Licensing 3.201/99 was subsequently issued in 1999 to define, in art.2, what might constitute such situations of national and public interest in which compulsory licences could be issued for patented products.⁵⁴ Yet despite these legislative developments, in policy terms the relationship between intellectual property rights and access to medicines at that time remained a topic largely unknown to NGOs in Brazil, particularly given the legal complexity of the issues involved.⁵⁵

This changed in 2001 when, faced with the challenge of carrying on its HIV/AIDS programme at a considerably higher cost,⁵⁶ the Brazilian federal government opted to initiate negotiations with a number of the major pharmaceutical companies designed to reduce the price of ARVs. These negotiations were backed by the threat of compulsory licensing, with the possibility of using in particular the procedures mandated by arts 68 and 71 of Law 9.279/96.

Using the threat of compulsory licences as a negotiating tool, by 2001 the Brazilian federal government had been able to agree to substantial price reductions for ARVs with several pharmaceutical manufacturers, including a 64.8 per cent price reduction for indinavir, 59 per cent for efavirenz, 40 per cent for nelfinavir and 46 per cent for lopinavir. In addition, a technology transfer agreement was established between Merck and the Ministry of Health's main national laboratory Farmanguinhos⁵⁷ to enable local working of some of Merck's patented pharmaceutical products.

Then, on January 9, 2001, the United States requested that the WTO Dispute Settlement Body (DSB) establish a panel to resolve its complaint against Brazil in relation to the provisions of Law 9.279/96 that authorise the use of compulsory licences and parallel importation to promote the local working of patents.⁵⁸ In what was widely viewed as a reaction to the Brazilian federal government's interference on the production and pricing of highly profitable ARV drugs patented by or exclusively licensed to US-based pharmaceutical multinationals, the US government then began consultation procedures.

The US complaint focused on art.68 of the 1996 Brazilian Industrial Property Law 9.279/96. The United States complained that art.68 violated the TRIPS Agreement which set out the principle of non-discrimination in the protection of patent rights and the exclusive rights to be enjoyed by patent holders by discriminating against US owners of Brazilian patents whose products are imported into Brazil but not locally produced and curtailing the rights of these owners to utilise the patents.⁵⁹ The United States demanded from Brazil written guarantees that it would not issue compulsory licenses for products patented

⁵³ See also Kenneth Shadlen, "The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies" (2009) 42 *Comparative Politics* 41, 48.

⁵⁴ In 2003 an additional Presidential Decree 4.830/03 further clarified the scope of these situations under art.71. This decree provided clearer definitions of "national emergency" and "public interest" and simplified the mechanism for issuing compulsory licences by giving the Ministry of Health greater authority to act. According to Shadlen, "The Politics of Patents and Drugs in Brazil and Mexico" (2009) 42 *Comparative Politics* 41, 48, Presidential Decree 4.830/03 crucially stipulates that private firms supplying the government constitutes "public use" and is thus acceptable under art.71. The decree also requires patent owners to transfer technological knowledge in the case of compulsory licences, thus increasing the Ministry of Health's capacity to leverage price reductions from patent-holding pharmaceutical firms.

³⁷ James P. Love, "TRIPs, TRIPs+, and New Paradigms: The Role of NGOs in Shaping the Debate", paper prepared for the Chicago-Kent College of Law Conference on "Intellectual Property, Trade and Development: Accommodating and Reconciling Different National Levels of Protection", Chicago, October 12–13, 2006, p.2.

⁵⁸ Brazil—Measures Affecting Patent Protection, Request for the Establishment of a Panel by the United States, January 9, 2001, WT/DS199/3, available at http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=73103 [Accessed November 18, 2011]. See also Press Communiqué by the Government of Brazil, June 25, 2001, available at http://www.cptech.org/ip/health/c/brazil/brazilstatement06252001.html [Accessed November 18, 2011]. In this press communiqué, Brazil maintained its conviction that art.68 is fully consistent with the TRIPS Agreement and an important instrument available to the Government, in particular in its efforts to increase access of the population to medicines and to combat diseases such as AIDS.

⁵⁹ WTO Reporter, "United States Drops WTO Case against Brazil Over HIV/AIDS Patent Law", June 26, 2001, available at http://www.cptech.org /ip/health/c/brazil/bna06262001.html [Accessed November 18, 2011].

⁵⁵ A notable exception was the statement made by the then Minister of Health the previous year. Statement of José Serra, Minister of Health, to the 2001 USTR Special 301 Report, May 3, 2001, available at *http://www.cptech.org/ip/health/c/brazil/serra05032001.html* [Accessed November 18, 2011].

^{2011].} ⁵⁶ The Ministry of Health's budget for purchasing antiretroviral drugs in 2007 was BRL 984 million. Authoritative estimates demonstrate that 80% of this money is used to acquire patented medicines and 20% is spent on generic drugs that are manufactured domestically by Brazilian companies. The fact that such a huge portion of the budget is being spent on patented medicines has put the sustainability and universality of this healthcare policy in jeopardy.

or exclusively licensed to US companies. Following the refusal of the Brazilian government to meet these demands, the United States requested the establishment of a WTO panel against Brazil, on February 1, 2001. The DSB then established a WTO dispute settlement panel to report on this matter on May 30, 2001.⁶⁰

For HIV/AIDS NGOs in Brazil, the US complaint was a catalyst that focused attention on the fact that intellectual property rights can act as a barrier to access to medicines, particularly for people living with HIV/AIDS in developing countries.⁶¹ Brazilian NGOs such as GIV and ABIA articulated their opposition to the US complaint by using the language of human rights and the right to health enshrined in art.196 of the Brazilian Constitution to claim that the complaint by the United States to the WTO had the potential to infringe the human rights of people living with HIV/AIDS. In recognition of the fact that the Brazilian HIV/AIDS programme had been a success and should be protected, HIV/AIDS NGOs in Brazil were quick to support their federal government. On March 7, 2001, these NGOs began to demonstrate against the United States outside the US Embassy in São Paulo.

This was the first time that the relationship between intellectual property rights and access to medicines had been discussed openly by NGOs in Brazil, and the timing of this meeting was significant. Faced with the need to respond to the US complaint against Brazil at the WTO, Brazilian HIV/AIDS NGOs began to act. Driven by the objective of protecting human rights, they began to collaborate with their international counterparts, particularly Mèdecins Sans Frontiéres (MSF) and Oxfam, on the implications of the TRIPS Agreement for public health and access to medicines.

Academic experts brought in by international NGOs were able to highlight the fact that s. 204 and s.209 of Title 35 of the US Patent Code, which specified local manufacturing of publicly-financed patented products and products patented by the US government, were remarkably similar to those on which the United States had challenged Brazil at the WTO.⁶² The United States countered this by arguing that, whereas the aforementioned articles of its Patent Act referred to contractual terms for publicly-financed projects, art.68 of Brazil's Law 9.279/96 was a blank requirement applicable to all patented goods, regardless of their origin. Nevertheless, international NGOs and the academic experts associated with them had provided crucial information on the US Patent Code and had also brought pressure to bear on the United States by means of protests with ample media coverage.

On June 25, 2001, in the face of enormous negative publicity from international and Brazilian NGOs and legal arguments about the similarity between s.204 and s.209 of Title 35 of the US Patent Code and art.68 of Brazilian Law 9.279/96, the United States withdrew the complaint. It did so after receiving assurances that it would be notified before any products patented by or exclusively licensed to US companies were subject to compulsory licensing in Brazil.⁶³ Brazil and the United States also agreed that, before using the disputed provision in art.68 of Brazilian Law 9.279/96 against a US patent holder, a "consultative mechanism" would be initiated in an attempt to resolve the matter bilaterally.⁶⁴

⁶³ de Mello e Souza, The Power of the Weak (2005), p.203.

⁶⁴ Brazil—Measures Affecting Patent Protection. Notification of Mutually Agreed Solution, July 19, 2001, WT/DS199/4, G/L/454, IP/D/23/Add.1. See also Joint US-Brazil Statement, 25 June 2001, available at http://www.cptech.org/ip/health/c/brazil/statement06252001.html [Accessed November 18, 2011]. See also Deere, The Implementation Game (2008), p.166.

⁶⁰ de Mello e Souza, *The Power of the Weak* (2005), p.201.

⁶¹ J. Beloqui, interview with the author, March 19, 2006.

⁶²35 USC s.204(2006), titled "Preference for United States industry", states: "Notwithstanding any other provision of this chapter, no small business firm or nonprofit organisation which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organisation, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licenses that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible."

Alongside the technical inputs from academic experts brought on board by international NGOs, Brazilian NGOs proved adept at framing the dispute in terms of the human rights of people living with HIV/AIDS who would be adversely affected by the continued use of patents for pharmaceutical products in Brazil. With public perception that the human rights of people living with HIV/AIDS in Brazil would be undermined by the US complaint to the WTO, the US WTO case against Brazil looked increasingly unsavoury.⁶⁵

In June 2001 the United States announced that it was officially withdrawing its case against Brazil on the first day of the first United Nations Special Session devoted to a public health issue. The session, whose context was HIV/AIDS, culminated in "The Declaration of Commitment" on HIV/AIDS on June 27, 2001. The Declaration framed the issue in terms of access to medicines and human rights to explain why it was of such crucial significance.⁶⁶ The United States and Brazil subsequently notified the WTO DSB that a mutual agreed understanding had been reached to settle the dispute. In effect, however, the United States had stepped back from further confrontation on this issue, subject to a bilateral understanding to the effect that, should Brazil seek to issue a compulsory licence on grounds of failure to work the patent locally, it would consult the United States before doing so.⁶⁷

The continued existence of the safeguard provisions on compulsory licences in arts 68 and 71 of Law 9.279/96 in Brazil has been described by the Report of the UN High Commissioner on the impact of the TRIPS Agreement as helpful in improving the implementation of the country's HIV/AIDS treatment programme.⁶⁸ Moreover, while no compulsory licence was actually issued under Brazilian Law 9.279/96 until 2007, the provisions were nevertheless instrumental in negotiating lower prices with the owners of patents on pharmaceutical products.⁶⁹ The Report of the High Commissioner concluded:

"[O]n the facts that have been provided by the Government of Brazil, it is possible to say that the Brazilian case demonstrates how the provisions of the TRIPS Agreement can be implemented in ways that respect, protect and fulfil the right to health. Through careful legislative implementation of TRIPS provisions ... the Brazilian IP law supports the implementation of national health policy aimed at providing essential drugs to those who need them."⁷⁰

Framing intellectual property rights and access to medicines as a human rights issue in India

Human rights have also played an important role in defining the way that Indian NGOs have engaged with the impact of intellectual property rights on access to medicines. When India's struggle for independence from British colonial rule ended in 1947, human rights and in particular the right to life

⁷⁰ Sub-Commission on the Promotion & Protection of Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 2001, para.58.

⁶⁵ Sell, Private Power, Public Law (2003), p.158.

⁶⁶ Ultimately, however, Oxfam retained its distance from the core group. ActionAid subsequently withdrew from access to medicines issues in Brazil altogether in a move described by some Brazilian HIV/AIDS activists as "pitiful": Sell, *Private Power*; *Public Law* (2003), p.158; de Mello e Souza, *The Power of the Weak* (2005), p.214.

⁶⁷C. Raghavan, US to Withdraw TRIPs Dispute against Brazil, South-North Development Monitor, available at http://www.twnside.org.sg/title /withdraw.htm [Accessed November 18, 2011].

⁶⁸ Sub-Commission on the Promotion & Protection of Human Rights, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights: Report of the High Commissioner, June 27, 2001, E/CN.4/Sub.2/2001/13, para.56.

⁶⁹ On May 4, 2007, Brazil finally issued a compulsory licence for the ARV efavirenz after failing to reach an agreement with the patent owner, Merck, to lower prices of the drug. Announcing the compulsory licence, the Ministry of Health said that the action would reduce the cost of purchasing efavirenz, currently used by 75,000 of the 180,000 people living with HIV/AIDS in Brazil, by up to US\$240 million between 2007 and 2012, when Merck's patent expires. Meanwhile President Luiz Inácio Lula da Silva, signing the decree granting the compulsory licence, said "between our business and our health, we are going to take care of our health": "Brazil Issues Compulsory Licence for AIDS Drug", *Bridges Weekly Trade Digest*, May 9, 2007. In other instances, the Brazilian government has opted for voluntary agreements with multinational pharmaceutical companies. On May 9, 2006, for instance, Minister of Health Agenor Álvares and the Vice-President of Gilead Science, Joseph Steele, signed an agreement that resulted in a 51% price reduction of the ARV drug tenofovir. The price of each capsule consequently reduced from US\$7.68 to US\$3.80, representing an immediate saving to the Brazilian National STD and AIDS Programme of US\$31.4 million per annum: "Brazilian deal on tenovofir", translation of Ministry of Health press release of May 9, 2006, posted on IP-Health list server by Michel Lotrowska, MSF, May 16, 2006.

enshrined in the Indian Constitution formed the basis of the report on the future of the patent system prepared by the Committee on the Revision of the Patents Laws (1957–1959), known as the Ayyangar Committee. The Committee looked more specifically at poverty issues, noted the high mortality rates in India⁷¹ and recommended that granting patents in critical areas such as food and medicines be curtailed since the high price of patented products could deny Indian citizens access to resources and violate the right to life, enshrined in art.21 of the Constitution of India.⁷² Article 21 specifically provides: "No person shall be deprived of his life or personal liberty except according to procedure established by law." The Committee's reasoning for this recommendation was that the prohibitively high price of patented products could violate the right to life.

Of particular concern to the Ayyangar Committee was the fact that, at that time, foreign pharmaceutical companies supplied almost 85 per cent of medicines in India and, according to the United States Senate Subcommittee on Anti-Trust and Monopoly (the Kefauver Subcommittee), by 1961, prices for pharmaceutical products in India were amongst the highest in the world.⁷³

So, in order to protect the constitutional right to life and promote industrial development in India, the Ayyangar Committee recommended that product patents should not be granted in critical areas such as food and pharmaceutical products.⁷⁴ Instead, patent protection should be limited to the method of making food, pharmaceuticals and chemicals, leaving the final products free from patent protection and consequently allowing local generic drug companies to manufacture without infringing patent rights.⁷⁵ The Ayyangar Committee also recommended that India ensure that patented inventions were worked locally to facilitate industrial development, with the government giving powers to revoke patents or issue compulsory licenses in order to redress instances where foreign patent owners were not working the invention locally.⁷⁶

As a result of the Ayyangar Committee's recommendations, the Patents Act of 1970, which came into force on April 20, 1972, was designed as a response to growing concerns in India about how best to strike a balance between patent rights as incentives to innovate on the one hand and how best to protect the public interest and promote industrial development in India on the other. In line with the Ayyangar Committee's recommendations, s.5 of the Act introduced differential treatment of food, pharmaceutical and chemical inventions by making available patent rights only for the processes of manufacture.⁷⁷ By excluding protection of the end product, several manufacturers could each own patents for different processes of manufacturing the same pharmaceutical products.⁷⁸

The Indian Patents Act of 1970 also limited the term of protection for process patents on food, pharmaceutical and chemical inventions to five years,⁷⁹ with a license of right authorising any person to manufacture a patented product,⁸⁰ notwithstanding the patentee's approval, available for food,

⁷¹ High mortality rates had been identified in India's First Five Year Plan in 1950.

⁷² The Supreme Court has held subsequently in *Bandhua Mukti Morcha v. Union of India* (AIR [1984] SC 802) that the right life in art.21 includes the right to health. The Supreme Court has also made clear in *State of Punjab v. Mohinder Singh Chawla* ([1997] 2 SCC 83) that the Indian government has a constitutional obligation to provide health facilities. It stated in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal* (AIR [1996] SC 2426 at 2429 para.9) that failure to provide a patient timely medical treatment was a violation of the patient's right to life. In State of Punjab v. Ram Lubhaya Bagga ([1998] 4 SCC 117), it stated that there was an obligation on the State to maintain health services. K. Mathharan, "The Fundamental Right to Health Care" (2003) 11 *Indian Journal of Medical Ethics* 4. See also Srividhya Ragavan, "Of the Inequals of the Uruguay Round" (2006) 10 *Marquette Intellectual Property Review* 273.

⁷³ B.K. Keayla, "Amended Patents Act: A Critique" (2005) 4(2) *Combat Law* 2, available at *http://www.indiatogether.org/cgi-bin/tools/pfriend.cgi* [Accessed November 18, 2011].

⁷⁴N. Rajagolala Ayyangar, Report on the Revision of the Patents Law (1959), para.101.

 ⁷⁵ Ragavan, "Of the Inequals of the Uruguay Round" (2006) 10 Marquette Intellectual Property Review 273, 286.
 ⁷⁶ Ragavan, "Of the Inequals of the Uruguay Round" (2006) 10 Marquette Intellectual Property Review 273, 287.

⁷⁷ Sudji Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries* (New Delhi: Oxford University Press, 2005), p.37.

⁷⁸ Dwijen Rangnekar, "No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime", CSGR Working Paper No.176/05 (Warwick: Centre for the Study of Globalisation and Regionalisation, University of Warwick, 2005), p.4; Ragavan, "Of the Inequals of the Uruguay Round" (2006) 10 *Marquette Intellectual Property Review* 273, 289.

⁷⁹ Indian Patents Act 1970, s.53(1)(a).

⁸⁰ Indian Patents Act 1970, s.88.

pharmaceutical or chemical inventions after three years.⁸¹ With the objective of encouraging local manufacturing of inventions, the Indian Patents Act of 1970 also introduced powers for the Comptroller of Patents to issue compulsory licences based on the patent owner's ability to work the invention in India to the public's advantage.⁸²

This system of not granting patents for inventions that related to food, pharmaceutical or chemical products prevailed until the coming into force of the TRIPS Agreement and allowed the Indian pharmaceutical industry to develop considerable expertise in reverse engineering and developing new methods of manufacture in order to become highly efficient producers of generic medicines.

This human rights approach in turn informed the subsequent strategy of NGOs working to ensure that amendments to India's patent legislation utilised to the full extent flexibilities contained in the TRIPS Agreement. In the post-TRIPS implementation period, as other NGOs become involved with patents and access to medicines issues, their approach was once again informed by an underlying concern that the human rights of people living with HIV/AIDS were being abused.

The Indian government did not seek the views of NGOs or other stakeholders before undertaking initial negotiations on the TRIPS Agreement in the late 1980s.⁸³ Nevertheless, a number of well-informed individuals came forward to articulate concern about the increased cost of pharmaceutical products that would result from new international norms requiring patent protection regardless of the products in question.⁸⁴ In particular, the National Working Group on Patent Laws provided the focal point for informed debate in India.⁸⁵

In 1993 the National Working Group on Patent Laws convened the first People's Commission. It consisted of three former judges of the Supreme Court, together with a retired chief justice of the Delhi High Court.⁸⁶ Crucially, the Commission's report made explicit reference to the fact that the impact of the TRIPS Agreement on drug prices and access to medicines in India could conflict with the right to life enshrined in art.21 of the Constitution of India.⁸⁷ Pointing out that the Supreme Court of India had concluded that the right to health, including access to medical treatment, is a fundamental right,⁸⁸ the report argued that the Indian Patents Act 1970 could not be rewritten to allow the grant of patents for pharmaceutical products since this would constitute a violation of art.21 of the Constitution.⁸⁹ So, from the outset, the National Working Group on Patent Laws was adept at framing concerns about the impact of the TRIPS Agreement on access to medicines as a human rights issue.

This led in turn to NGOs originally versed in human rights law to engage to a greater extent with the technical aspects of patent law. They began initiating pre-grant patent oppositions against pharmaceutical product patent applications in a way these groups could not have foreseen when they originally began campaigning on human rights issues associated with HIV/AIDS some years earlier.

⁸⁴ Matthews, Globalising Intellectual Property Rights (2002), p.31.

⁸⁵ Rangnekar, "No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime", CSGR Working Paper No.176/05 (Warwick: Centre for the Study of Globalisation and Regionalisation, University of Warwick, 2005), p.7.

⁸⁶ Justice V.R. Krishna Iyer, Justice O. Chinnappa Reddy, Justice D.A. Desai and Justice Rajinder Sachar.

⁸⁷ V.R. Krishna Iyer, O. Chinnappa Reddy, D.A. Desai and Rajinder Sachar, *People's Commission on the Constitutional Implications of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations* (New Delhi: Centre for Study of Global Trade System and Development, 1996), p.61.

⁸⁸ Vincent v. Union of India, AIR [1987] SC 990.

⁸⁹ Iyer, Reddy, Desai and Sachar, People's Commission on the Constitutional Implications of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (1996), p.62.

⁸¹ Indian Patents Act 1970, s.87(1).

⁸² Indian Patents Act 1970, s.84.

⁸³Keshab Daz, *The Domestic Politics of TRIPS: Pharmaceutical Interests, Public Health, and NGO Influence in India* (Ahmadabad: Gujarat Institute of Development Research, 2003), paper prepared for the Research Project on "Linking the WTO to the Poverty-Reduction Agenda" as part of the DFID-funded Globalisation and Poverty Research Programme.

As NGOs in India began to use human rights to good effect to frame their arguments about the impact of intellectual property rights on access to medicines, this contributed to a policy-making climate in which, since 2006, the Indian government has been markedly more receptive to concerns raised by NGOs on these issues. By framing the issue in terms of human rights, NGOs are of the opinion that their viewpoints are now taken more seriously by the Indian government.

Conclusion

This article has sought to demonstrate that the extent that human rights have been used by NGOs seeking to highlight the adverse impacts of intellectual property rights on access to medicines is far greater than was previously thought.

This human rights-based approach first came to prominence a decade ago when international NGOs began to frame intellectual property-related issues by using the emotive language of human rights to underpin substantive arguments that public health, access to medicines, the right to health and the right to life were at risk due to the patent provisions of the TRIPS Agreement. International NGOs began to campaign for access to medicines through the full utilisation of flexibilities contained in the TRIPS Agreement and framed the issue in terms of human rights. By so doing, the human rights frame ultimately added moral authority to the access to medicines campaign, which in turn contributed to a greater emphasis on the importance of using in-built flexibilities in the TRIPS Agreement and the need to permanently amend the TRIPS Agreement provisions on compulsory licensing.

However, while the strategy of international NGOs in framing the access to medicines campaign as a human rights issue has been recognised widely, rather less attention has been paid to the parallel activities of NGOs that have been using similar human rights-based approaches in developing countries. NGOs representing people living with HIV/AIDS in South Africa, for instance, have used strategies that had worked previously to such good effect during the anti-apartheid struggle and highlighted primacy of human rights principles under the country's constitution. In *Minister of Health v Treatment Action Campaign*, human rights principles enshrined in the South African Constitution were used to overturn the decision of the South African government's refusal to make nevirapine available in the public health sector and to set out a timeframe for a national programme to prevent MTCT of HIV.

Similarly, following the ending of military rule in Brazil, NGO activists used their knowledge of human rights acquired during the struggle for democracy to campaign successfully for universal access to ARVs for people living with HIV/AIDS. This belief in the primacy of human rights, particularly the right to health enshrined in the Brazilian Constitution, impacted subsequently on the decision of NGOs to mobilise in support of the Brazilian government in its attempts to achieve a balance between the patents for pharmaceutical products and the right to health through the compulsory licensing provisions of federal law. Those provisions were subject to a US complaint to the WTO and in turn led to sustained and detailed engagement with issues relating to patents, public health and access to medicines on the part of the Brazilian NGO community.

Human rights have also played an important role in defining the way that Indian NGOs have engaged with the impact of intellectual property rights on the poor, the disadvantaged and vulnerable sectors of society. When India's struggle for independence from British colonial rule ended in 1947, human rights and in particular the right to life enshrined in the Indian Constitution formed the basis of the Ayyangar Committee's recommendation that granting patents in critical areas such as food and medicines be curtailed. The Committee's reasoning for this recommendation was that the prohibitively high price of patented products could violate the right to life. This human rights approach in turn informed the subsequent approach of NGOs working to ensure that amendments to India's patent legislation utilised to the full extent flexibilities contained in the TRIPS Agreement. In the post-TRIPS implementation period, as other NGOs become involved with patents and access to medicines issues, their approach was once again

informed by an underlying concern that the human rights of people living with HIV/AIDS were being abused. This led in turn to NGOs originally versed in human rights law to engage to a greater extent with the technical aspects of patent law, particularly by initiating pre-grant patent opposition proceedings against pharmaceutical product patent applications in a way that they could not have foreseen when they originally began campaigning on human rights issues associated with HIV/AIDS some years earlier.

Over the past decade, therefore, NGOs have played a critical role in reappraising the relationship between intellectual property and access to medicines through the frame of human rights principles in a range of ways that will continue to have profound implications for many years to come.

The Politicisation of Intellectual Property: IP Conflicts and Social Change

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Intellectual property; Politics

In the last 15 years a remarkable string of contentious mobilisations has emerged to challenge the normative and institutional frameworks that regulate how knowledge is produced, appropriated, and used. The mobilisation for access to essential medicines,¹ the conflict about software patents in Europe,² the advent of pirate parties in various European countries,³ the establishment of the Creative Commons project,⁴ the struggles against "biopiracy" (i.e. the private appropriation of traditional (indigenous) knowledge),⁵ the conflicts about file sharing in peer-to-peer networks,⁶ and the coming together of the access to knowledge (A2K) movement⁷ are all examples of mobilisations that question the current regimes governing intellectual property (IP).

In this article I argue that these conflicts are more than contingent phenomena of fluctuating protest patterns. They are rooted in the growing global economic and political importance of immaterial goods. On a more fundamental level, they address a set of new cleavages that originate in the social transformations of the knowledge society.

⁷ Krikorian and Kapczynski (eds), Access to Knowledge in the Age of Intellectual Property (2010).

¹Ellen 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha" (2002) 27 Chicago Journal of International Law 39; Nathan Ford, "Patents, Access to Medicines and the Role of Non-governmental Organisations" (2004) 1 Journal of Generic Medicines 137; Amy Kapczynski, "The Access to Knowledge Mobilisation and the New Politics of Intellectual Property" (2008) 117 Yale Law Journal 804; Susan K. Sell, "TRIPs and the Access to Medicines Campaign" (2002) 20 Wisconsin International Law Journal 481.

² Philippe Aigrain, "An Uncertain Victory: The 2005 Rejection of Software Patents by the European Parliament" in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (New York: Zone Books, 2010); Julian Eckl, "Die Auseinandersetzungen über die EU—'Software patent'—Richtlinie als Testfall für demokratische Beteiligungsmöglichkeiten an der Gestaltung der internationalen politischen Union", October 2005; Thomas R. Eimer, "Zwischen Allmende und Clubgut—Der Einfluss von Free/Open Source Akteuren in der Europäischen Union", available at *http://www.fernuni-hagen.de/imperia/md/content/politikwissenschaft/polis_63_thomas_eimer.pdf* [Accessed November 20, 2011]; Sebastian Haunss and Lars Kohlmorgen, "Lobbying or Politics? Political Claims-making in IP Conflicts" in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property* (Cheltenham: Edward Elgar Publishing, 2009); Sebastian Haunss and Lars Kohlmorgen, "Conflicts about Intellectual Property Claims: The Role and Function of Collective Action Networks" (2010) 17 *Journal of European Public Policy* 242.

³ Henning Bartels, Die Piratenpartei: Entstehung, Forderungen und Perspektiven der Bewegung (Berlin: Contumax, 2009); Christoph Bieber,

[&]quot;Wahlkampf als Onlinespiel? Die Piratenpartei als Innovationsträgerin im Bundestagswahlkampf 2009" in Martin Eifert and Martin Hoffmann-Riehm, Innovation, Recht, öffentliche Kommunikation (Baden-Baden: Nomos, 2011); Marie Demker, "Sailing along New Cleavages", available at http://goo .gl/6jll2 [Accessed May 17, 2011].

⁴ Sharee L. Broussard, "The Copyleft Movement: Creative Commons Licensing" (2007) 26 Communication Research Trends 3; Leonhard Dobusch and Sigrid Quack, "Epistemic Communities and Social Movements: Transnational Dynamics in the Case of Creative Commons", available at http:// /www.mpifg.de/projects/govxborders/downloads/Dobusch_Quack_2008_DP_EpistemicComm.pdf [Accessed October 31, 2011]; Severine Dusollier, "The Master's Tools v. The Master's House: Creative Commons v. Copyright" (2006) 29 Columbia Journal of Law and the Arts 271; Lawrence Lessig, "The Creative Commons" (2003) 55 Florida Law Review 763.

⁵ Arturo Escobar, "Whose Knowledge, Whose Nature? Biodiversity, Conservation, and the Political Ecology of Social Movements" [1998] *Journal of Political Ecology* 53; Sabil Francis, "Who Speaks for the Tribe? The Arogyapacha Case in Kerala" in Haunss and Shadlen (eds), *Politics of Intellectual Property* (2009); Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (Boston: South End Press, 1997); Peter K. Yu, "Cultural Relics, Intellectual Property, and Intangible Heritage" (2008) 81 Temple Law Review 434.

⁶Jan Krömer and Evrim Sen, No Copy—Die Welt der digitalen Raubkopie (Leipzig: Tropen, 2006).

Why now?

The institutions that govern IP are not particularly new. The Berne Convention for the Protection of Literary and Artistic Works that governs copyrights and related rights came into existence in 1886 and was last revised in 1971. The Paris Convention for the Protection of Industrial Property that governs, among others, patents, trademarks, and designs dates back to 1883. Even the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which is often seen as the most important recent change in IP governance, was signed already in 1994. IP rights (IPRs) are obviously not a new political issue. They have been around internationally for more than a century and for much longer periods in national legislation.

These regimes have always been contested to some degree. There was no timeless consensus about the merits of strong IP rights among states, within national administrations, or in the scholarly community. The tension between strong patent rights and anti-trust legislation, for example, led to several shifts in US IP policies in the 20th century. In that period, strong patent right in the beginning were followed by strong anti-trust policies in the name of free competition, which were again followed by a re-evaluation of IPRs in the 1980s in light of the growing economic importance of international trade in immaterial goods.⁸

But these ups and downs in breadth and scope of IPRs have not been accompanied by political mobilisations that involved actors other than the immediate economic stakeholders. Conflicts like the ones mentioned above are relatively new. To understand why IP has become a contentious issue it is necessary to take into account four parallel processes:

- (1) the growing economic importance of knowledge-based industries;
- (2) the growing internationalisation of IP issues, exemplified in the growing number and reach of international treaties and trade agreements that centrally address IP;
- (3) the growing attention IP issues receive in non-specialist and high-level political fora; and
- (4) and the trend to personalise IP rules.

The growing *economic importance* and *internationalisation* of IP has been extensively discussed in the scientific literature.⁹ The growing political importance of IP in non-specialist fora can be gauged by their changing prominence in the G8 summit declarations. In these highly symbolic political documents intellectual property rights are first mentioned in 1996—but only as a minor sub-issue. A decade later, in 2007, they have advanced to a prominent position and are addressed as a major point on fourth position after global growth and stability, financial markets, and freedom of investment, and before climate change, responsibility for raw materials, corruption, and trade.¹⁰ In 2011 they are finally the top issue, when they appear in the G8 declaration prepared by the French presidency even before nuclear safety, climate change, development, and peace.¹¹

Personalisation of IP finally describes the trend that IP laws increasingly affect individual citizens directly. Traditionally IPRs regulated relationships between industrial market actors and were mainly aimed at firms, corporate actors, or at least entrepreneurs. In their core they regulated the industrial production of knowledge and information. Until recently, as James Boyle has aptly noted, for an individual

⁸ Susan K. Sell and Christopher. May, "Moments in Law: Contestation and Settlement in the History of Intellectual Property" [2001] *Review of International Political Economy* 467, 486 ff.

⁹ Kenneth J. Arrow, "Economic Welfare and the Allocation of Resources for Invention" in *The Rate and Direction of Inventive Activity* (Princeton: Princeton University Press, 1962); Peter Drahos, "Information Feudalism in the Information Society" (1995) 11 *The Information Society* 209; Christopher May, *A Global Political Economy of Intellectual Property Rights: The New Enclosure*? (London: Routledge, 2000); Meir P. Pugatch, *The International Political Economy of Intellectual Property Rights* (Cheltenham: Edward Elgar Publishing, 2004); Peter K. Yu, "International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia" [2007] *Michigan State Law Review* 1; Peter K. Yu, "The Global Intellectual Property Order and Its Undetermined Future" [2007] 1 *WIPO Journal* 1.

 ¹⁰ "Heiligendamm Summit: Chair's Summary", available at http://www.g-8.de/Content/EN/Artikel/_g8-summit/anlagen/chairs-summary,templateld
 =raw,property=publicationFile.pdf/chairs-summary.pdf [Accessed October 31, 2011].
 ¹¹ G8 Declaration—Renewed Commitment for Freedom and Democracy, May 26–27, 2011, available at http://www.g20-g8.com/g8-g20/root/bank

¹¹ G8 Declaration—Renewed Commitment for Freedom and Democracy, May 26–27, 2011, available at http://www.g20-g8.com/g8-g20/root/bank/print/1314.htm [Accessed October 31, 2011].

citizen "it used to be relatively hard to violate an intellectual property right".¹² With digitalisation and the proliferation of the internet, this has changed fundamentally so that IP laws now increasingly target individual citizens who do not profit economically from their incriminated activities of file-sharing or from otherwise using or providing IP protected content.

Taken together these macro and micro processes have facilitated the politicisation of IP. Politicisation means that, on the one hand, more and more diverse actors are getting involved in IP issues. Industry, legal specialists, national administrations, patent and trademark offices, and specialist courts are being joined by academics, farmers, indigenous people, consumers, political activists, and NGOs. On the other hand, the range of issues is expanding, and the forms of action are getting more diverse. The issues that are being raised include biopiracy, health, access to medicines, fair use, access to knowledge, and the limits of patentability. Conflicts are carried out in various arenas, ranging from international organisations, national parliaments, and courts to the public sphere, where actors try to influence the policy process by exerting political and economic power, by lobbying and petitioning decision-makers, or by organising street demonstrations, boycotts and other tactics from the repertoire of contentious politics.

This politicisation of IP is embedded in more wide-ranging processes of social change associated with the transformation of industrial societies into knowledge societies. The current conflicts about IPRs are harbingers of a new class of conflicts addressing new cleavages. They reveal a number of underlying conflict lines specific to the type of society that authors have variously labelled information society, network society,¹⁴ post-industrial society,¹⁵ knowledge society,¹⁶ risk society¹⁷ or programmed society.¹⁸

In the recent IP conflicts mentioned above, new collective actors emerge to challenge the current order of the knowledge society and to establish an alternative version of a knowledge society based on democratised access to knowledge and far-reaching limits to the propertisation of ideas, knowledge and cultural goods. In the remainder of this article I will briefly discuss the four most important mobilisations-important in terms of mobilisation strength or the number of involved actors. I will then show which new cleavages of the knowledge society are addressed in them.

Conflict constellations

The conflict about software patents in Europe, the worldwide mobilisation about access to medicines, the creation of pirate parties, and the establishment of Creative Commons are the largest, most visible, and thus most important contentious mobilisations around IP issues in the last two decades.

The conflict about software patents in Europe turned out to be one of the most conflictual issues that the European Parliament has seen so far.¹⁹ From its beginning in 1997 to its end in 2005, more and more actors became involved in a conflictual mobilisation that brought the former specialist issue into the TV evening news. The conflict started in June 1997 when the European Commission published a Green Paper on the Community patent and the patent system in Europe.²⁰ It ended eight years later on June 6, 2005

¹² James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain" (2003) 66(1-2) Law and Contemporary Problems 40.
 ¹³ David Lyon, *The Information Society: Issues and Illusions* (Worcester: Polity Press, 1988).

¹⁴ Manuel Castells, "Materials for an Exploratory Theory of the Network Society" (2000) 51 *British Journal of Sociology* 5.

¹⁵ Daniel Bell, The Coming of Post-industrial Society: A Venture in Social Forecasting (New York: Basic Books, 1999).

¹⁶Nico Stehr, Knowledge Societies (London: Sage, 1994).

¹⁷ Ulrich Beck, *Risikogesellschaft: Auf dem Weg in eine andere Moderne* (Frankfurt: Suhrkamp, 1986).

¹⁸ Alain Touraine, *Die postindustrielle Gesellschaft* (Frankfurt: Suhrkamp, 1972). In this article I will use the term "knowledge society" because it is the most generic term, capturing the central element that distinguishes these societies from earlier forms. The social and economic structures of these societies are organised around the creation, valorisation and use of knowledge.

Taken from the author's interview with Michel Rocard in Strasbourg, January 17, 2007.

²⁰ Commission of the European Communities, Promoting Innovation Through Patents: Green Paper on the Community Patent and the Patent System in Europe (Brussels: 1997)

when the European Parliament rejected the directive with a majority of 648–14 votes. Between these dates lies a contentious mobilisation in which new collective actors emerged and entered the area of IP politics in Europe. Such mobilisation has lastingly altered the power relations in this field.²¹

On a global level, the broadest and most prominent conflict about IPRs certainly was the conflict about access to (essential) medicines. In its core it was, and still is, a conflict about the effects of patents for pharmaceutical products on access to drugs for patients living in countries of the Global South. It was fuelled, in particular, by the issue of access to HIV/AIDS medications. The coordinates for this conflict were set by the dual dynamics of an accelerating rate of HIV infections in a number of developing countries in Africa, Asia and South America and a ratcheting up of IP protection that culminated in the 1995 TRIPs agreement.²² It is a prime example of a truly international mobilisation, involving several hundred core activists, supported by tens of thousands of people engaged in local mobilisations. Like in the software patents case, actors not previously known in the field of international IP politics have stepped on the stage of international IP politics, and a remarkable coalition of NGOs and government actors from developing countries has been formed.

The pirate parties are an important case because they have contributed to bring IP issues closer to the centre of the parliamentary system. Their electoral campaigns not only bestowed on them an elected representative in the European Parliament, but also forced other parties to position themselves in relation to the issues raised by the pirate parties.²³

Creative Commons is the smallest mobilisation in terms of immediately involved activists, ranging in the area of hundreds, but not the thousands or tens of thousands in the other mobilisations. But its importance is reflected not mainly in the number of activists engaged in the project, but in the remarkable adoption rate of its alternative license by millions of internet users, who in a very short time have already created a sizable pool of creative works that are free for everyone to use.²⁴

The radiance far beyond the core activist group that these transnational mobilisations developed, together with the diversity of the mobilised actors, are an indicator that they address more general cleavages that are relevant to much wider constituencies than those immediately affected by the concrete problems from which the mobilisations started. This does not mean that the mobilisations are really about something else; it only means that they have a second dimension beyond the respective concrete policy issue. Just as protests for women's rights to legal abortions have also been struggles for women's rights in general as well as struggles against the patriarchal order of societies, the campaign for access to medicines is also a struggle about the limits of private appropriation of knowledge, whose aim does not facilitate the provision of AIDS medications to poor people in developing countries.

The more general social conflict lines in which the four conflicts are embedded are:

- (1) the mode of innovation;
- (2) the rules governing access to knowledge; and
- (3) the limits of anonymous markets.

²¹ Haunss and Kohlmorgen, "Lobbying or Politics? Political Claims-making in IP Conflicts" in Haunss and Shadlen (eds), *Politics of Intellectual Property* (2009); Haunss and Kohlmorgen, "Conflicts about Intellectual Property Claims" (2010) 17 *Journal of European Public Policy* 242; Philip Leifeld and Sebastian Haunss, "Political Discourse Networks and the Conflict over Software Patents in Europe" (2011) 50 *European Journal of Political Research* (forthcoming).

²² 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha" (2002) 27 Chicago Journal of International Law 39, Susan K. Sell and Ascem Prakash, "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights" (2004) 48 International Studies Quarterly 143; Sell, "TRIPs and the Access to Medicines Campaign" (2002) 20 Wisconsin International Law Journal 481.
²³ Bartels, Die Piratenpartei (2009); Demker, "Sailing along New Cleavages: Understanding the Success of the Swedish Pirate Party in the European

²⁵ Bartels, *Die Piratenpartei* (2009); Demker, "Sailing along New Cleavages: Understanding the Success of the Swedish Pirate Party in the European Parliament Election 2009", available at *http://goo.gl/6jl12* [Accessed May 17, 2011].
²⁴ Lessig, "The Creative Commons" (2003) 55 *Florida Law Review* 763; Kembrew McLeod and Peter DiCola. *Creative License: The Law and*

²⁴ Lessig, "The Creative Commons" (2003) 55 *Florida Law Review* 763; Kembrew McLeod and Peter DiCola. *Creative License: The Law and Culture of Digital Sampling* (Durham: Duke University Press, 2011).

Mode of innovation

The software patents conflict, the access to medicines mobilisation, and the Creative Commons project directly address the issue of the appropriate mode of innovation. A mode of innovation is a set of social mechanisms that determine how and where innovation is to be produced. In the industrial era industrialised mass production is accompanied by industrialised mass innovation—innovation that is concentrated in large industrial units. This centralised mass production of innovation is reflected in the patenting patterns in industrialised countries. In her empirical analysis of Australian and US patent ownership, Hazel Moir shows that the distribution of patents among patent owners follows a power law: a small number of firms are frequent patenters, owning several hundred or even thousands of patents, while the large majority of firms and a small number of individuals and non-profit organisations own only a small number of patents each.²⁵ Patent-protected innovation is thus strongly centralised and dominated by a small number of powerful corporations.

This centralised, industrial model of innovation is directly challenged in three of the conflicts and criticised in the pirate parties' manifestos. In the software patents conflict, this challenge was most obvious. The opponents of software patents argued that the "real" innovators of the European high-tech sector would not be the handful of large transnational corporations, which extensively make use of the patent system; rather, they are the many thousands of small- and medium-sized software and technology companies, which would suffer, rather than profit, from patent protection in the software area.²⁶

In the access to medicines conflict, the industrial innovation model was challenged from a different angle. The core criticism here was not so much that the big pharmaceutical companies would not be the "real" innovators, but that the innovation they produce would be driven by the wrong incentives. The access coalition argued that in the area of medicines, the aim of innovation should be providing drugs for those who need them the most.²⁷ Because the current model directs innovation to the needs of those able to pay the most, public authorities should be able to intervene and redirect innovation processes and make existing drugs available according to human needs, but not according to the patients' wallets.²⁸

Creative Commons poses a fundamental challenge to the centralised, industrial model of innovation, even though it is an initiative in the copyright area, rather than in the patent area. By offering tools to protect access to knowledge and cultural goods, Creative Commons has greatly enhanced the visibility of dispersed and distributed innovation processes that build upon each other and make use of a growing pool of shared resources.²⁹ The existence of millions of Creative Commons licensed works also helps build a consciousness that the centralised, industrial mode of innovation is only one model among many. The rules governing the production and use of knowledge therefore should not account for only this model.

The focus on political priorities in the access to medicines campaign and the strategy of the opponents of software patents to politicise the conflict further challenge the industrial innovation model on another level. In both cases the social movement actors insisted that knowledge policies should not be shaped by business actors and the patent community, but by the people and/or accountable and democratically legitimised institutions.

²⁵ Hazel V.J. Moir, "Who Benefits? An Empirical Analysis of Australian and US Patent Ownership" in Haunss and Shadlen (eds), *Politics of Intellectual Property* (2009).

²⁶ Haunss and Kohlmorgen, "Conflicts about Intellectual Property Claims" (2010) 17 Journal of European Public Policy 242; Leifeld and Haunss, "Political Discourse Networks and the Conflict over Software Patents in Europe" (2011) 50 European Journal of Political Research (forthcoming).

²⁷ Ruth Mayne, "The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective" in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access, and Development* (Basingstoke: Palgrave, 2002), p.248.

²⁸ Sell and Prakash, "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights" (2004) 48 International Studies Quarterly 143, 153.

²⁹ Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven: Yale University Press, 2006); Lawrence Lessig, "The Architecture of Innovation" (2002) 51 *Duke Law Journal* 1783; Lessig, "The Creative Commons" (2003) 55 *Florida Law Review* 763.

Access to knowledge

The second meta-conflict to which the empirical conflicts speak is a conflict about general rules that govern access to knowledge. All four contentious mobilisations challenge the notion that privatisation and propertisation of knowledge are economically the most efficient and politically the most desirable solutions to encourage innovation and creativity. In the software patents conflict, the open source business model is offered as an alternative to the closed, proprietary model of large information technology corporations. In the access to medicines conflict, compulsory licenses are propagated as a tool to enforce better access, and alternative research financing models (prize funds or patent pools) are offered as measures to combat the propertisation of knowledge on a more general level.³⁰ The pirate parties demand drastically shorter protection periods for knowledge goods, broad exceptions to enable general access for private and non-commercial use, and-in the case of the Swedish Piratpartiet-even the complete abolishment of the patent system.³¹ And Creative Commons provides tools to enable access to knowledge and to broaden the pool of available non-proprietary knowledge goods.

Within the mobilisations the issue of access to knowledge is raised on four levels: First, the general norms that allow patent holders to exclude others from using their propertised knowledge are challenged. Secondly, the specific problem of access to knowledge caused by the "digital divide"32-the gap between the affluent countries of the Global North and the poor countries of the Global South is addressed.

On a third level, limits to access rooted in individual privacy and personality rights are demanded. And fourthly, transparency and access to public records and to information held by authorities, are demanded, in order to enable citizens to hold decision-makers accountable. The overarching questions on all four levels are: Who should be able to access which knowledge and information? On which norms should the limits to access be based? And who should be able to set these norms?

These four aspects describe in essence two sides of the same coin. On the one side, the open access perspective asserts primacy of public over private interests, where public means the population at large while private means corporate, economic interests. This perspective questions the neoliberal assertion of private property as an essential precondition of freedom. It highlights the need for state intervention to balance inequalities and secure social standards.

On the other side, the privacy perspective defends the primacy of the private in terms of personal integrity and autonomy against state and corporate control. This perspective highlights what Isaiah Berlin has called "negative freedom",³³ the freedom from interference. Together these four aspects illustrate that the issue of access to knowledge goes beyond the question of private ownership and exclusive property rights. The question of access is ultimately a question of power-of corporations and states-and its limits.

Theorists of the knowledge society have largely neglected the aspects that a central conflict line of the knowledge society is about controlling access to knowledge and that the core gatekeeping mechanism is the creation of IP. Stehr briefly mentions IP as an area of conflict dating back to the 19th century.³⁴ But because he claims that knowledge would replace property as the defining characteristic of society, he does not see major conflicts related to the IP issue. Nor does the control of access to knowledge by IPRs play a significant role in either in Castells³⁵ or Bell's³⁶ account of the knowledge society. Moreover, the aspect

³⁰ James Love and Tim Hubbard "Prizes for Innovation of New Medicines and Vaccines" (2009) 18 Annals of Health Law 155

³¹ Piratpartiet, "Principprogram version 3.4 [Declaration of Principles 3.4]", available at http://www.piratpartiet.se/principer [Accessed October 31, 20111

³² Pippa Norris, Digital Divide: Civic Engagement, Information Poverty, and the Internet Worldwide (Cambridge: Cambridge University Press,

^{2001). &}lt;sup>33</sup> Isaiah Berlin, *Two Concepts of Liberty: An Inaugural Lecture Delivered Before the University of Oxford on October 31, 1958* (Oxford: Clarendon Press, 1959). ³⁴ Stehr, Knowledge Societies (1994), p.256.

³⁵ Castells, "Materials for an Exploratory Theory of the Network Society" (2000) 51 British Journal of Sociology 5; Manuel Castells, The Rise of ³⁶ Bell, *The Coming of Post-industrial Society* (1999); Daniel Bell, "Welcome to the Post-industrial Society" (1976) 28 *Physics Today* 46.

of regaining autonomy over one's own personal data is absent in all three theories. The three authors' ignorance of the conflict dimension embedded in the access to knowledge issue is not just an empirical oversight but a theoretical shortcoming. The access dimension of the conflicts addresses the question of digital citizenship in its dimensions of individual freedom and social inclusion.

Privacy rights and demands for accountability and access to information on which administrative decision-making is based are contentious, because they circumscribe an area of liberal freedoms in the virtual realm of the knowledge society. Like their counterparts in the material world, these freedoms have to be won in struggles against authorities and private corporations wishing to curb these rights.

The conflict about the limits of IPRs and the rules and norms governing access to knowledge is the knowledge society's pendant to the struggle about limits of individual and corporate property rights in the industrial age. Castells has claimed that the industrial order in which power was based on property will be superseded in the network society by a power based on controlling the network and the information flows.³⁷ That claim, however, has to be modified in light of the recent IP conflicts. The same is true for Bell's claim that skill and education are becoming new bases of power.³⁸ The enormous expansion of IPRs in terms of protected subject matter, protection length and geographical coverage show that property has far from ceased to be an important base of power. Skill and education do not replace the old bases of power. Instead property is redefined to include knowledge and information, which are the preconditions for skill and education.³⁹

The struggles of the industrial age to limit power based on material property have led in some countries to more- or less-encompassing welfare systems and redistributive policies, limiting the rights and expanding the obligations of property owners. Their success depended to a significant amount on the strength of the workers' movements. In the conflicts about access to knowledge, various actors rally for the establishment of similar limits to immaterial property rights. Their success again will likely depend on their ability to become a collective actor.

The limits of anonymous markets

The third conflict line that the four mobilisations address is about the limits of anonymous markets. None of the actors involved in the conflicts question the view that anonymous markets are extremely efficient institutions to solve certain information and allocation problems. But the conflicts question the neoliberal assumption that anonymous markets are in general superior to social forms of organisation. They question this assumption of superiority of market mechanisms on two levels. First, they contradict the assumptions that markets would lead to an optimal allocation of resources and that economic incentives would most effectively solve the problem of underprovision of public goods on the market. Secondly, the conflicts contradict the idea that the production of knowledge goods (and possibly also material goods) would necessarily be driven by cost-benefit calculations.

The first claim is made most explicitly in the access to medicines conflict. The core argument of the access coalition was that market mechanisms may well spur innovation and lead to the production of the most profitable medications, but those mechanisms will not necessarily lead to a sufficient provision of the most needed drugs to save human lives. For this, political governance that imposes priorities based on normative considerations is needed. In this aspect, the access to knowledge conflict is another iteration of the much older conflict between market liberalism and state intervention.

³⁷Castells, "Materials for an Exploratory Theory of the Network Society" (2000) 51 British Journal of Sociology 5, 20.

³⁸ Bell, *The Coming of Post-industrial Society* (1999), pp.358 ff.

³⁹ Peter Drahos with J. Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? (New York: New Press, 2003); Lessig, "The Architecture of Innovation" (2002) 51 Duke Law Journal 1783.

The second claim is more specific to the knowledge society. It undermines the idea that the rational, utility-maximising actor would be the appropriate model to understand the mechanisms that lead to the creation of cultural and knowledge goods. Classical economic theory assumes that rational economic actors would have no incentive to produce knowledge goods. Their non-rivalrous nature would make it irrational for anyone to produce them because everyone would try to forgo the costs of producing them by free riding on the goods produced by others.⁴⁰ Knowledge goods therefore should either be provided by the state or through additional incentives in the form of monopoly rights created to spur private production.

The success of Creative Commons and open source software fundamentally challenges this assumption. Obviously the millions of internet users, who have made the products of their creative activities freely available under Creative Commons licenses did not need additional economic incentives to create cultural goods. While one might object by noting that the majority of these goods was created by individuals and never intended to generate profits, this is certainly not true for open source software, which is produced by large for-profit corporations (like Google, IBM, Oracle, MySQL, or even Microsoft), SMEs, individuals in their spare time, or academics as part of their research. The important insight is that knowledge goods are produced for a variety of reasons, and digitisation and the internet have dramatically altered the conditions under which these various motives can become relevant.

The internet offers the possibility to coordinate distributed collaboration on a previously unknown scale and with minimal costs. It enables peer production-that is, "effective, large-scale cooperative efforts" -- on a global scale and under conditions of abundance. In pre-knowledge societies innovation and the creation of knowledge was always hampered by conditions of scarcity. Education and expertise were limited to a small section of the population. Geographic distances and different languages made the exchange of information costly and slow. The transaction costs of creating knowledge were high. In the 21st century this scarcity is in some areas being replaced by abundance. Coupled with rapidly decreasing costs for transmitting, storing, and acquiring information, this fundamentally alters the conditions for the creation of knowledge.

The Creative Commons project, along with the other mobilisations with their claims about the importance of values and norms in the governance of innovation and knowledge, thus questions the logic of the current IP system, which is based on the assumption of isolated, utility-maximising economic actors. All of these conflicts highlight the fact that innovation or the creation of knowledge and cultural goods is a social process. They do not deny that this process is driven by utilitarian incentives, but they claim that the process is *also* driven by other incentive structures. That these other incentives—based in the social norm of sharing, for example—have already become significant in some areas. They should become dominant in other areas as well.

This conflict line adds another dimension to the theory of the knowledge society that has been overlooked so far. The theories of the knowledge society are all centred around core processes of change that first and mainly affect the economic order of societies and then have wider effects in other sectors. The idea that knowledge production may be driven by other than economic reasons is present in Bell's and Stehr's writings, but only in the form of an internal logic of knowledge production. Bell describes the incessant branching of science,⁴² and Stehr stresses the self-reflexivity of theoretical knowledge.⁴³ What is missing is the idea put forward by Yochai Benkler, who provides a theoretical explanation for the rise of Wikipedia

⁴⁰ Arrow, "Economic Welfare and the Allocation of Resources for Invention" in *The Rate and Direction of Inventive Activity* (1962); Jeremy Bentham, "A Manual of Political Economy" in John Bowring (ed.), The Collected Works of Jeremy Bentham (Edinburgh: W. Tait, 1843); Garrett Hardin, "The Tragedy of the Commons" (1968) 162 Science 1243; William D. Nordhaus, Invention Growth, and Welfare: A Theoretical Treatment of Technological Change (MIT Press, 1969).

Benkler, The Wealth of Networks (2006), p.5.

⁴² Bell, The Coming of Post-industrial Society (1999), Ch.3.

⁴³ Stehr, Knowledge Societies (1994), Ch.5.

and other instances of peer production. He claims that in "networked information economies", knowledge production is essentially a social process, driven to an important degree by decisions based on social norms, and not only by utility-maximising economic decisions.⁴⁴

The relationship between IP conflicts and social change

The general conflict lines, along which the four conflicts about software patents, access to medicines, pirate parties and Creative Commons have developed, are related to a number of processes of change. These processes of change have enabled or at least accelerated the development along the lines mentioned above.

The most fundamental of these changes is the one lying at the base of Manuel Castells' network society: the establishment of a *networking logic* that displaces the hierarchical organisation of economic and social relations and permeates all aspects of current society. Castells claims that power in the network society depends ultimately on the ability to program the network.⁴⁵ Given the centrality of controlling the networking logic, it is no wonder that the conflicts are all related to this process of change.

The conflict about digital civil rights, on the one hand, is an attempt to limit the reach of the networking logic and to regain some space for personal privacy. On the other hand, it is a struggle for democratic control over dispersed decision-making structures where governance networks are replacing government institutions. In the other conflicts, the collective actors strive to establish alternative networking logics of distributed innovation, collaboration and sharing. These conflicts are not just the consequences of the processes of social change; the actors involved in these conflicts are also trying to modify the processes of change while the processes are happening. These actors offer alternative versions of the knowledge society, but not an alternative to the knowledge society.

This is most explicit with regard to digitisation—the technological process of change. The digital revolution was clearly a necessary precondition for the development of current knowledge societies. Only in digital form can information in today's quantities be stored, transferred, and processed in a global information network. This technological change is directly related to the changes in the property structure of the knowledge society—the increasing propertisation of knowledge and other immaterial goods. The Conflicts react to this technological change by embracing its possibilities. The attempts to foster a culture of sharing, to strengthen access to knowledge, and to develop models of distributed open innovation all built upon the potential of more egalitarian access to knowledge and information. Only in the conflict about digital civil rights does a cautionary perspective prevail to broach the issue of surveillance and privacy.

The growing "propertisation of knowledge" is opposed in all recent conflicts of the knowledge society. This process of change was certainly the immediate source of the conflicts about software patents and access to medicines in which the more general conflicts of the modes of innovation and access to knowledge have been addressed.

It should be noted though that the conflict lines that surface in the four contentious mobilisations are not directly connected to a number of other processes of change that appear prominently in the theoretical literature on the knowledge society. None of the conflicts has resulted from the transition from manufacturing to service, the core process of change in Bell's description⁴⁶ of the knowledge society. The transformation in the economy that Castells associates⁴⁷ with the displacement of the hierarchical industrial corporation by the network enterprise is also not at the root of the current most visible contentious mobilisations. The detachment of cultural production from local experience that Castells identifies as a

⁴⁴ Benkler, The Wealth of Networks (2006), Ch.3.

⁴⁵ Castells, "Materials for an Exploratory Theory of the Network Society" (2000) 51 *British Journal of Sociology* 5, 20.

⁴⁶ Bell, *The Coming of Post-industrial Society* (1999).

⁴⁷ Castells, *The Rise of the Network Society*, 2nd edn (2010).

major process of change in the cultural realm has also not yet become a source of conflictual action.⁴⁸ Neither do the current conflicts immediately reflect the changes in gender relations, women's roles in society and production that Castells identifies as one of the core processes of social change in the network society.⁴⁹ This does not mean that these changes have happened without conflicts. It only means that these processes of change have not immediately influenced the trajectories of the most prominent contentious mobilisations of the knowledge society so far.

Nevertheless, what this rough sketch of the relationships between processes of change and conflicts in the knowledge society tells us is that a new set of conflicts has emerged that is no longer rooted in the cleavages of the industrial area. While the changes in the economic and occupational structures may still be addressed in a slightly modified framework of conflictual interaction developed in the industrial era, the conflicts that have been addressed in the contentious mobilisations discussed in this article seem to warrant new frameworks of interpretation and collective action. The unusual coalitions of actors that characterise all four conflicts are an expression of this. The analysis of the empirical conflicts thus reveals an area of contention that existing theories have largely ignored. But without accounting for these conflicts any understanding of the social dynamics of the knowledge society would be seriously flawed.

In the conflicts an alternative version of the knowledge society is proposed. In this alternative version of a knowledge society knowledge still remains the base for profit-driven economic activity. But it will be a knowledge society in which this economic activity is based on social production and on shared knowledge resources, and no longer on maximal exclusion. If this vision should see any chance to become a reality, then it will have to be backed by a strong collective actor able to establish it as the hegemonic version of the knowledge society. Clearly no such collective actor exists today, but traces of a social movement that may at some point become the agent of such an alternative version of the knowledge society can be seen in the current contentious mobilisations.

⁴⁸ Castells, "Materials for an Exploratory Theory of the Network Society" (2000) 51 British Journal of Sociology 5.
 ⁴⁹ Manuel Castells, The Power of Identity (Oxford: Blackwell, 1997), Ch.4.

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