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TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP

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TRIPS WAS NEVER ENOUGH: VERTICAL FORUM SHIFTING, FTAS, ACTA, AND TPP

*Susan K. Sell**

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I. INTRODUCTION

Fifteen years ago, trade negotiators signed off on the most comprehensive multilateral intellectual property agreement in history. It was both sweeping in scope and legally binding. Hailed as a major change to international market regulation at the time, in retrospect, it looks like a relatively timid and permissive agreement. In the years since, advocates for ever-higher standards of property protection aggressively pushed their agendas through bilateral (Bilateral Trade Agreements, Bilateral Investment Agreements, and European Partnership Agreements), regional (Free Trade Agreements), and plurilateral negotiations (Anti-Counterfeiting Trade Agreement and Trans-Pacific Partnership).

Invariably, these extra-multilateral agreements have required stronger and broader standards of intellectual property protection, and have eliminated much of the legally permitted flexibility under TRIPS.¹ This process has expanded and accelerated over time, underscoring the fact that TRIPS was a beginning and not an endpoint. This Article traces the development of the so-called “TRIPS-plus,” “U.S.-plus,” and even “ACTA-plus” initiatives, such as the Trans-Pacific Partnership, and their implications for international market regulation and economic development.

Despite the fact that a TRIPS advocate triumphantly exclaimed, “we got 95% of what we wanted,” that 5% has always mattered, and 95% was never enough. While many countries believed that they were negotiating a ceiling on intellectual property rules,² they quickly discovered that they actually had negotiated only a floor. Looking back on the past fifteen years of intellectual property norm setting and governance, critics’ initial objections to TRIPS look almost mild, and I, for one, never imagined that the original TRIPS would look so good.

The past fifteen years have been marked by ups and downs, victories and defeats both for those who seek to ration access to intellectual property and for those who seek to expand access. Changes in technology—and particularly the digital revolution—have presented new regulatory challenges. The HIV/AIDS pandemic helped to galvanize the access-to-medicines campaign that scored important victories with both the Doha Declaration on TRIPS and Public Health and the TRIPS amendment to allow countries with no domestic generic drug manufacturing capacity to import drugs produced under compulsory

¹ Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

² SUSAN SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 48 (2003) (quoting Interview with Jacques Gorlin, Aanser, IPC, in Washington, D.C. (Jan. 22, 1996)).

licenses. Developing countries became much more fully engaged in intellectual property norm-setting activities, and, at their insistence, the World Intellectual Property Organization (WIPO) adopted the “Development Agenda” in 2007. In May that same year, the United States Congress decided to remove tough public health provisions in bilateral FTAs in order to better support developing countries’ public health needs and more fully comply with the Doha Declaration.³

At the same time, the international intellectual property policymaking arena has grown ever more congested and complex. This multi-level policy arena has expanded horizontally, across more multilateral institutions, and it has expanded vertically, from the multilateral level to the most granular—even down to individuals. While it may be too soon to tell if and when the complicated, competing, and inconsistent norm-setting and rule-making processes may find an equilibrium, it seems that the horizontal forum-shifting has provided some opportunities for crusaders for expanded access to intellectual property. The vertical forum shifting, from the multilateral down to the individual, with multiple levels in-between, thus far has redounded to the benefit of stronger parties who seek to ration access to intellectual property.

However, these processes are recursive and vertical shifts are not only top-down. Causal arrows are bidirectional. In fact, in the rapidly shifting geopolitical and economic power dynamics in the wake of the 2008 financial crisis, it is clear that some bottom-up innovation is beginning to have an impact on the system as a whole. Brazil, China, and India most likely will write the next chapters in the intellectual property policy saga. In the U.S., the financial crisis both has engendered accelerated TRIPS-plus activity (under the banner of resurrected 1980s rhetoric about competitiveness and innovation) and also has generated resistance to the agenda from cash-strapped state governments seeking to contain health care costs.

I will begin by discussing forum-shifting and regime complexity. I then show how that “5%” that TRIPS advocates did not get in the Uruguay Round routinely has been inserted into regional and bilateral trade and investment agreements. I will discuss top-down vertical forum shifting in greater detail, as this has been intellectual property rationers’ preferred strategy in the face of multilateral stalemate. Instances of extreme vertical forum shifting—what I call “going granular”—will highlight the pervasiveness of this technique. Finally, the Article will conclude by discussing some domestic innovations in India and

³ Jean-Frederic Morin, *Multilateralizing TRIPS-Plus Agreements: Is the US Strategy a Failure?*, 12 J. WORLD INTEL. PROP. 191 (2009). Subsequent US-FTAs with Colombia, Peru and Panama relaxed provisions on data exclusivity, patent linkage, and patent extension. For complaints about these changes, see *International Enforcement of Intellectual Property Rights and American Competitiveness: Hearing before the S. Finance Comm.*, July 15, 2008 (statement of Jeff Kindler, Chairman and CEO, Pfizer, Inc.), available at <http://finance.senate.gov/imo/media/doc/071508jktrest.pdf> [hereinafter Kindler testimony].

China that have the potential to have a broader impact on the intellectual property policymaking arena.

II. FORUM SHIFTING AND REGIME COMPLEXITY

Countries frequently have reverted to forum shifting. Opportunities for this have increased due to the proliferation of forums that address intellectual property. Laurence Helfer argues that both strong and relatively weak parties can engage in forum shifting.⁴ States can use institutions strategically in an effort to achieve better outcomes for themselves. For instance, the United States shifted intellectual property out of WIPO and into the General Agreement on Tariffs and Trade (GATT)⁵ in the 1986 Uruguay Round of GATT negotiations. The U.S. was frustrated that WIPO was paying too much attention to developing countries and that WIPO had no enforcement mechanisms. With WIPO's one-state, one-vote rule, the U.S. was less able to exert leverage to achieve its desired policies.

GATT was more promising because it would give rich states with large markets the opportunity to use market access as leverage to induce higher levels of intellectual property protection through the trade regime. Later, when public health discussions dominated the WTO, the U.S. realized it would not be able to press for its desired TRIPS-plus norms there,⁶ so the U.S. returned to WIPO to restart the Substantive Patent Law Treaty (SPLT) negotiations in 2002. Developing countries worked with NGOs on intellectual property and health issues at the World Health Organization (WHO), which led to the Doha Declaration on TRIPS and Public Health⁷ in November 2001.

When the U.S. and the EU sought to restart SPLT in 2002, their aim was to achieve much higher global standards for intellectual property than they secured with TRIPS. Developing countries resisted. Instead, they countered with the Development Agenda, much of which had evolved out of their work in the Convention on Biological Diversity (CBD),⁸ which took a much more development-friendly approach to intellectual property. For example, the CBD endorsed access, benefit sharing, and prior informed consent for those seeking to acquire biological material located in developing countries. This horizontal forum shifting—across multilateral organizations—has provided opportunities for developing countries to achieve some positive results. However, at the

⁴ Laurence Helfer, *Regime-shifting: The TRIPs Agreement and the New Dynamics of Intellectual Property Policymaking*, 29 YALE J. INT. L. 1 (2004).

⁵ General Agreement on Tariffs and Trade (GATT), Apr. 15, 1994, 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994) [hereinafter GATT].

⁶ Peter K. Yu, *TRIPS and Its Achilles' Heel*, 18 J. INTELL. PROP. L. 479 (2011).

⁷ World Trade Organization, Ministerial Declaration of 19 November 2001, WT/MIN(01)/Dec/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

⁸ United Nations Convention on Biological Diversity, June 5, 1992, 31 I.C.M. 818 (1992) [hereinafter CBD].

same time, it has led to greater inconsistency and incoherence across the regime as different venues adopt different approaches to intellectual property.

Regime complexity refers, in part, to the plethora of venues that host and shape negotiations over intellectual property norms and rules. Yet, it also highlights the fact that numerous intellectual property-related treaties are inconsistent with each other. For instance, the CBD has very different rules for access and benefit sharing than does TRIPS. Benvenisti and Downs argue that the fragmentation of a regime redounds to the benefit of the powerful at the expense of the weak. They state that:

Fragmentation provides powerful states with the opportunity to abandon – or threaten to abandon – any given venue for a more sympathetic venue if their demands are not met. This further exacerbates the competition between institutions and effectively marginalizes the role of weaker states.⁹

This is precisely the dynamic that gave rise to TRIPS when the U.S., EU, and Japan—frustrated with WIPO—pushed for intellectual property protection in the trade regime, first in GATT and then in the WTO.

Ironically, horizontal forum shifting can lead to vertical forum shifting. Vertical forum shifting refers to negotiating norm-setting, rule-making, implementation, and enforcement at levels below the multilateral level (e.g., plurilateral, bilateral, unilateral, and granular/local).

While horizontal forum shifting may offer benefits to weaker parties, top-down vertical forum shifting clearly favors the powerful. Stronger parties often engage in vertical forum shifting when they are unable to achieve their goals in a multilateral forum. Prior to and throughout the TRIPS negotiations, the U.S. engaged in bilateral and regional negotiations with developing countries to eliminate their resistance to TRIPS. The U.S. was able to wield the carrot of increased market access and potential future investment along with the stick of economic coercion in order to get developing countries to sign on to much higher standards of intellectual property protection. Since TRIPS, the U.S. and Europe have continued to negotiate TRIPS-plus¹⁰ treaties bilaterally and regionally. Vertical forum shifting has continued to animate the norm-setting, rule-making, implementation, and enforcement agendas of Organisation for Economic Co-Operation and Development (OECD) countries—for instance, with WIPO’s “technical assistance” programs¹¹ and the plurilateral negotiations

⁹ Eyal Benvenisti & George Downs, *The Empire’s New Clothes: Political Economy and the Fragmentation of International Law*, 60 STANFORD L. REV. 595 (2007) [hereinafter *New Clothes*].

¹⁰ “TRIPS-plus” refers to provisions that require higher or broader standards of protection than TRIPS, or that remove TRIPS flexibilities.

¹¹ CAROLYN DEERE, *THE IMPLEMENTATION GAME* (2008).

for an Anti-Counterfeiting Trade Agreement (ACTA)¹² and the proposed Trans-Pacific Partnership Agreement (TPP).¹³

Top-down vertical forum shifting in intellectual property norm-setting, rule-making, implementation, and enforcement serves to construct, reinforce, and deepen inequity. Strong states that believe that their vital interests are at stake and that their preferences are distinctly at odds with the vast majority of other states often engage in vertical forum-shifting.¹⁴

The following presents four levels of vertical forum-shifting that demonstrate how the process allows stronger parties—including private parties backed by their governments—to achieve TRIPS-plus results outside of the multilateral regime. This includes bilateral and regional treaties, plurilateral treaties, and targeting individuals to promote TRIPS-plus results. The conclusion discusses the prospects for effective resistance to these efforts.

III. VERTICAL FORUM SHIFTING 1.0: BILATERAL AND REGIONAL NEGOTIATIONS AND TREATIES

Vertical forum shifting was an important component of U.S. strategy to achieve TRIPS. Using Special 301 of the Trade Act,¹⁵ the U.S. exerted bilateral pressure on developing countries to soften their resistance to TRIPS during the Uruguay Round. Since signing TRIPS, the U.S. has entered into bilateral treaties that include intellectual property provisions with numerous developing countries: Australia, Bahrain, Cambodia, Central American countries, Chile, Colombia, the Dominican Republic, Jamaica, Korea, Laos, Latvia, Lithuania, Morocco, Nicaragua, Oman, Panama, Peru, Singapore, South Korea, Trinidad and Tobago, and Vietnam. As Morin points out, “asymmetry in economic power presents powerful states with an alternative path in creating desired norms that they would not be able to achieve at the multilateral level.”¹⁶

¹² Anti-Counterfeiting Trade Agreement, Dec. 3, 2010, *opened for signature* May 1, 2011, available at http://trade.ec.europa.eu/doclib/docs/2010/december/tradoc_147079.pdf [hereinafter ACTA].

¹³ See Meredith Lewis, *The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?*, 34 B.C. INT'L & COMP. L. REV. 27 (2011). The proposed Trans-Pacific Partnership is a regional Asia-Pacific trade agreement. The U.S. currently is negotiating with Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam (*see* <http://www.ustr.gov/tpp>) [hereinafter TPP Intellectual Property Negotiations].

¹⁴ Eyal Benvenisti & George Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT'L L. 21 (2004) [hereinafter *Distributive Politics*].

¹⁵ Office of the United States Trade Representative, 2010 Special 301 Report, Annex 1 (2010), available at http://www.ustr.gov/webfrm_send/1906.

¹⁶ Morin, *supra* note 3.

A. TRIPS-PLUS AND MEDICINES: THE ADDITIONAL 5%

TRIPS permits countries to exceed TRIPS standards, and the U.S. has been pressuring them to do so. It has offered countries WTO-plus market access in exchange for TRIPS-Plus policies.¹⁷ Particular provisions in these bilateral and regional trade agreements include: data exclusivity provisions; prohibitions of parallel importation; linkage between drug registration and patent protection; highly restrictive conditions for issuing compulsory licenses; and patent term extensions. The brand-name pharmaceutical industry has crafted all these provisions with the assent of the United States Trade Representative (USTR) and these serve to reduce the availability of affordable drugs. I will discuss each of these in turn.

Brand name pharmaceutical firms favor data exclusivity provisions because they offer new rights and opportunities to maximize returns on their products by delaying competition. Under Article 39.3 of TRIPS, WTO members must protect undisclosed test data on pharmaceutical products against unfair competition.¹⁸ Brand name pharmaceutical companies are required to submit efficacy and safety test data as part of the drug approval process. However, the FTA provisions require signatories to grant at least five years of data exclusivity counted from the date on which the product was approved, whether or not it was patented and whether or not the data was disclosed. It also covers chemical entities that are not new.¹⁹

These provisions are designed to require generic pharmaceutical producers to generate their own clinical trial test data, rather than rely on safety and efficacy findings of the brand name drugs in the generic drug approval process. Brand name pharmaceutical companies, in effect, have acquired a new form of intellectual property right in their test data and information generated by that data.²⁰ This new right is independent of patent status and therefore presents a huge obstacle to generic competition. Jerome Reichman points out that restricting the use of clinical trial data “could effectively empower rights holders to negate a state’s ability to authorize marketing approval of equivalent drugs for a period of five to ten years.”²¹

Parallel importation is the importation of patented goods from another country. Using parallel importation, countries can take advantage of differential

¹⁷ Ken Shadlen, *Policy Space for Development in the WTO and Beyond: The Case of Intellectual Property Rights* 11 (Tufts Univ. Global Dev. & Env’t Inst. Working Paper No. 05-06, 2005), available at <http://ase.tufts.edu/gdae>.

¹⁸ TRIPS art. 39.3.

¹⁹ Carlos Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 401 (2006).

²⁰ Shadlen, *supra* note 17, at 19.

²¹ JEROME REICHMAN, UNDISCLOSED CLINICAL TRIAL DATA UNDER THE TRIPS AGREEMENT AND ITS PROGENY: A BROADER PERSPECTIVE 2 (2004), available at http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

pharmaceutical pricing policies in order to obtain cheaper patented goods. For example, if a brand name pharmaceutical company sells a patented product more cheaply in country *X* than in country *Y*, country *Y* could import the drug from country *X* and save money. This is perfectly permissible under TRIPS.

TRIPS-plus provisions limit parallel imports of patented drugs by providing the patent owner with an exclusive right to prohibit parallel importing contractually. Brand name member firms of the Pharmaceutical Research and Manufacturers Association (PhRMA) failed to get other states to support a prohibition on parallel importation in the TRIPS negotiations, but, to achieve what it could not get multilaterally, it pressed the U.S. to vertically shift to regional and bilateral forums. This eliminates a TRIPS-compliant opportunity to access more affordable patented drugs; this is especially crucial in the case of second-line HIV/AIDS drugs that are patented and for which no generics are available.

Patent protection and drug registration are not linked in TRIPS, but *are* linked in many TRIPS-plus agreements. Under these provisions, national health authorities are required to refuse to provide marketing approval to a generic drug if a patent on the drug is in force, unless the patent owner consents to such approval. Additionally, the health authorities must inform patent owners of any applications for generic product approval.²² This patent and registration linkage and the data exclusivity provisions delay the entry of generic drugs to market and may deter generic competition.

TRIPS permits compulsory licensing, albeit with some significant restrictions. The negotiators agreed to amend TRIPS just before the WTO Hong Kong Ministerial meeting in December 2005 to allow for countries without generic manufacturing capacity to benefit from compulsory licensing. While this amendment incorporated some cumbersome procedural requirements, TRIPS retained far more flexibility to issue such licenses than bilateral and regional agreements have. These bilateral and regional agreements restrict compulsory licensing to a very limited set of circumstances. Drug registration/patent linkage and data exclusivity provisions mean that “prospective licensees are unlikely to replicate test data, and governments cannot normally wait until a new set of test data has been developed.”²³ The net effect of these features is reduced competition and access.

Finally, these bilateral and regional agreements incorporate automatic patent term extensions beyond TRIPS’ twenty year term. These extensions are not limited in time, despite the fact that the U.S. limits extensions to compensate for delays in marketing approval to five years.

Therefore, the bilateral and regional agreements not only are TRIPS-plus but also are, in fact, U.S.-plus. These agreements provide for automatic extensions

²² Correa, *supra* note 19, at 401.

²³ *Id.* at 402.

for delays in patent examination. This is troubling in developing countries, because their patent offices are under-staffed and stretched to the limit.²⁴ Significantly, these provisions inject considerable uncertainty into the calculations of would-be generic competitors and could delay the introduction of competing and affordable products.²⁵

Former-USTR-turned-PhRMA-lobbyist Mickey Kantor offered a vigorous defense of TRIPS-plus provisions in the bilateral and regional trade agreements reflecting the brand-name pharmaceutical industry position. He contends that labeling these provisions as “TRIPS-plus” is misleading because they do not violate TRIPS.²⁶ He argues that the provisions are TRIPS-compliant.

His rhetoric misses the point. No one has ever charged that TRIPS-plus provisions were illegal or violated TRIPS. Indeed, TRIPS explicitly provides that states may adopt provisions that exceed the requirements of TRIPS. Critics of TRIPS-plus provisions instead tend to question their merits on public health, moral, human rights, and economic development grounds.

IV. VERTICAL FORUM SHIFTING 2.0: ACTA (FTA-PLUS AND TRIPS-PLUS AND U.S.-MINUS)

In intellectual property norm setting, developing countries successfully rebuffed the U.S. and European efforts to pursue a TRIPS-plus Substantive Patent Law Treaty (SPLT) at WIPO. This prompted another vertical forum shift. In 2007, just after WIPO adopted the Development Agenda, the U.S., Europe, and Japan announced their plans to negotiate a plurilateral Anti-Counterfeiting Trade Agreement (ACTA) with a smaller group of like-minded countries (many of whom had already signed TRIPS-plus FTAs with the U.S.).²⁷ In October 2007, then-USTR Susan Schwab announced that the U.S. and key trading partners would “(seek to negotiate . . . [a] new, higher benchmark for [IP] enforcement) and emphasized that the negotiations would not be part of any existing international organizations.”²⁸ As Benvenisti and Downs argue, if weaker states succeed in shaping an institution to better reflect their interests, as

²⁴ PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2010).

²⁵ Correa, *supra* note 19, at 401.

²⁶ Mickey Kantor, *U.S. Free Trade Agreements and the Public Health*, submission to WHO CIPIH 1, 5 (2005) available at <http://www.who.int/intellectualproperty/submissions/USFTASandthePublicHealth.pdf>.

²⁷ Chow, *supra* note 12. These included Jordan, Korea, Mexico, Morocco, Singapore, and the United Arab Emirates.

²⁸ Emily Ayob, *The Anti-Counterfeiting Trade Agreement*, 28 CARDOZO ARTS & ENT. L.J. 175, 179 (2010) (quoting Press Release, Office of the United States Trade Representative, Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes (Oct. 23, 2007), available at <http://www.ustr.gov/ambassador-schwab-announces-us-will-seek-new-trade-agreement-fight-fakes>).

one may argue that they did with WIPO's Development Agenda, powerful states may either withdraw from, or switch, venues.²⁹ Powerful states, unhappy with WIPO deliberations on the Development Agenda, decided to "exploit their agenda-setting power to set up a parallel and competing set of negotiations with other powerful states."³⁰

With ACTA, these countries could engage in non-transparent negotiations for much higher standards of intellectual property protection and enforcement than they could ever hope to achieve in the multilateral WIPO. Inevitably, TRIPS-plus ACTA provisions will reappear in bilateral and regional trade agreements going forward in an effort to raise global standards of protection. As USTR Stan McCoy stated, the USTR hopes that "other countries will join over time, reflecting the growing international consensus on the need for strong IPR enforcement" and it "looks forward to partnering with developing countries through ACTA, and cooperating with ACTA partners to provide technical assistance to developing countries."³¹

Notably, some of ACTA's negotiating members have been, or still are, on the USTR's Special 301 Report that engages countries in negotiations about lax intellectual property protection under threat of trade sanctions.³² Perhaps this economic coercion has propelled that so-called "consensus." Notably, the developing country ACTA partners are already yoked to higher standard IP agreements with the U.S.

While copyright and trademark-based industries have been concerned about enforcement for many years, the most recent push for a new approach emerged in 2004 at the first annual Global Congress on Combating Counterfeiting. The Global Business Leaders' Alliance Against Counterfeiting (GBLAAC)—whose members include Coca Cola, Daimler Chrysler, Pfizer, Proctor and Gamble, American Tobacco, Phillip Morris, Swiss Watch, Nike, and Canon—sponsored the meeting in Geneva.³³ Interpol and WIPO hosted the meeting. (At the July 2005 Group of 8 (G8) meeting, Japanese representatives suggested the development of a stricter enforcement regime to battle "piracy and counterfeiting."³⁴)

Despite its name, ACTA is not a trade treaty. It is an intellectual property treaty. Until the spring of 2010, when leaked text became widely available on the Internet, negotiators and officials cloaked the entire negotiating process in

²⁹ *Distributive Politics*, *supra* note 14, at 614.

³⁰ *Id.* at 615.

³¹ Ayoob, *supra* note 28, at 192.

³² Special 301 Report, *supra* note 15.

³³ Aaron Shaw, *The Problem with the Anti-Counterfeiting Trade Agreement (and what to do about it)*, 2 KNOWLEDGE ECOLOGY STUD. (2008), <http://www.kestudies.org/ojs/index.php/kes/article/view/34/59>.

³⁴ The Group of 8 is a forum for the governments of France, Germany, Italy, Japan, the United Kingdom, the United States, Canada, and Russia. Heads of governments meet at the annual G8 Summit.

secrecy. Only after numerous text leaks, a 633-13 European Parliament vote to make the negotiating text available in spring 2010, and pressure from public interest groups did the negotiating parties agree to make the text available. Much of the treaty had already been negotiated and only industry insiders, not consumers, had been consulted in its development.

Driven by the content industry and initially motivated by concerns over copyright piracy, ACTA aims to enlist the public sector in enforcing private rights. This means that taxpayers' dollars would be used to protect private profits. The opportunity costs of switching scarce resources for border enforcement of IP "crimes" are huge. There surely are more pressing problems for law enforcement in developing countries than ensuring profits for OECD-based firms.

Other concerns address the lopsided nature of the ACTA approach, favoring rights holders above all else and presuming suspects to be guilty. Due process of law will be sacrificed to the interests of IP rights holders and there will be few, if any, checks on abuses of rights.³⁵ Border guards and customs agents may be authorized to search laptops, iPods, and cell phones for infringing content. Customs officials would have authority to take action against suspected infringers even without complaints from rights holders; they could confiscate the laptops and iPods. Privacy issues arise over extensive data sharing and possible wire tapping that could be involved in ramped up enforcement efforts. ACTA proposes to ratchet up enforcement without a complementary ratcheting up of due process.³⁶

ACTA seeks to require Internet Service Providers (ISPs) to police and control their systems for infringing content.³⁷ Shifting enforcement burdens to ISPs raises important questions about data privacy and reporting requirements for ISPs. ACTA also would raise substantially criminal penalties for copyright infringement. ACTA has quite liberal provisions for damages (to be calculated on the basis of "lost profits" and injunctions).³⁸

Its one-size-fits-all policy exacerbates the problems that, even the far more forgiving and flexible TRIPS revealed. While some of the substantive provisions are in fact TRIPS-plus and even U.S.-plus, it is also TRIPS-minus insofar as it omits any TRIPS flexibilities, and U.S.-minus because it lacks provisions for fair use, limitations and exceptions to copyright, and due process provisions to protect the innocent. It sharply reduces policy space for developing countries to design appropriate policies for their public policy for innovation and economic development.

³⁵ ROBIN GROSS, IP JUSTICE WHITE PAPER ON THE PROPOSED ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA) (2008), <http://ipjustice.org/wp/2008/03/25/ipj-white-paper-acta-2008/>.

³⁶ I thank Jonathan Band for this point.

³⁷ GROSS, *supra* note 35.

³⁸ James Love, *Comments on ACTA Provisions on Injunctions and Damages*, KNOWLEDGE ECOLOGY INT'L 1 (2006), <http://keionline.org/node/826>.

ACTA also would create an additional international intellectual property governance layer atop an already remarkably complex and increasingly incoherent intellectual property regime. As Shaw points out, “instead of merely shifting the debate from one forum to another, the ACTA supporters now seek to create an entirely new layer of global governance.”³⁹ One chapter of the ACTA text is devoted to new institutional arrangements, including a Secretariat. There is no discussion of how such an institution would mesh with or stand apart from WIPO and/or WTO. This injects substantial uncertainty into the IP regime.

The most recent text is problematic in that it is not restricted to large-scale commercial counterfeiting (intentional trademark infringement with the intent to deceive consumers) and copyright piracy. Also targeted are “personal use,” “non-commercial uses,” patent infringement, and transshipment of generic drugs.⁴⁰

According to Timothy Trainer, former President of the International Anti-Counterfeiting Coalition, “ACTA is an initiative that allows governments to voluntarily commit themselves to whatever TRIPS+ standards are agreed.”⁴¹ ACTA negotiations are ongoing despite increasing consumer concerns over potential negative consequences across a broad range of issue areas.⁴²

The G8’s 2007 Heiligendamm Declaration emphasized intellectual property protection and enforcement as top priorities.⁴³ As in the process leading up to TRIPS, private actors have collaborated with OECD governments and various governmental and intergovernmental agencies to increase intellectual property rationing.

The discourse animating this push for higher standards of protection and enforcement echoes the 1980s focus on “competitiveness”⁴⁴ but also has added

³⁹ Shaw, *supra* note 33, at 2.

⁴⁰ ACTA, *supra* note 12.

⁴¹ Timothy Trainer, *Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation?)*, 8 J. MARSHALL REV. INTELL. PROP. L. 47 (2008).

⁴² *Copyright Deal Would Toughen Laptop, iPod Laws*, CALGARY HERALD, May 24, 2008, <http://www.canada.com/calgaryherald/news/story.htm?id=642326df-30e7-4822-b919-1f6cd8860c9d>; see, e.g., *ACTA and the Drug Monopoly Enforcement Agenda: A Windfall for Big Drug Companies; Higher Medicine Prices for American Families*, ESSENTIAL ACTION ACCESS TO MEDICINES PROJECT, July 27, 2009, <http://www.essentialaction.org/access/index.php?/categories/18-Drug-Monopoly-Enforcement>.

⁴³ Sebastian Haunss & Lars Kohlmorgen, *Political Claims-Making in IP Conflicts*, Paper Presented at ECPR Workshop 14: The Politics of Intellectual Property (Apr. 11–16, 2008).

⁴⁴ This is to be expected as the U.S. faces significant trade deficits with China in the early twenty-first century. This is reminiscent of the significant trade deficits with Japan in the 1980s that led to Section 301 of the U.S. Trade and Tariff Act and the beginning of bilateral pressure to raise IP protection standards abroad. Notably in so-called “rust-belt” states, the Democratic candidates for the Presidential nomination of 2008, such as Hillary Clinton, resuscitated much of the protectionist narrative that fueled the adoption of 301 as a hedge against tariffs and trade wars. See SELL, *supra* note 2.

a “security” narrative highlighting both national security (“terrorism”) and “criminalization.”⁴⁵ This new framing has created new possibilities for mobilization. Introducing a security frame for intellectual property has allowed these intellectual property maximalists to enlist new actors—namely, law enforcement agencies—in their cause. Law enforcement agencies have become eager recruits to the intellectual property maximalists’ network.

At a CropLife America meeting on December 1, 2007, Dan Glickman, then-head of the Motion Picture Association, recommended that advocates of stronger intellectual property rights underscore the danger of counterfeited and pirated goods.⁴⁶ Through fear mongering, intellectual property enforcement agenda advocates are constructing a big tent that includes all types of intellectual property: trademarks, patents, and copyrights. As Haunss and Kohlmorgen suggest:

The criminality issue functions as a master frame that unites diverse interests of the music and film industry, large software firms (esp. Microsoft) and luxury goods manufacturers. The argument . . . is about fighting product piracy and that . . . [it] is necessary to protect consumers from counterfeit goods.⁴⁷

Suddenly, spinning intellectual property enforcement as a consumer protection issue is fascinating. Given the extent to which overly strong property rights and rampant rent-seeking in the pharmaceutical industry are often understood to deny consumer access to things consumers actually need to live, there is a bit of the Alice Through the Looking-Glass quality (in which everything is backward) to this new tack. The 2007 G8 Heiligendamm official declaration stated that, “The protection of IPRs is of core interest for consumers in all countries, particularly in developing countries”; this is rather ironic given the whole access to medicines controversies in the Global South.⁴⁸

Despite the very real differences between all the types of intellectual property—copyright, patent, and trademark—contained in the intellectual property enforcement agenda’s “big tent” approach, there is one thing that Kate Spade bags, copyrighted software, games, music and movies, and patented pharmaceuticals do have in common, and that is high prices.⁴⁹ High prices are

⁴⁵ INTERNATIONAL ANTI-COUNTERFEITING COALITION, WHITE PAPER: THE NEGATIVE CONSEQUENCES OF INTERNATIONAL INTELLECTUAL PROPERTY THEFT: ECONOMIC HARM, THREATS TO THE PUBLIC HEALTH AND SAFETY, AND LINKS TO ORGANIZED CRIME AND TERRORIST ORGANIZATIONS (2005), available at <http://counterfeiting.unicri.it/docs/International%20AntiCounterfeiting%20Coalition.White%20Paper.pdf>; Haunss & Kohlmorgen, *supra* note 43.

⁴⁶ Glickman was the keynote speaker at this event in Washington, DC at The Federalist Society offices at which I also was a speaker.

⁴⁷ Haunss & Kohlmorgen, *supra* note 43, at 14.

⁴⁸ *Id.*

⁴⁹ MEDIA PIRACY IN EMERGING ECONOMIES (Joe Karaganis ed., 2011) [hereinafter MPEE].

directly related to the demand for counterfeit products. This campaign is characterized by strategic obfuscation; its message is intentionally misleading. For example, it is difficult to imagine a “dangerous” counterfeit handbag, or a “dangerous” DVD. Even more baffling are references to the dangers of “counterfeit cigarettes” to public health!⁵⁰ Consumers must be protected to ensure access to the real fatal stuff, not the fake fatal stuff!

The Motion Picture Association (MPA) and the Recording Industry Association of America (RIAA) have pushed hard for the intellectual property enforcement agenda. While the first line of attack appeared to be copyrights and trademarks, patents are not far behind. Kevin Outterson and Ryan Smith have provided a careful analysis of the deliberate rhetorical obfuscation over “counterfeit” drugs.⁵¹ The authors point out not only that the evidence for counterfeit drugs is anecdotal rather than empirical, but also that the only comprehensive collection point for global data on counterfeiting is the Pharmaceutical Security Institute—a trade organization created by the security directors of fourteen global drug companies—that does not make its data available to the public.⁵² Furthermore, they point out that, “the terms fake or counterfeit have included a wide range of drug products, from those resulting in criminal acts of homicide, to placebos, to safe and effective drugs from Canada.”⁵³ The consumer safety issue actually is far narrower and should be restricted to “contaminated products peddled by criminal gangs.”⁵⁴ No consumer advocates want tainted or deliberately toxic counterfeit drugs. All the misleading data and rhetoric is geared towards winning broad political support for much more stringent IP enforcement measures.

By casting this wide rhetorical net, global pharmaceutical companies hope to curtail drug importation from Canada, parallel importation, and the TRIPS-compliant use of compulsory licenses—three important avenues for increasing access to essential medicines. In a thinly veiled reference to TRIPS-compliant compulsory licensing of drugs (think Thailand), David Chavern, United States Chamber of Commerce Vice President, noted that a broad and “disturbing

⁵⁰ INTERNATIONAL ANTI-COUNTERFEITING COALITION, *supra* note 45.

⁵¹ Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, the Bad, and the Ugly*, 16 ALB. L.J. SCI. & TECH. 525 (2006). For studies that rely on industry-generated figures and narratives, see Amy Bunker, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 493 (2007); Candace S. Friel, *The High Cost of Global Intellectual Property Theft: An Analysis of Current Trends, the TRIPS Agreement, and Future Approaches to Combat the Problem*, 7 WAKE FOREST INTELL. PROP. L.J. 209 (2007); Bradley Olson et al., *The 10 Things Every Practitioner Should Know about Anti-Counterfeiting and Anti-Piracy Protection*, 7 J. HIGH TECH. L. 106 (2007); Cortney M. Arnold, *Protecting Intellectual Property in the Developing World: Next Stop – Thailand*, 2006 DUKE L. & TECH. REV. 10; Bryan Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279 (2006).

⁵² Outterson & Smith, *supra* note 51, at 526–27.

⁵³ *Id.* at 530.

⁵⁴ *Id.* at 534.

trend is essentially the expropriation of intellectual property by governments with support of NGOs, with noble-sounding reasons why they're doing it, but ultimately with the same effect [as counterfeiters and pirates] – crush the innovative engine, not only of our economy, but ultimately of the worldwide economy.”⁵⁵

Furthermore, films and music, and even apparel, do not fit in to the “danger” trope, even though U.S. State Department ads about dangerous counterfeits (e.g. pills, exploding cell phones, faulty electrical cords, failing car brakes, and DVDs?!) include images of DVDs. Also, it is reasonable to assume that Microsoft would prefer that poor people use bootleg Microsoft software rather than Linux, in order to get them hooked on the Windows platform.⁵⁶ Monsanto just might not mind the unauthorized transfer of GMO seeds across borders from Argentina to Brazil to circumvent biosafety regulations, because once the proverbial cat is out of the bag it is hard to go back.⁵⁷

Hypocrisy is also evident in the narrative that counterfeiters cause injury.⁵⁸ According to the USPTO-commissioned study on the subject, governments are obligated to protect public health. Yet IP enforcement agenda advocates actively oppose government efforts to protect public health when it comes to compulsory licensing and parallel imports, even when millions of patients are at risk of death.

The big tent approach to “counterfeiting” and “piracy” is designed to capture behavior that is legal.⁵⁹ Indeed, Drahos warns of the dangers of complex implementation measures that involve self-interested interpretation; this framework offers potential for abuse.⁶⁰ It is allowing proponents to construct a multi-pronged attack on the access to knowledge and development agendas.⁶¹ The U.S. seeks to undo developing countries’ abilities to issue compulsory licenses. The EU’s Cariforum Economic Partnership Agreement

⁵⁵ Phillip Kurata, “Business Experts call for Intellectual Property Protection” March 27, 2008. ARCHIVES, US EMBASSY MONTEVIDEO, available at <http://archives.uruguay.usembassy.gov/usaweb/2008/08-192EN.shtml>.

⁵⁶ Carlos A. Osorio, *A Contribution to the Understanding of Illegal Copying of Software: Empirical and Analytical Evidence Against Conventional Wisdom* (Mass. Inst. Tech., Center Tech., Pol’y & Indus. Dev. Working Paper) (June 2002), available at <http://dspace.mit.edu/handle/1721.1/1479>.

⁵⁷ Peter Newell, *Technology, Food, Power: Governing GMOs in Argentina*, in CORPORATIONS IN AGRIFOOD GOVERNANCE 283 (Doris Fuchs & Jennifer Clapp eds., 2009).

⁵⁸ MICHELE FORZLEY, INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, COUNTERFEIT GOODS AND THE PUBLIC’S HEALTH AND SAFETY 32, available at [http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/public%20health%20and%20safety\(1\).pdf](http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/public%20health%20and%20safety(1).pdf).

⁵⁹ Essential Action Comments on the Anti-Counterfeiting Trade Agreement, Posting of Peter Maybarduk to <http://lists.essential.org/pipermail/ip-health/2008-March/012375.htm> (Mar. 21, 2008, 5:53:22 PM).

⁶⁰ Peter Drahos, *Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines*, 28 LIVERPOOL L. REV. 11 (2007).

⁶¹ ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY (Gaelle Krikorian and Amy Kapczynski eds. 2010), available at http://www.zonebooks.org/titles/KRIK_ACC.html.

(EPA) transfers European Intellectual Property standards to ACP countries, extending rights of complainants to access private information such as banking records and to have goods seized.⁶² Complainants may pursue injunctions against some intellectual property uses without needing to prove harm. Third party intermediaries, who are not they themselves infringers, are targeted. The EPA includes no limitations and exceptions to protect defendants. Like most of the intellectual property enforcement agenda, it is one-sided in favor of rights-holders.

V. VERTICAL FORUM SHIFTING 3.0: TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS

Any hopes that access campaigners may have had that President Barack Obama would break the bi-partisan upward intellectual property ratchet certainly have been dashed. From the Group of 8 meetings to the FTAs, ACTA, and TPP, and to the appointment of an “IP Czar” (former USTR for intellectual property, Victoria Espinel), Obama has proven to be fully on board with an intellectual property maximalist agenda. In a striking case of *déjà vu*, he has resuscitated all the 1980s rhetoric about jobs and competitiveness and innovation as justification for negotiating non-transparently both ACTA and TPP. This 1980s trope brought us TRIPS and unprecedented private sector influence on trade negotiations.

Obama is channeling 1980s rhetoric about competitiveness and jobs; he has renamed The President’s Economic Recovery Advisory Board as the President’s Council on Jobs and Competitiveness. Jeff Kindler, Chairman and CEO of Pfizer, Inc., has resuscitated the simple formula that his predecessors advocating for TRIPS emphasized: “The protection of intellectual property equals innovation. Innovation equals competitiveness. Competitiveness equals jobs.”⁶³ In the 1980s, Japan was the bugbear, in the twenty-first century it is China.

Furthermore, Obama has “bought” the intellectual property maximalists’ arguments and promoted them internationally, despite the fact that his own government has found them factually wanting. For example, the content industry argues that copyright piracy causes grievous harm to the American economy. Congress asked the Government Accounting Office to come up with hard numbers to back up these claims. On April 13, 2010, the U.S. Government Accounting Office (GAO), which, under the PRO-IP Act of

⁶² DALINDYEBO SHABALALA, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, INTELLECTUAL PROPERTY IN THE EUROPEAN UNION: ECONOMIC PARTNERSHIP AGREEMENTS WITH THE AFRICAN, CARIBBEAN AND PACIFIC COUNTRIES: WHAT WAY FORWARD AFTER THE CARIFORUM EPA AND THE INTERIM EPAS?, *available at* http://www.ciel.org/Publications/Oxfa_m_TechnicalBrief_5May08.pdf.

⁶³ Kindler testimony, *supra* note 3.

2008,⁶⁴ had been asked to provide quantitative estimates of the losses to the U.S. economy from copyright piracy, issued a devastating report that cast significant doubt upon the industry figures and substantially reduced the credibility of arguments behind ACTA.⁶⁵

Not only did the government's *own* report undercut the empirical basis for U.S. foreign economic policymaking in intellectual property, it also suggested that copyright piracy can offer benefits to consumers. Furthermore, countering industry claims that the lost billions are truly "lost," the GAO report pointed out that this money is not lost, but rather re-allocated to different sectors of the economy. The money that people save by buying "fake" Kate Spade bags gets spent on food, or education, or health care. These expenditures help to provide "Main Street" jobs for Americans.⁶⁶ In a particularly telling exchange in the report, an industry representative stated that the most important issue was not lost profits, but rather lost intellectual property rights. The representative stated that these losses mean that someone else can make the item cheaper, or better.⁶⁷

Yet that is the very basis of capitalism—creative destruction and competition. This was a stark, albeit unwitting, admission that ACTA really is about stifling competition and permitting continued rent seeking by firms with threatened business models. In response, the USTR has chosen to ignore the GAO report and continue to repeat the industry arguments. Joe Karaganis, while at the Social Science Research Council, conducted a multi-country study on copyright piracy and found similar results and also found many instances in which piracy had spurred local innovation.⁶⁸

Until ACTA drafts were leaked on the Internet, the negotiating process kept the public in the dark. While luxury brand name, pharmaceutical, and entertainment industries remained fully involved and informed in the negotiations, two public interest groups—Public Knowledge (PK) and the Electronic Frontier Foundation (EFF)—unsuccessfully sued USTR for access to negotiation documents under the Freedom of Information Act. In 2009, the Obama administration classified ACTA as a national security issue, so PK and EFF dropped the lawsuit.

The negotiations on a Trans-Pacific Partnership Agreement demonstrate that ACTA does not go nearly far enough in ratcheting up intellectual property standards to suit the interests of American rights holders. In 2010, the TPP negotiators met formally four times to proceed with negotiating an agreement

⁶⁴ PRO-IP Act, H.R. 4279, 110th Cong. (2007). The MPA and RIAA pushed for this law May 2, 2008. The bill would create a new copyright enforcement division within the U.S. Department of Justice and permit law enforcement agents to seize property from copyright infringers.

⁶⁵ GOVERNMENT ACCOUNTABILITY OFFICE, INTELLECTUAL PROPERTY: OBSERVATIONS ON EFFORTS TO QUANTIFY THE ECONOMIC EFFECTS OF COUNTERFEIT AND PIRATED GOODS, GAO-10-423 (2008) [hereinafter GAO REPORT].

⁶⁶ I thank Varun Piplani for this point.

⁶⁷ GAO REPORT, *supra* note 65, at 12.

⁶⁸ MPEE, *supra* note 49.

between the U.S., Australia, New Zealand, Chile, Brunei, Singapore, Peru, Vietnam, and Malaysia. A December 2010 leaked document enumerated the business coalition's goals for the TPP.⁶⁹ Using the U.S.–Korean FTA as a baseline, the TPP would limit the abilities of governments to engage in reference pricing for pharmaceuticals. The industry coalition presents cost containment policies for drug pricing as non-tariff barriers. The industry statement states that the TPP should provide that “IP rights should not be undermined by other government pricing and regulatory mechanisms that significantly devalue IP protection.”⁷⁰ This language alludes to mechanisms such as cost-effectiveness research and reference pricing systems.⁷¹ The U.S.–New Zealand FTA, for example, addresses access to “cost effective” medicines. For the TPP, PhRMA has proposed replacing “cost effective” with “effective and innovative.”⁷²

PhRMA has never been happy with the May 2007 U.S. congressional rolling back of some of the health-related FTA provisions, such as data exclusivity and patent registration linkage. Pfizer CEO Jeff Kindler complained that the May 2007 agreement weakened intellectual property rights in the pharmaceutical sector in ways that make it more difficult to compete.⁷³ Thus, it is no surprise that the business coalition is seeking to undo these changes in the TPP. In January 2011, *Inside US Trade* reported that the U.S. has not yet come to an internal resolution on how to handle the May 2007 IPR deal on FTAs.⁷⁴

While the TPP process has also been non-transparent, if ACTA is any indication, it is likely that much of industry's wish-list will be included in U.S. negotiating proposals. ACTA-plus provisions on that wish list include: banning camcording in theaters; insisting on full reproduction rights for temporary copies online (so-called cache copies); permitting trademark owners to seek cancellation of a mark that is identical or similar to a well-known mark (e.g., eliminating an important consumer signal for house brands like CVS' versions of Sudafed or Nyquil); giving customs officers *ex officio* powers and the ability to seize goods in transit (e.g., the Indian generic drugs seized in Rotterdam); requiring full implementation of the WIPO Internet Treaties; and making sure

⁶⁹ IP Task Force of the U.S. Business Coalition for the Trans-Pacific Partnership Agreement, TPP Intellectual Property Negotiations (2010) (leaked paper), available at <http://keionline.org/sites/default/files/Business%20Coalition%20Letter.doc>. The coalition includes Citibank, CropLife America, Pfizer, Cargill, the MPAA, the Coalition of Services Industries, the National Association of Manufacturers, IBM, Phillip Morris, and GlaxoSmithKline.

⁷⁰ *Id.* at 2.

⁷¹ Thomas Faunce & Ruth Townsend, *The Trans-Pacific Partnership Agreement: Challenges for Australian Health and Medicine Policies*, 194 MED. J. AUSTL. 83, 83 (2011).

⁷² *Id.* at 83–86.

⁷³ Kindler testimony, *supra* note 3.

⁷⁴ *U.S. to Hold Off on Tabling IPR Text at next TPP Round*, INSIDE U.S. TRADE, Jan. 14, 2011. It also reported that it had yet to resolve internal positions on secondary liability for ISPs.

that doctors and health care providers “have the freedom to prescribe medications that best address patients’ needs.”⁷⁵

Already, one TPP negotiating partner, New Zealand, has raised profound objections to the TPP. New Zealand is pushing back hard to prevent TRIPS-plus provisions from ending up in the final agreement. As a net technology importer, New Zealand shares the concerns of many developing countries about the implications of TRIPS-plus provisions for their ability to innovate, acquire goods affordably, and utilize TRIPS flexibilities for economic development. New Zealand also strongly objects to the inclusion of the WIPO Internet treaties in the TPP, suggesting that copyright issues in the digital environment are at an early stage of norm development, and “the treaties have limited ability to recognize the reality of emerging new business models and new ways of consuming creating works via the Internet.”⁷⁶

The TPP negotiations highlight some sharp inconsistencies in the Obama administration’s approach to health care issues. On the one hand, it appears to be negotiating an ACTA-plus agreement that would eliminate many TRIPS flexibilities and raise the costs of drugs. Domestically, Obama has made health care cost containment a centerpiece of his legislative agenda. This inconsistency has not been lost on state governments. On Friday, January 21, 2011, the National Legislative Association on Prescription Drug Prices (NLARx) issued a resolution opposing the inclusion of a pharmaceutical chapter in the TPP. Representing cash-strapped state governments, NLARx urged the USTR to stop considering pharmaceutical reimbursement programs within Special 301 annual reviews, and to omit any pharmaceutical reimbursement programs from the TPP and any future or pending FTA.⁷⁷ The legislators argued that any proposals to limit foreign reimbursement programs would be likely to lead to foreign pressure to limit such programs in the U.S. If such limits were to be applied to Medicaid and other state programs, this would hamper states’ efforts to contain medical costs.⁷⁸

On the other hand, USTR Ron Kirk has expressed support for Pfizer’s proposal to require limits on pharmaceutical reimbursement programs (e.g., preferred drug lists (PDL)) both domestically and abroad.⁷⁹ PDLs routinely are used in Medicare drug programs, public programs, and veterans’ hospitals. As

⁷⁵ TPP Intellectual Property Negotiations, *supra* note 13.

⁷⁶ New Zealand Intellectual Property Chapter, Horizontal Issues/Overall Structure, General Provisions and Cooperation (2010) (leaked document), *available at* <http://www.citizen.org/documents/NZleakedIPpaper-1.pdf>.

⁷⁷ National Legislative Association on Prescription Drug Prices, *Resolution Opposing the Inclusion of a Pharmaceuticals Chapter in the Trans-Pacific Partnership*, Jan. 21, 2011, *available at* <http://forumdemocracy.net/article.php?id=570>.

⁷⁸ *Id.*

⁷⁹ Ron Kirk, United States Trade Representative, Remarks at the Global Intellectual Property Center Annual Summit (Sept. 30, 2009), *available at* <http://74.10.93.59/about-us/press-office/spceches/transcripts/2009/september/remarks-ambassador-ron-kirk-global-intelle>.

Sharon Treat, NLARx's Executive Director, stated: "At a time when health budgets everywhere are strapped, the U.S. should not be promoting a new global regulatory agenda that would attack the most effective tools we have to combat excessive medicine prices in our health programs."⁸⁰ In response to U.S. concerns about having the highest drug prices in the world, PhRMA seeks to get others to pay higher prices by eliminating reference pricing and caps on PDL drugs in the TPP.

The Obama administration continues to demonstrate inconsistency in its approach to PhRMA. A leaked industry letter outlining its goals for the TPP, representing PhRMA and MPAA, reminds the USTR that, "strong patent protection fosters innovation."⁸¹ Yet on January 23, 2011, the *New York Times* reported that the Obama administration has decided to create a billion-dollar drug development center in the National Institutes of Health (NIH) to fill the need for new medicines. Despite very high levels of patent protection in the U.S., the non-generic pharmaceutical industry's "research productivity has been declining for 15 years."⁸² At the very least, this suggests that PhRMA's business model—spending twice as much on marketing as it does on research—is questionable and that the correlation between patents and innovation may be completely spurious in the contemporary context. Thus while Obama is pushing PhRMA's preferences internationally, he recognizes some serious problems with them at home. Many see the PhRMA model as broken and many organizations are advocating new models for innovation in medicine, such as patent pools (UNITAID) and prize funds (KEI).

Finally, many TRIPS-plus and ACTA-plus advocates are wrapping their cause in the mantle of consumer safety. This can be comical, especially when the consumer advocate is Phillip Morris! However, a devastating investigative report in *Vanity Fair* has exposed dangerous cost-saving practices of brand name pharmaceutical firms. The report documents a sharp spike in the number of clinical trials conducted abroad. The inspector general for the Department of Health and Human Services found that, in 2008 alone, "80 percent of the applications submitted to the F.D.A. for new drugs contained data from foreign clinical trials. Increasingly, companies are doing 100 percent of their testing offshore."⁸³ According to the report, companies contract out the clinical trials and favor testing on poor, illiterate populations in countries with lax regulations and virtually no risk of litigation if something goes horribly wrong. China and

⁸⁰ Sean Flynn, *U.S. Legislators Call for Halt of Trade Restrictions on Pharmaceutical Pricing*, INFOJUSTICE.ORG, <http://infojustice.org/archives/910>.

⁸¹ IP Task Force of the U.S. Business Coalition for TPP, *Key Goals and Objectives (Draft)*, available at <http://www.wcl.american.edu/pijip/download.cfm?downloadfile=469D4589-E11E-18EE-A21EB9A1630511EC&typename=dmFile&fieldname=filename>.

⁸² *Id.*

⁸³ Donald Bartlett & James Steele, *Deadly Medicine*, VANITY FAIR, Jan. 2010, available at <http://www.vanityfair.com/features/2011/01/deadly-medicine>.

India are major sites of such clinical trials, with 1,861 and 1,457 clinical trials respectively. Companies are not required to report, and often do not report, all of the clinical trials that they conduct abroad. Dangerous drugs, such as Pfizer's Celebrex and Sanofi-Aventis' Ketek, won FDA approval based on foreign clinical trials. One U.S. researcher working on Ketek went to jail for fifty-seven months for falsifying her data. Bartlett and Steele point out that now, with widespread private outsourcing of clinical trials,

The people doing the work on the front lines are not independent scientists. They are wage-earning technicians who are paid to gather a certain number of human beings; sometimes sequester and feed them; administer certain chemical inputs; agribusiness, not research.⁸⁴

The article further underscores why Pfizer and the Business Coalition for the TPP are adamant that doctors shall retain the freedom to prescribe the drugs that they deem best. As Bartlett and Steele state: "Doctors who insist the drug you take is perfectly safe may be collecting hundreds of thousands of dollars from the company selling the drug."⁸⁵ Furthermore, "the economic incentives for doctors in poor countries to heed the wishes of the drug companies are immense. . . . In Russia a doctor makes two hundred dollars a month, and he is going to make five thousand dollars per Alzheimer's patient that he signs up."⁸⁶

Cataloging a number of conflicts of interests and perverse outcomes, the authors report that, in 2009, 19,551 people died in the U.S. as a direct result of the prescription drugs they took, according to the Institute for Safe Medication Practices.⁸⁷ They claim that, since only an estimated 10% of such deaths get reported, a conservative annual estimate of deaths from FDA-approved prescription drugs considered to be "safe" is about 200,000.⁸⁸ These deaths outnumber those deaths due to traffic accidents, street drug use, diabetes, and kidney disease. So, when Jeff Kindler testifies before the Senate Finance Committee to express his concern over counterfeiters who have concocted the drugs "in a dirty basement somewhere in a part of the world that lacks the strong safety system of the United States,"⁸⁹ and expresses his alarm and anguish over the 800 Americans who became "violently sick" from tainted Chinese heparin, one would like to ask him about Pfizer's outsourcing of its

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Kindler testimony, *supra* note 3.

clinical trials and ask him where his anguish is over the 200,000 Americans who die annually from these badly regulated products.⁹⁰

VI. VERTICAL FORUM SHIFTING 4.0: GOING GRANULAR

“Going granular” allows the more powerful actors to increasingly exploit resource and power disparities as the arena becomes more localized; like an arrow shot vertically, it becomes sharper and more effective as it hits the ground. Not only states participate; private actors such as pharmaceutical corporations have taken foreign governments to court, sued developing country regulators, and directly threatened patient groups. Sub-state actors, such as aid agencies providing technical assistance, have offered highly skewed interpretations of what is permissible under international law.⁹¹ Invariably, technical assistance has provided TRIPS-plus interpretations and provisions.

Going granular and ground-level infiltration can refer to processes as insidious as having brand-name pharmaceutical representatives engage with patient groups to convince them that generic versions of drugs are “substandard” or dangerous, leading to the perverse result that impoverished patients reject their doctors’ prescriptions for affordable high quality generic versions of drugs in favor of high-priced brand-name drugs. Sub-state providers of technical assistance—such as OECD patent offices—have also cultivated what Peter Drahos refers to as “technocratic trust,”⁹² and what Jason Sharman has referred to as “negative shaming,”⁹³ which, in essence, are the carrot and stick of the process. The purpose is to get states to adopt and implement wildly inappropriate and potentially damaging policies that only benefit the rights holders, and to discourage behavior that seeks to exercise flexibilities in IP policy that help both the poor and consumers in general.

Vertical forum shifting may lead actors to deploy law in ways that reinforce, deepen, and exacerbate inequities—particularly between the OECD and the global south in the area of intellectual property. Several brand name pharmaceutical firms have shocked some observers by bullying patients, AIDS NGOs, and particular individuals. The following sections look at four cases: Novartis’ targeting of leukemia patients in South Korea, Abbott Laboratories’ threatening legal action against ACT-UP Paris, Pfizer’s aggressive lawsuits against two *individuals* in the Philippines, and a successful PhRMA campaign to demote an international civil servant.

⁹⁰ *Id.*

⁹¹ DEERE, *supra* note 11.

⁹² DRAHOS, *supra* note 24.

⁹³ Jason Sharman, *Power and Discourse in Policy Diffusion: Anti-Money Laundering in Developing States*, 52 INT’L STUD. Q. 635 (2008).

A. GOING AFTER PATIENTS AND CUSTOMERS

A particularly pernicious example of going granular is the Gleevec case in South Korea. Gleevec is a leukemia drug that was developed with assistance from the U.S. Orphan Drug Act, under which the U.S. government paid for 50% of the private sector costs of clinical trials.⁹⁴ Swiss drug maker Novartis owns the patent. The drug costs roughly \$27,000 per year per patient in the U.S., keeping it out of reach of most. In late 2001, Novartis suspended the supply of Gleevec to South Korea because Novartis failed to get the price it sought from the South Korean government. The U.S., Switzerland, and Japan had accepted the price of \$19.50 (U.S.) per pill⁹⁵ during the Novartis-South Korean negotiations.

Novartis directly approached Korean leukemia patients, offering them a co-payment exemption if they would convince the South Korean government to accept that price. The patients refused. Rather than negotiating a lower price, the South Korean government sought to contain costs by excluding chronic phase chronic myelogenous leukemia (CML) patients from insurance coverage. Hae-joo Chung, Director of Equipharm project, issued a plea, on behalf of the People's Health Coalition for Equitable Society, to global consumer and health groups to endorse its quest to get the South Korean government to restart negotiations with Novartis and resume supply—even if it meant resorting to compulsory licensing in line with the Doha Declaration on TRIPS and Public Health.⁹⁶ These health groups appealed to the Korean Intellectual Property Office and requested adjudication for the grant of a non-exclusive license to import generic Gleevec from India for the public interest because unstable supplies and high prices imperiled Korean CML patients.⁹⁷

While Novartis is a Swiss company, the USTR supported Novartis in this case. Facing declining profitability in the European market, makers of potentially high profit drugs like Gleevec are turning to emerging middle-income markets in Asia and Latin America to make up the difference.⁹⁸ In order to ensure the success of this strategy, they must fend off generic challengers in these markets. As Benevisti and Downs suggest, the USTR intervened on behalf of Novartis in order to “prevent a precedent that might eventually damage the profitability of products manufactured by its own firms.”⁹⁹ Indeed, the Korean decision to reject the generic importation option under compulsory license incorporated the very language that USTR Robert

⁹⁴ Call for Endorsements on Glivec [sic] from South Korea, Posting of Paul Davis to <http://lists.essential.org/pipermail/ip-health/2001-November/002490.html> (Nov. 30, 2001 17:41:40 EST).

⁹⁵ Daily dosages range from four to eight pills.

⁹⁶ Call for Endorsements, *supra* note 94.

⁹⁷ Text of Korean Decision in Glivec Case, Posting of James Love to <http://lists.essential.org/pipermail/ip-health/2003-March/004482.html> (Mar. 10, 2003 10:32:23 EST).

⁹⁸ *New Clothes*, *supra* note 9.

⁹⁹ *Id.*

Zoellick had been promoting in his original efforts to limit the scope of the 2001 Doha Declaration on TRIPS and Public Health. The Korean government denied the petition on the grounds that CML was neither “infectious” nor likely to cause “an extremely dangerous situation in our nation.”¹⁰⁰ As James Love of CpTech¹⁰¹ remarked, “the U.S. government does not control the price of drugs in its own country but it is telling Korea what they should charge.”¹⁰²

This example highlights the intrusive reach of what Drahos calls the “nodal enforcement pyramid” that global intellectual property-based firms and their governments deploy.¹⁰³ Asymmetrical power relations and the political influence of global high-technology and content intellectual property-based industries continue to shape intellectual property policy. Given the expansion of intellectual property rights and unequal distribution of economic and political power across the globe, developing countries face new challenges in navigating the system to their benefit.

B. GOING AFTER HIV/AIDS ACTIVISTS

In early 2007, Abbott Laboratories threatened to withdraw all of its pending drug applications in Thailand, after Thailand announced plans to issue compulsory licenses for several drugs, including the heat stable HIV/AIDS drug Kaletra.¹⁰⁴ Thai AIDS patient groups appealed to ACT-UP Paris to protest Abbott’s actions by attacking Abbott’s web site. ACT-UP Paris posted a link on its website that protestors could click on to overwhelm Abbott’s server on the eve of its annual shareholder meeting.¹⁰⁵ On May 23, 2007, Abbott filed suit in France, charging ACT-UP Paris with launching a cyber attack on Abbott’s website.¹⁰⁶ This abruptly broke a long-standing taboo against harassing AIDS patient groups. As Justine Frain of GlaxoSmithKline PLC pointed out, “early on we realized it was important to work with the activist groups.”¹⁰⁷

Other pharmaceutical executives indicated that Abbott’s actions regarding Thailand were a public relations disaster for the industry as a whole. ACT-UP Paris defended its actions as the lawful exercise of free speech. While Abbott

¹⁰⁰ Text of Korean Decision, *supra* note 97; see also Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 328 (2005).

¹⁰¹ Now named Knowledge Ecology International (KEI).

¹⁰² *Distributive Politics*, *supra* note 14.

¹⁰³ Peter Drahos, *Securing the Future of Intellectual Property: Intellectual Property Owners and their Nodally Coordinated Enforcement Pyramid*, 36 CASE W. RES. J. INT’L L. 53 (2004).

¹⁰⁴ *Abbott Blockade against Thailand: People with HIV/AIDS invite CEO to Crisis Resolution Meeting*, WALL ST. J., July 16, 2007.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

eventually withdrew the lawsuit, its public reputation was in tatters. Furthermore, Abbott refused to reverse its “deadly blockade of its lifesaving HIV medication Aluvia,”¹⁰⁸ underscoring the withholding power of patent owners. And, in April 2007, the USTR named Thailand to its Section 301 Watch List on the basis of its TRIPS-compliant compulsory licensing activity.

C. GOING AFTER REGULATORS PERSONALLY

Brand-name pharmaceutical firms have continued to engage in aggressive tactics in developing countries. While the 1998 South African case in which brand name pharmaceutical firms sued Nelson Mandela is well known,¹⁰⁹ an ongoing case in the Philippines demonstrates that these tactics persist. Pfizer is suing the Philippine government for parallel importation of Norvasc, a high blood pressure treatment. In the Philippines, this product is only available from Pfizer. There, the Pfizer drug costs twice as much as it does in Indonesia and Thailand. India sells the drug for 650% less than the Philippine price. The Philippines imported and registered, but did not market, 200 tablets of the patented drug from India.¹¹⁰ The Bureau of Food and Drug (BFAD) provided Pfizer with written assurances that it would not market the drug until Pfizer’s patent expired. Pfizer charged the government with infringement and not only sued the BFAD and Philippine International Trading Corporation (PITC) but is also sued BFAD Director Leticia Barbara Gutierrez and Emilio Polig (a BFAD officer) for damages.

Pfizer claims that it is acting to protect its patent; it denies that it is a parallel importation case because Pfizer does not believe that the Indian supplier was a Pfizer-authorized source. PITC filed a countersuit against Pfizer. Stanford alumni and graduate students launched a signatory campaign to remove Pfizer CEO Henry McKinnell from the Stanford Advisory board over Pfizer’s “bullying” of Philippine government drug regulators.¹¹¹ In attacking portions of the 2006 WHO Commission on Intellectual Property, Innovation, and Public Health report, Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers & Associations argued that the report repeated the “myth that patents give the power to set prices.”¹¹² He went on to state that

¹⁰⁸ *Abbott Drops Lawsuit, Maintains Deadly Blockade, European Aids Treatment Group*, GLOBAL HIV NEWS, July 22, 2007, available at <http://www.eatg.org/eatg/Global-HIV-News-archive/Abbott-dro=ps-lawsuit-maintains-deadly-blockade>.

¹⁰⁹ Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians*, 29 INT’L J. HEALTH SERV. 765 (1999).

¹¹⁰ *Pfizer Fights IP Flexibilities in the Philippines*, INTELL. PROP. WATCH, Apr. 30, 2006, available at <http://www.ip-watch.org/weblog/2006/04/30/pfizer-fights-ip-flexibilities-in-the-philippines>.

¹¹¹ *Id.*

¹¹² Eric Noehrenberg, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health: an Industry Perspective*, 84 BULLETIN WORLD HEALTH ORG. 419 (2006); World Health Organization Commission on Intellectual Property Rights, Innovation, and Public Health, *Report*

“such a misrepresentation ignores the effect of competition between drugs.”¹¹³ However, in the Philippines case, it is precisely the *lack* of competition that has caused the problem. Pfizer sought to prevent, or at least delay, competition.

This behavior clearly poses dangers to public health. Expanded intellectual property rights, economic concentration, and strong-arm tactics against vulnerable populations add up to a dangerous situation. These cases highlight the vulnerabilities associated with relying only on the decisions of private companies. As Drahos and Braithwaite conclude:

Patent-based R&D is not responsive to demand, but to ability to pay. . . . Much of what happens in the . . . health sectors of developed and developing countries will end up depending on the bidding or charity of biogopolists as they make strategic commercial decisions on how to use their intellectual property rights.¹¹⁴

D. GOING AFTER AN INTERNATIONAL CIVIL SERVANT¹¹⁵

Thailand is another noteworthy site of resistance to the one-way TRIPS-plus ratchet. Thailand was one of the first to suffer in the HIV/AIDS pandemic and the U.S. has targeted Thailand as a culprit in numerous trade disputes over intellectual property and pharmaceuticals. PhRMA consistently has complained about Thailand and the USTR placed Thailand on its Section 301 Watch List every year between 1996 and 2000.¹¹⁶ In 2001, Thai activists challenged Bristol-Myers Squibb over its antiretroviral drug didanosine (DDI) because the public, taxpayer funded, U.S. National Institutes of Health (NIH) developed the drug. That same year, the U.S. threatened to impose trade sanctions against Thailand if it pursued compulsory licensing to produce DDI. As Dylan Williams states:

In 2002, a Thai court cited international statutes when it ruled that Thai HIV/AIDS patients could be injured by patents and had legal standing to sue if drug makers holding patents restricted

on Public Health, Innovation, and Intellectual Property (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

¹¹³ Noehrenberg, *supra* note 112.

¹¹⁴ PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 167–78 (2002).

¹¹⁵ This section is drawn from Susan Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL L. REV. 41 (2007), and Susan Sell, *Business and Democracy? Pharmaceutical Firms, Intellectual Property, and Developing Countries*, in *THE CHALLENGE OF GLOBAL BUSINESS AUTHORITY: DEMOCRATIC RENEWAL, STALEMATE, OR DECAY?* 145 (Tony Porter & Karsten Ronit eds., 2010).

¹¹⁶ SELL, *supra* note 2, at 128.

the availability of drugs through their pricing policies. This verdict was upheld in January 2004.¹¹⁷

Bristol Myers Squibb settled out of court, surrendering its version of the drug to the Thai Department of Intellectual Property.

The U.S. had been trying to negotiate a U.S.-Thailand FTA and these deliberations became embroiled in a national political crisis. In April 2006, “after one of the longest anti-government mobilizations in Thailand’s history,” care taker Prime Minister Thaksin Shinawatra relinquished his post.¹¹⁸ While initially protesters focused on Thaksin, the People’s Alliance for Democracy (PAD) expanded its attack to include the U.S.-Thailand FTA negotiations. In a non-transparent process, acting-Prime Minister Thaksin had been conducting these negotiations unilaterally without consulting Parliament.¹¹⁹ Eager to develop and expand Asian markets for its firms’ pharmaceutical products, the U.S. hoped that a U.S.-Thailand FTA would provide a template for similar deals with Malaysia and Indonesia.¹²⁰

On January 9, 2006, the chief American WHO representative to Thailand, Dr. William Aldis, published an opinion piece in the Bangkok Post warning Thailand about the high stakes involved in the U.S.-FTA negotiations. His op-ed appeared in the midst of the sixth round of U.S.-Thailand FTA negotiations in Chiang Mai. He wrote that:

If the outcomes of other US bilateral trade negotiations are anything to go by, Thailand may well be in for a rough ride. . . . To the surprise of many observers, these countries have bargained away reasonable flexibilities and safeguards in the implementation of intellectual property rights provided by the World Trade Organization.¹²¹

He went on to point out that, of the over 600,000 Thais living with HIV/AIDS, more than 80,000 have access to life-prolonging treatments “thanks to the supply of cheap locally produced generic drugs, and the target is 150,000 by 2008. As a result, Aids (sic) deaths in Thailand have fallen by an

¹¹⁷ Dylan C. Williams, *World Health: A Lethal Dose of US Politics*, ASIA TIMES, June 16, 2006, available at http://www.atimes.com/atimes/Southeast_Asia/HF17Ae01.html.

¹¹⁸ Jacques-chai Chomthongdi, *Thaksin’s Retreat: Chance for Change or Consolidation of Power?*, FOCUS ON THE GLOBAL SOUTH, Apr. 5, 2006, available at <http://focusweb.org/thaksins-retreat-chance-for-change-or-consolidation-of-power.html>.

¹¹⁹ Williams, *supra* note 117.

¹²⁰ *Id.*

¹²¹ William Aldis, *It Could Be a Matter of Life and Death: Thailand Should Think Carefully about Surrendering its Sovereign Right under WTO – and Access to Cheap Medicine – in Exchange for an FTA with the United States*, BANGKOK POST, Jan. 9, 2006, available at <http://www.aegis.org/news/bp/2006/BP060102.html>.

extraordinary 79%.”¹²² He concluded by stating that “giving up internationally agreed flexibilities in the implementation of intellectual property rights would put at risk the survival of hundreds of thousands of Thai citizens, and would likely bankrupt the 30 baht scheme in the process.”¹²³

In late March 2006, the late WHO director-general Lee Jong-wook¹²⁴ transferred Dr. Aldis from Bangkok to a research position in New Delhi. An *Asia Times Online* investigative report into this transfer revealed U.S. industry lobbying behind what amounted to a demotion. At the time of his death in May 2006, according to the report, “Lee had closely aligned himself with the US government and by association US corporate interests, often to the detriment of the WHO’s most vital commitments and positions, including its current drive to promote the production and marketing of affordable generic antiretroviral drugs.”¹²⁵ Lee recalled Dr. Aldis after serving just over 15 months in what is traditionally a four-year posting.¹²⁶ While a regional WHO official in New Delhi attributed Aldis’ removal to his “inefficiency,” “Thai officials who worked alongside him through the 2004 tsunami and on-going avian-influenza scare have privately contested this characterization.”¹²⁷

In fact, it appears that Dr. Aldis was being punished for his January op-ed opposing the TRIPS-plus provisions of the U.S.-Thailand FTA proposals. The British medical journal *The Lancet* implied as much in its June 2006 article, in which it characterized Dr. Aldis’ transfer as a direct result of the editorial and “a clear signal of US influence on WHO.”¹²⁸ Aldis was critical of the U.S. mixing of commercial and public-health agendas and “chafed at WHO regional headquarters’ instructions to receive representatives from US corporations and introduce them to senior Thai government officials to whom the private company representatives hoped to sell big-ticket projects and products.”¹²⁹ During the spring of 2006, long-time TRIPS advocates Pfizer and IBM requested WHO personnel in Thailand to facilitate access to senior Thai officials; “some senior WHO staff members have expressed their concerns about a possible conflict of interests, as the requested appointments were notably not related to any ongoing WHO technical-assistance program with the Thai government.”¹³⁰

On March 23, 2006, a U.S. ambassador to the U.N. in Geneva met with Lee privately and expressed concerns about Aldis’ editorial. “A follow-up letter

¹²² *Id.*

¹²³ *Id.* The 30 baht scheme refers to the inclusion of HIV treatment in Thailand’s 30 baht health care program, designed to contain costs and make essential medicines available to those in need.

¹²⁴ He died of a sudden brain hemorrhage on the eve of the WHA meeting in late May 2006.

¹²⁵ Williams, *supra* note 117.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ Paul Benkimoun, *How Lee Jong-wook Changed WHO*, 367 LANCET 1806 (2006).

¹²⁹ Williams, *supra* note 117.

¹³⁰ *Id.*

from the US government addressed to Lee impressed Washington's view of the importance of the WHO to remain 'neutral and objective' and requested that Lee personally remind senior WHO officials of those commitments."¹³¹ The next day Lee contacted the regional WHO New Delhi office and told it of his decision to recall Aldis.¹³² A Bangkok-based U.S. official leaked the news of Aldis' transfer. A senior WHO official believes that Lee's decision and the U.S. government's news leak were "specifically designed to engender more self-censorship among other WHO country representatives when they comment publicly on the intersection of US trade and WHO public-health policies."¹³³ Williams concludes that the Bush administration's tactics of trying to bring U.N. agencies into line with U.S. commercial and political interests came at the expense of the WHO's "stated mission, commitments and global credibility as an impartial and apolitical actor."¹³⁴

In the meantime, Suwit Wibulprasert, senior adviser to the Thai Public Health Ministry, requested that the WHO provide an explanation for Dr. Aldis' abrupt removal.¹³⁵ This issue sparked considerable consternation about the lack of transparency and suppression of freedom of speech for WHO employees, but remains unresolved. Subsequently, and in concordance with Aldis' judgment, the World Bank concluded that the U.S.-Thailand FTA would have severely restricted its ability to issue compulsory licenses and would have cost Thailand an extra \$3.2 billion over twenty years.¹³⁶

This case points in two directions. It demonstrates the power of citizen activism in protesting TRIPS-plus provisions and bottom-up efforts to alter the intellectual property policy landscape. Yet, it also reveals a disturbing anti-democratic pattern of business interests using non-transparent back channels to subvert more democratic processes and to impede openness and public debate.

XI. CONCLUDING THOUGHTS

Vertical forum shifting highlights the importance of the increasingly micro-level politics of intellectual property. More micro-level research will be important going forward. One question animating much of these politics is: how can developing countries be persuaded that the interests of U.S. intellectual property rights holders align with their own interests? Economic coercion has yielded some results, but the lack of enforcement suggests that this has not

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *String Pulling: Aldis Warned Against Thai-US Free Trade Pact*, BANGKOK POST, June 20, 2006, available at http://www.caramasia.org/index.php?option=com_content&task=view&id=176&itemid=1&date=2034-06-01.

¹³⁶ ANA REVENGA ET AL., *THE ECONOMICS OF EFFECTIVE AIDS TREATMENT: EVALUATING POLICY OPTIONS FOR THAILAND* (2006).

been fully effective. One mechanism could be “socialization by external inducements.”¹³⁷ As Morin suggests:

This socialization, originating from the institutionalized cooperation formalized in bilateral agreements, leads the elites of developing countries to believe that US norms are in their best interest. This change in belief can result from technical assistance, capacity-building programmes or the frequent contacts with foreign authorities that usually follow the signature of an FTA.¹³⁸

Both Carolyn Deere¹³⁹ and Peter Drahos¹⁴⁰ have led a fruitful research agenda exploring these very issues.

What are the prospects not merely for resistance but for the development of counter-regime norms that prioritize *access* to intellectual property? The technical assistance from WIPO and the WTO for developing countries is invariably TRIPS-plus, so potential counter-regime norms are undermined through these very powerful processes. However, a number of analysts offer a more nuanced assessment of the prospects for counter-regime norms. For instance, Gregory Shaffer and Mark Pollack highlight the recursive impact of the politics of implementation; as they state, “Existing international law may be ambiguous and . . . different interests hold power in domestic settings at the implementation stage.”¹⁴¹

Domestic actors then may interpret the law in a particular way that allows them to offer a new approach that others may choose to emulate. Rochelle Cooper Dreyfuss points out that not only can these new approaches be shared, but also that: “these practices achieve recognition as they are defended in international courts and put on the agendas of international organizations.”¹⁴² Amy Kapczynski calls this “counter-harmonization.”¹⁴³ For example, China, India, and Andean states have prior informed consent and access and benefit sharing in domestic law that reflects the more development-friendly Convention on Biological Diversity rather than TRIPS. India has introduced

¹³⁷ G. John Ikenberry & Charles A. Kupchan, *Socialization and Hegemonic Power*, 44 INT’L ORG. 283 (1990).

¹³⁸ Morin, *supra* note 3, at 178.

¹³⁹ DEERE, *supra* note 11.

¹⁴⁰ DRAHOS, *supra* note 24.

¹⁴¹ Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706, 784 (2010).

¹⁴² Rochelle Cooper Dreyfuss, *The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms & Intellectual Property and Intellectual Property Lawmaking* (IICJ Working Paper 2009).

¹⁴³ Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CAL. L. REV. 1571 (2009).

limits on patentable subject matter, has introduced a very high inventive step requirement for patent grants, and has included pre- and post-grant opposition provisions, limits on injunctive remedies, and strong patent misuse standards. The Philippines recently adopted provisions of the Indian Patent Law (Article 3(d)) that help to prevent the granting of frivolous patents. Brazilian public health NGOs pursued pre-grant opposition on an anti-retroviral drug, and as a result, the Gilead Tenofovir patent was denied.¹⁴⁴ Jerome Reichman also has documented institutional innovations in China that overcome the standard sequestration of patent policy in a single institute (a patent and trademark office).¹⁴⁵ Different ways of administering intellectual property laws are important, and a more integrated institutional perspective can facilitate greater sensitivity to broader public policy implications of particular intellectual property provisions. Vertical forum shifting may be bi-directional, and institutional innovation at the domestic level may find its way into higher levels of aggregation, not just horizontal emulation.

Domestic implementation involves actors who were not parties to multilateral negotiations. Therefore, implementation engages a different set of political considerations. This makes enforcement difficult. For example, policy makers caught between external pressures for enforcement and internal pressures for a more lax approach to expand access to intellectual property may feel more favorably disposed to their internal constituency.

With the ongoing geopolitical and geo-economic power shift, rising powers—such as India, China, Brazil, and Thailand—are pushing back against the IP-plus-more-IP agenda. India threatened to take the EU to the WTO over the EU's seizure of Indian generic drug shipments. Even New Zealand is expressing deep concerns about the TRIPS-plus excesses in the TPP drafts. Benvenisti and Downs argue that:

It is . . . possible that the major developing democracies such as India, Brazil, South Africa, and South Korea could evolve into an anti-fragmentation coalition. . . . The size of their economies would . . . give the coalition considerable clout. Such a coalition . . . might be able to pressure major powers to reduce their reliance . . . on the tactics of regime shifting and threatening to retaliate in kind (for example, withdrawing from aspects of WTO's intellectual property regime).¹⁴⁶

Regime complexity and forum shifting, as documented here, may be a disadvantage to less nimble, less well-resourced actors. However, it also may

¹⁴⁴ *Id.*

¹⁴⁵ REICHMAN, *supra* note 21.

¹⁴⁶ Benvenisti & Downs, *supra* note 9, at 629.

serve to reduce the costs of non-compliance by virtue of policy ambiguity and the choice of diverse norms across institutions. In this way, perhaps weaker actors can retain or expand their policy space to craft their own approaches to intellectual property regulation that better fit their level of development and the balance between importing and exporting intellectual property-based goods and services.

New thinking about the relationship of intellectual property to innovation is driving the dialogue at WIPO and informing scholarship that could get everyone to think more creatively about new models of innovation and reward.¹⁴⁷ It is clear that the existing system is far from perfect and may be doing more harm than good.

Finally, it is important to emphasize that “enforcement” is not a one-sided concept. Enforcement means not only enforcing intellectual property holders’ rights, but also enforcing balance, exceptions and limitations, fair use, due process, civil rights, privacy rights, and antitrust (or competition policy). Peter Yu has suggested that perhaps one can think about enforcing rights to clean water, sanitation, education and health as an alternative to the single-minded and notably narrow focus on intellectual property rights enforcement.¹⁴⁸ Ongoing contestation is the central process of the politics of intellectual property. A constructive broadening of the range of relevant considerations is both welcome and long overdue.

¹⁴⁷ Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257 (2010); IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION’S DEVELOPMENT AGENDA (Jeremy de Beer, ed., 2009).

¹⁴⁸ Yu, *supra* note 6.