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SUSAN K. SELL

TRIPS-PLUS FREE TRADE AGREEMENTS AND ACCESS TO MEDICINES

ABSTRACT. The battle over access to essential medicines revolves around the rights to issue compulsory licenses and to manufacture and export generic versions of brand name drugs to *expand* access. Global brand name pharmaceutical firms have sought to *ration* access to medicines and have used their economic and political clout to shape United States trade policy. They have succeeded in getting extremely restrictive TRIPS-Plus, and even US-Plus, intellectual property provisions into regional and bilateral free trade agreements. Asymmetrical power relations continue to shape intellectual property policy, reducing the amount of leeway that poorer and/or weaker states have in devising regulatory approaches that are most suitable for their individual needs and stages of development. While the overall trend is disturbing, some recent activities in the World Health Organization and evidence of greater unity behind health-based TRIPs flexibilities provide some grounds for cautious optimism.

KEY WORDS: access to medicines, Agreement on Trade-related Aspects of Intellectual Property Rights, Free Trade Agreements, intellectual property, HIV/AIDS drugs, World Health Organization, World Trade Organization, Doha Round

Introduction

In recent years developing countries, non-governmental organizations (NGO) activists, multinational corporations and their home governments increasingly have clashed over intellectual property policies. The dramatic expansion of intellectual property rights threatens to reduce access to life-saving medicines. Intellectual property policies have contributed to the high cost of essential medicines, keeping them out of reach of the world's poor. The strong trend toward transforming life-saving drugs into private commodities for sale at premium prices through higher levels of intellectual property protection has made them less available to those who need them most. This paper examines the "North-South" politics of access to HIV/AIDS drugs by analyzing the politics surrounding patent policies pertaining to drugs. Challenges to providing effective access to medicines include trade pressures, economic coercion, multi-layered governance (i.e., local, national, bilateral, regional, and international), the complexity of

intellectual property policy, and unequal access to resources and institutions.

This article starts by highlighting what is at stake. It goes on to highlight the controversies between global pharmaceutical firms and their champions, and the access to medicines campaign. The next section discusses the structural power of global pharmaceutical firms and some problematic instances of their exercise of that power. The subsequent section examines TRIPS-Plus[1] provisions in bilateral and regional Free Trade Agreements (FTAs) that present barriers to access to essential medicines. It then explores some examples of resistance to this trend in the World Health Organization and in Thailand, and finally offers conclusions about the prospects for a TRIPS-Plus future.

What is at Stake?

At the global level, the most important international public law governing intellectual property rights is the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO). Unlike most international law, TRIPS is binding and enforceable. The WTO may authorize states to sanction those found to be in violation of the agreement. TRIPS reflects the interests of intellectual property owners. TRIPS extends patent rights for 20 years, requires developing countries to offer patent protection for pharmaceuticals, sharply circumscribes the conditions under which states may issue compulsory licenses, and reduces states' autonomy in crafting domestic intellectual property policies that suit their diverse levels of innovation and economic development. Overall, TRIPS reflects and promotes the interests of global corporations that seek to extend their control over their intellectual property. These firms, acting through the United States government (and with the support of Europe and Japan), largely captured the WTO process and succeeded in making public international law to suit their particular needs.[2]

[1] TRIPs-Plus refers to provisions that either exceed the requirements of TRIPS or eliminate flexibilities in implementing TRIPs.

[2] Braithwaite, John and Drahos, Peter, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000), p. 12; Mathews, Duncan, *Globalizing Intellectual Property Rights: The TRIPS Agreement* (Routledge, London New York, 2002), p. 7; Sell, Susan K., *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, Cambridge, 2003), p. 75.

The rationale for intellectual property rights is that they provide incentives for the creation and dissemination of innovation. Without the compensation made possible by intellectual property rights, public goods will be underprovided. However, the merits of granting exclusive rights to intellectual property owners have to be balanced against the economic effects of higher product and transaction costs and the potential "exclusion from the market of competitors who may be able to imitate or adapt the invention in such a way that its social value is increased."[3] This trade-off is particularly acute in medicines; generic imitators can increase social value by providing affordable alternatives to brand name drugs thereby increasing access for the poor.

The market-based, or commodification, justification for strong intellectual property rights is that patents and licenses provide incentives to "increase the number of commercially available products and thereby serve the public interest."[4] However, it is important to ask: which publics are served? In health, stakeholders include non-generic pharmaceutical companies, generic pharmaceutical companies, public sector health providers, and people who need health care. Rights-holders benefit, as do those who have the resources to participate in the commercial market. But market-based solutions alone fail to serve the poor and the marginalized, such as the millions afflicted with HIV/AIDS in Africa and Asia. Of the estimated 42 million infected with HIV/AIDS in the developing world, and the 6 million with full-blown AIDS who need anti-retroviral treatment to stay alive, only 300,000 are receiving these drugs and 100,000 of them are in Brazil.[5]

Market mechanisms to deliver innovation into the public domain fail spectacularly in the oligopolistic markets of the contemporary life sciences industries. Indeed, "international markets for technologies are inherently subject to failure due to distortions attributable to concerns about appropriability, problems

[3] Trebilcock, Michael and Howse, Richard, *The Regulation of International Trade* (London, Routledge, 1995), p. 250.

[4] Lieberwitz, Rosa, "Book Review: the Marketing of Higher Education: the Price of the University's Soul: Universities in the Marketplace: the Commercialization of Higher Education; By Derek Bok", *89 Cornell Law Review* (2004), p. 763, 782.

[5] Lamptey, Peter, "Future Challenges in the Global Fight against HIV/AIDS in Developing Countries", 17 *Emory International Law Review* (2003), p. 645, 650.

of valuing information by buyers and sellers, and market power, all strong justifications for public intervention at both the domestic and global levels.''[6] Therefore, the policy challenge is where to strike the balance, and to pursue options that may maximize the benefits provided by intellectual property rights while minimizing the harms produced by over-extension of such rights. Policymakers must make room for humanitarian intellectual property policies that promote social goals such as protecting public health and ensuring access to essential medicines. Intellectual property policy is not merely economic; it is normative, social and political. It is not just about expanding the economic pie, but is also about the distribution of scarce resources.

Access to Medicines: Arguments and Actors

The battle over access to essential medicines revolves around the rights to issue compulsory licenses and to manufacture and export generic versions of brand name drugs to *expand* access. Global brand name pharmaceutical corporations seek to restrict the ability of generic manufacturers to produce and distribute essential medicines; they seek to *ration* access.[7] African countries in the grip of the HIV/AIDS pandemic, Brazil, India, Thailand, and their non-governmental organization (NGO) advocates have sought to clarify interpretations of TRIPS that permit compulsory licensing, parallel importing, generic manufacture and export. The debate over TRIPS and access to medicines has galvanized a broad range of stakeholders. Brand name pharmaceutical companies, developed and developing country governments, the Office of the United States Trade Representative (USTR) the USTR, NGOs representing public health and consumer interests, and generic drug manufacturers are all participating in this vigorous debate. Among the competing values embedded in TRIPS are the generation of knowledge, the facilitation of ''undistorted'' trade, and the protection of public health.[8]

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[6] Maskus, Keith, and Reichman, Jerome H., ''The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods'' 7 *J. Int*'l Econ. L (2004), p. 279, 288.

[7] I thank Ken Shadlen for urging me to clarify this point.

[8] Shaffer, Gregory, ''Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides?'', 7 *J. Int*'l Econ. L. (2004), p. 459, 460.

On one side of the TRIPS and access to medicines debate are those who support strong intellectual property protection for pharmaceuticals and argue that, if anything, TRIPS is too weak. These advocates highlight the high costs of developing new drugs, the importance of strong property rights as incentives for innovation, and the need for substantial compensation for providing life saving drugs.[9] The brand name global pharmaceutical industry, the United States, and the USTR promote this perspective. It has also been influential in the WTO and the World Intellectual Property Organization (WIPO). The industry fears that any expansion of cut-rate drugs will undermine its markets, particularly if they find their way into high income industrialized country markets. They also are eager to develop markets in middle-income countries in Asia and Latin America. Global pharma highlights the potential health dangers of widespread generic production, "piracy," and the use of drugs without the supervision, dosing instructions, and regulatory controls covering global pharma's products.[10]

Perhaps the most frequently offered argument from supporters of global pharma is that the big problem is not patents but poverty.[11] Industry-supported American think tanks such as the American Enterprise Institute and the International Intellectual Property Institute (IIPI) have promulgated this view. Recent statements by Mickey Kantor, former US Secretary of Commerce and former USTR-turned-industry-lobbyist, Harvey Bale (head of the International Federation of Pharmaceutical Manufacturers & Associations—IFPMA), and Eric Noehrenberg (IFPMA) continue to echo this "poverty not patents" line.[12]

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[9] Grabowski, Henry, "Patents, Innovation and Access to New Pharmaceuticals", 5 *J. Int*'l Econ. L. (2002), p. 849, 850–853.

[10] Symposium, "Global Intellectual Property Rights: Boundaries of Access and Enforcement", 12 *Fordham Intell. Prop. Media Ent. L. J.* (2002), p. 675, 729.

[11] Calfree, John E, "Patently Wrong: Free Drugs are No Panacea for Poor Nations", *Wash. Times*, Jan. 28, 2003, at A21; Bate, Roger and Tren, Richard, *Do NGOs Improve Wealth and Health in Africa?* at http://www.aei.org/docLib/20030612_batepub.pdf (June 12, 2003).

[12] Noehrenberg, Eric, Report of the Commission on Intellectual Property Rights, Innovation and Public Health: an Industry Perspective, *84 Bulletin of the World Health Organization* (2006), p. 419, 420; IFPMA, *WHO Commission Report on Biomedical Innovation, Patents and Public Health Contains many Sound Proposals but Mistakenly Underestimates Vital Role of Patents*, April 3, 2006 *at* http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=3D4628 (2006); Mickey Kantor, *US Free Trade Agreements and the Public Health*, submission to WHO CIPIH *at* http://www.who.int, 1, 5 (2005).

The United States-based Pharmaceutical Research and Manufacturing Association (PhRMA), an industry lobbying group, frequently cites a "Harvard study" that "proves" that patents are no obstacle to access to antiretroviral medicines in Africa.[13] Amir Attaran was an adjunct lecturer in public policy at Harvard, and his coauthor, Lee Gillespie-White, worked for a PhRMA-supported think tank IIPI. The oft-cited paper originated as a study that PhRMA commissioned with its think tank (IIPI) headed by Bruce Lehman, former United States Commissioner of Patents.[14] The United States trade delegation relied on this then-unpublished study in its Talking Points in late September 2001 in the run up to the WTO Doha Ministerial meeting.[15]

PhRMA is hardly subtle about its efforts to enlist academics to promote its cause. The *Washington Post* has referred to these as "hall-of-mirrors techniques by which special interests amplify their arguments through seemingly unconnected third parties."[16] For example, for 2004, PhRMA budgeted $1 million for an:

> [I]ntellectual echo chamber of economists – a standing network of economists and thought leaders to speak against federal price control regulations through articles and testimony." It has set aside $550,000 "for placement of op-eds and articles by third parties" and at least $2 million for outside research and policy groups "to build intellectual capital and generate a higher volume of messages from credible sources" backing industry positions. Overall, the group will devote $12.3 million to "alliance development," ... with ... economists, doctors, patients, and minority groups.[17]

Substantively, advocates of PhRMA's position object to any weakening of intellectual property protection through public health exceptions. They reject compulsory licensing as a policy tool to bring the costs of essential medicines down. They reject parallel importing,[18] whereby states can take advantage of differential pricing policies and import the cheapest version of the brand name patented pharmaceutical product. Harvey Bale of IFPMA criticized a recent World Health Organization (WHO)[19] report for its repeated

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[13] Attaran, Amir and Gillespie-White, Lee, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", 286 *JAMA* (2001) p. 1886, pp. 1888–1891.

[14] Abbott, Frederick "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" 5 *J. Int*'l Econ. L. (2002), p. 469, 485, n. 62.

[15] *Id.* At 485.

[16] *Behind the Lobbying Curtain*, Wash. Post, June 9, 2003, at A20.

[17] *Id.*

[18] Symposium, *supra*, n. 10, at 727.

[19] CIPIH Report at www.who.int/intellectualproperty (2006).

references to compulsory licensing ''as a panacea for fundamental poverty and structural problems in developing countries' health care systems.''[20] In fact, no one has ever touted compulsory licensing as a panacea for poverty but rather as an instrument for promoting competition thus lowering prices. Instead, PhRMA advocates promote increased foreign aid, and drug donations from firms.

On the other side of the debate is an alliance of developing country governments and NGOs campaigning for access to essential medicines. They argue that patent protection *is* a barrier to access and that public health exceptions to patent rules are necessary to prevent needless deaths. They advocate compulsory licensing, generic competition, parallel importation, and fixed rates of compensation for pharmaceutical companies. It is noteworthy that none of these advocates has ever *denied* that poverty is a problem. The ''poverty not patents'' rhetoric sets up a false zero-sum metric. Of course poverty is a huge problem, but it is not one that we can fix quite so quickly and easily as altering the specific patent policies that *do* contribute to the problem of access.

Among the most outspoken advocates of this position are James Love of American consumer activist Ralph Nader's Consumer Project on Technology (CPTech), and Ellen 't Hoen of Médecins Sans Frontières (MSF). They consistently have attacked PhRMA's positions on these issues. Ellen 't Hoen points to strong intellectual property protection as one important barrier to access; she argues that patent protection leads to high prices and limited access.[21] MSF and other NGOs have expressed a number of concerns about TRIPS, including high drug prices, reduced availability of quality generic alternatives, inadequate research and development into tropical diseases, and bilateral pressures on developing countries to adopt patent protection that exceeds the requirements of TRIPS.[22] Furthermore, Love has challenged PhRMA's claims that its companies spend $500–800 million developing each new drug, and has argued that the majority of important HIV/AIDS drugs were actually developed by the public National Institutes of Health (NIH), and funded by taxpayers' dollars.[23] Love and others also offered

[20] IFPMA, *supra*, n. 12.

[21] Hoen, Ellen 't, ''TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha'', 3 *Chi. J. Int*'l l. (2002), p. 27, 29.

[22] *Id.* At 29–30.

[23] Consumer Project on Tech., Background information on Fourteen FDA Approved HIV/AIDS Drugs (June 8, 2000) *at* http://www.cptech.org/ip/health/aids/druginfo.html.

detailed substantive critiques of the Attaran and Gillespie-White ''poverty not patents'' argument.[24]

Brazil, India, and the African group of countries have been leaders in the intergovernmental efforts to address their public health emergencies. Health care activists have praised Brazil's policies of providing universal access to HIV/AIDS drugs.[25] Brazil has used the threat of compulsory licensing to negotiate steep drug discounts with global pharma. It also has committed resources to producing generic drugs. Its policies have helped to create a market for high quality generic drugs.[26] Creating a market has encouraged competition that has brought HIV/AIDS drugs prices down from $10,000 to $150 a year per patient.[27] As a WHO report concludes, ''[c]ompetition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs.''[28] Above all, the access to medicines campaign endorses the right of developing countries to compulsory license drugs, to produce, export, and import generic drugs, and to take advantage of parallel importing to seek out the lowest cost medicines.

German Velasquez argues that in recent years developing countries have won an important victory in the WTO for access to medicines.[29] The Doha Declaration of November 2001 affirmed WTO Member States' rights to implement TRIPS in such a way as to protect public health and to promote access to medicines for all.[30] After extensive and protracted negotiations, Member States also resolved the question of countries' ability to export generic drugs produced under compulsory license to countries lacking pharmaceutical manufacturing capacity (the so-called Paragraph 6 agreement). The deal authorized any member state lacking sufficient

[24] Symposium, *supra*, n. 9, at 732–735; Consumer project on Technology et al., Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa, *at* http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html (Oct. 21, 2001).

[25] Rosenberg, Tina, ''Look at Brazil'', *N.Y. Times*, Jan. 28, 2001 Section 6 (Magazine), at 26.

[26] Symposium, *supra*, n. 10, at 702.

[27] But see MSF on the continued high costs of second-line therapies, www.msf.org

[28] Quoted in Abbott, *supra*, n. 14, 472, n. 702.

[29] Velasquez, German Bilateral Trade Agreements and Access to Essential Drugs, Bermudez Jorge A. Z and Oliveira-Auxiliadora, Maria, Intellectual Property in the Context of the WTO TRIPS Agreements: Challenges for Public Health, ENSP/WHO – Oswaldo Cruz Foundation, 63 (2004).

[30] WTO, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, Fourth Session, Doha. WT/MIN(01)DEC/W/2, November 14 (2001).

pharmaceutical manufacturing capacity to import necessary medicines from any other member state. This waiver of TRIPS Article 31(f) (restricting compulsory licensing only to supply one's domestic market) included procedural safeguards to prevent diversion of cheap medicines to rich countries' markets.[31] Now, generic copies of drugs made under compulsory license can be exported to countries lacking production capacity.[32] The decision also included a Chairman's Statement, emphasizing the ''Members' 'shared understanding' that the Decision will be interpreted and implemented on a 'good faith' basis in order to deal with public health problems and not for industrial or commercial policy objectives'' and their agreement to take steps to prevent drug diversion to third markets.[33] According to Love, the Chairman's Statement was approved by Pfizer Chief Executive Officer (CEO) Hank McKinnell and the office of Karl Rove, President Bush's Deputy Chief of Staff in charge of policy.[34] In December 2005, Member States adopted the waiver as an amendment to TRIPS that includes Article 31bis, the waiver, one annex on terms and conditions, and an appendix on the assessment of pharmaceutical manufacturing capabilities.[35] A number of African delegations were pleased with the outcome, despite the fact that it did not mirror their original proposals. One delegate expressed relief that the uncertainty generated by the waiver was resolved as it is now a permanent part of TRIPS.[36] However, despite this forward

[31] WTO Council on TRIPS, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* IP/C/405 at http://wto.org (2003); Matthews, Duncan, ''WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Medicines Problem?'', 7 *J. INT'*L ECON. L. 73.

[32] IP-Watch, *WTO States Agreement on TRIPS and Public Health on Eve of* Ministeral, 6 December, *at* http://www.ip-watch.org (2005).

[33] Matthews, Duncan ''Is History Repeating Itself? Outcome of the Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation'', *Electronic Law Journal LGD,* 2004, p. 1, 11. Available *at*: http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews 2004.

[34] Love, James, *No Gift to the Poor: Strategies used by the US and EC to Protect Big Pharma in WTO TRIPS Negotiations*, WORKING AGENDA *at* http://workingagenda.blogspot.com/2005/12/no-gift-to-poor-strategies-used-by-us.html. (2005).

[35] IP-Watch, *supra*, n. 32.

[36] IP-Watch, *African Countries Ready to Accept TRIPS and Public Health Deal* December 6 *at* http://www.ip-watch.org (2005).

movement for access to medicines, Velasquez warns that TRIPS-Plus provisions of FTAs may "dash the hopes raised by Doha."[37] The following sections of this article explore this possibility.

The Pharmaceutical Industry: Profits, Power, and Perils

Global pharmaceutical firms have become increasingly profitable and politically powerful, especially in the United States' trade policymaking context. The pharmaceutical sector is characterized by marked economic concentration that has only increased over the past several decades. The combination of expanded intellectual property rights and relaxed anti-trust enforcement has led to economic concentration in the life sciences industries. In pharmaceuticals just since 1999, Zeneca acquired Astra, Hoescht acquired Marion Merrel Dow, Sandoz and Ciba-Geigy merged, Glaxo Wellcome and SmithKline Beecham merged, Pharmacia and Upjohn merged with Monsanto, Sanofi-Syntelabo SA was the object of a hostile takeover by Aventis, and Pfizer's acquisitions made it the largest world company with revenues of $53 billion in 2004 (roughly 40% more than #2 GlaxoSmithKline).[38] The global market shares of the largest non-generic pharmaceutical companies in 2003 were as follows: Pfizer, 11%; GlaxoSmithKline, 6.9%; Merck & Co. 5%; AstraZeneca, 4.8%, and Johnson & Johnson, 4.7%.[39] This situation has translated "economic power into greater influence over policymaking that has hitherto been seen as the realm of the public sphere."[40]

The increasing commercialization of medicine means that the diseases of the poor will be ignored by firms for sound economic reasons.[41] As a number of commentators point out, across a broad range of products, the current system skews research towards rich

[37] Velasquez, *supra*, n. 29, 65.
[38] Rosenberg, Barbara, "Market Concentration of the Transnational Pharmaceutical Industry and Generic Industries: Trends in Mergers, Acquisitions and Other Transactions", In Roffe, Pedro, Tansey, Geoff Vivas-Eugui, David (eds.), *Negotiating Health: Intellectual Property Rights and Access to Medicines*, vol. 65 (2006).
[39] *Id.* at 69.
[40] Buse, et al., "Globalisation and Health Policy: Trends and Opportunities", In: Kelly Lee et al (eds.). *Health Policy in a Globalising World*, vol. 261 (2002).
[41] Dutfield, Graham, "Should We Terminate Terminator Technology?", *European Intell. Prop. Rev.* (2003), p. 491, 495.

and middle-income countries' markets and sectors.[42] In the public health sector this means the neglect of tropical diseases in favor of cancer and so-called lifestyle drugs (i.e., for obesity, balding, and erectile dysfunction). For example, only 13 of 1233 new drugs marketed between 1975 and 1997 were approved for tropical diseases. "As a result, the rhetoric of strong intellectual property rights leading to innovation that meets social needs rings particularly hollow in this setting."[43]

According to Peter Drahos the US and its IP activist industries have been engaged in a "one-way ratchet" for intellectual property, systematically obtaining higher levels of protection.[44] The International Chamber of Commerce points out that, "the chain of national intellectual property laws will only be as strong as its weakest link, and the ability to meaningfully enforce rights will be crucial."[45] Industry lobbyists are eager to point out that nothing in TRIPS prevents states from adopting *stronger* forms of protection, and the US and its industries increasingly are coordinating enforcement through a number of venues. The structural power of global firms is reflected in the membership of key policy making committees in US trade institutions. These committees assist US trade negotiators in designing policies for multilateral, regional and bilateral trade. The USTR's Industry Trade Advisory Committee on Intellectual Property Rights includes representatives of Pfizer, Eli Lilly and Company, PhRMA, Merck & Company, Inc., Biotechnology Industry Organization, Time Warner, Inc., International Anti-Counterfeiting Coalition, Recording Industry Association of America, Intellectual Property Owners Association, John Wiley and Sons, Inc., and Association of American Publishers. *None* of these

[42] Barton, John, *Nutrition and Technology Transfer Policies*, (2003) *at* http://www.iprsonline; Lettington, Robert, *Small-Scale Agriculture and the Nutritional Safeguard under Article 8(1) of the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights: Case Studies from Kenya and Peru* (2003) *at* http://ww.iprsonline; Rai Arti and Eisenberg, Rebecca, "The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine", 66 *Law and Comtemporary Problems* (2003), p. 289.

[43] Hammer, Peter, "Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health", 5 *J. Int*'l Econ. L. (2002) p. 883, 888.

[44] Drahos, Peter, "Securing the Future of Intellectual Property: Intellectual Property Owners and their Nodally Coordinated Enforcement Pyramid", 36 *Case Western Reserve J. Int*'l Law (2004), p. 53, 55–61.

[45] International Chamber of Commerce, *Current and Emerging Intellectual Property Issues for Business: a Roadmap for Business and Policymakers*, *at* http://www.iccwbo.org, 1, 13 (2005).

firms or organizations is pressing for more balance between private rights and the public domain. The reach of these advisory committees can be quite broad and US-based firms work with their subsidiaries abroad to develop support for their positions. Significantly in the November 2002 US congressional elections a group of global PhRMA firms, headed by Pfizer CEO Hank McKinnell, raised $30 million for Republican congressional campaigns.[46] Not coincidentally, the Bush administration has been very supportive of and responsive to global pharma's objectives and strategies.

Industry representation in the USTR advisory committees, overlapping memberships in industry associations such as the PhRMA, Business Software Alliance (BSA) and the International Intellectual Property Alliance (IIPA) increase the information exchange among private actors and the USTR to monitor compliance, negotiate and enforce TRIPS-Plus[47] deals and lobby at national and multilateral levels. For example, Microsoft is a member of the IIPA, BSA and IFAC-3.[48] In addition to these more formal vehicles for representation and influence, firms also participate in ad hoc mobilization groups such as the American BioIndustry Alliance (ABIA).[49] Jacques Gorlin founded the ABIA in 2005. Gorlin was a key player in the original TRIPS negotiations as consultant to the Intellectual Property Committee (IPC). The IPC, made up of 12 CEOs of US-based global firms with large intellectual property portfolios, mobilized transnational private sector and governmental support for TRIPS and drafted major portions of TRIPS.[50] Gorlin formed the ABIA to continue industry advocacy in multilateral, bilateral, and US government forums. Member companies include: Bristol Myers-Squibb, Eli Lilly, Hana Biosciences, General Electric, Merck, Pfizer, Procter & Gamble and Tethys Research (ABIA). At least half of these firms participated in the original IPC. Gorlin serves as President, and Susan Finston, formerly of PhRMA, serves as Executive Director. ABIA is leading the lobbying fight to preserve and promote patents on life forms and is targeting activities at WIPO, WTO and Convention on Biological Diversity (CBD). The ABIA plans to lobby its allies, the US, Australia, Canada,

[46] Ireland, Doug, "Under the Counter", *POZ Magazine*, *at* http://www.poz.com/articles/1056_7008.shtml(2006).
[47] TRIPs-Plus refers to provisions that either exceed the requirements of TRIPS or eliminate TRIPS flexibilities.
[48] Drahos, *supra*, n. 44, at 69.
[49] *At* http://www.abialliance.com
[50] Sell, supra, n. 2.

Korea, Japan and New Zealand, as well as work with India's biotechnology industry to try to soften India's negotiating stance.[51] This thick and overlapping network has resulted in a centralized system of private governance that enlists the USTR for legitimation and enforcement and heightens opportunities for rent-seeking.[52]

Patents confer withholding power, the ability to restrict use, by constructing scarcity.[53] Patent owners can refuse to license patented products or processes, as James Watt did in the case of his steam engine technology.[54] Patent owners can refuse to make their products or processes available. The following pharmaceutical cases illustrate how this power to withhold can imperil public health.

Brand name pharmaceutical companies responded to developing country and NGO access campaigns by announcing generous price reductions, and expanded availability of their products for HIV/AIDS patients in developing countries. However, having earned their public relations kudos and positive reactions from their shareholders, they have not always followed through on their pledges. For instance in 2002 the sole producer of tenofovir disoproxil fumarate (Viread®), an important antiretroviral drug with fewer side effects for AIDS patients, Gilead announced that it would make Viread available at reduced prices to 97 developing countries through its Viread Access Program.[55] Over three years later, Viread is registered for use in only six countries.[56] Gilead has not even *requested* marketing clearance in most developing countries.

Abbott Laboratories received approval of Kaletra in the US in October 2005. Kaletra is a second-line fixed dose combination of protease inhibitor lopinavir and booster ritonavir (LPV/r) that has particular advantages for developing countries' HIV/AIDS patients.

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[51] IP-Watch, *Biotech Industry Fights Disclosure in Patents on Three IP Policy Fronts*, March 2 *at* http://www.ip-watch.org (2006).

[52] Drahos, *supra*, n. 44, at 77.

[53] May, Christopher and Sell, Susan K., *Intellectual Property Rights: A Critical History* (Boulder: Lynne Rienner, 2006), p. 36.

[54] Id. 38.

[55] Medecins Sans Frontieres, *Gilead*'s Tenofovir 'Access Program' for Developing Countries: A Case of False Promises? February 7 *at* http://www.doctorswithoutbordersorg/pr/2006/02-07-2006.htm (2006).

[56] *Id.* The six countries are: the Bahamas; Gambia; Kenya; Rwanda; Uganda; and Zambia.

Patients need only take 4 pills a day (versus six) and the pills require no dietary restrictions. Crucially the formula is heat stable, requiring no refrigeration.[57] WHO has recognized LPV/r as an essential medicine as part of a second-line HIV/AIDS therapy once first-line failure has occurred. Since May 2002 Abbott has been selling an earlier, non-heat stable formulation in Africa and least developed countries for $500 per patient per year. MSF has asked Abbott to register the new drug in developing countries and to set an affordable differential price for the new drug in developing countries. Abbott has claimed that it first needs to acquire a Certificate of Pharmaceutical Product (CPP) from Europe (the drug is manufactured in Germany) before it can register the new drug in developing countries. However, according to WHO guidelines and US regulations CPP's may be issued by the *exporting* country (the US FDA in this instance).[58] MSF placed a Kaletra order for 400 MSF patients in nine countries in March 2006. While Abbott announced that it would make the new drug available for $500 per patient per year in African and least developed countries, the drug is unavailable for purchase because Abbott has not registered it anywhere but South Africa. As MSF states, "if access to needed drugs depends on the marketing policies of pharmaceutical companies, then the lives of millions of people with HIV/AIDS remain at risk."[59]

A particularly pernicious example of this is the Gleevec case in South Korea. Gleevec is a leukemia drug that was developed with assistance from the US Orphan Drug Act, under which the US government paid for 50% of the private sector costs of clinical trials.[60] Swiss drug maker Novartis owns the patent. The drug costs roughly $27,000 per year per patient in the US, keeping it out of reach of most. In late 2001 Novartis suspended supply of Gleevec to South Korea because Novartis failed to get the price it sought

[57] Doctors Without Borders, *Abbott*'s New and Improved Kaletra: Only in the US … But What about the Rest of the World? March 14, *at* http://www.doctorswithoutborders.org/news/hiv-aids/kaletra_briefingdoc.cfm (2006).

[58] Doctors Without Borders, *Unnecessary Delays by Abbott: The "CPP" Myth Debunked*, March 14 *at* http://www.doctorswithoutborders.org/news/hiv-aids/kaletra_cppdoc.htm (2006).

[59] Doctors Without Borders, *More Empty Promises: Abbott Fails to Supply Critical New AIDS Drug Formulation to Developing Countries*, April 27 *at* http://www.doctorswithoutborders.org/pr/2006/04–27–2006_1.cfm (2006).

[60] Ip-health, *Re: Call for Endorsements on Glivec [sic] from South Korea*, Nov. 30 *at* http://lists.essential.org/pipermail/ip-health/2001–November (2001).

from the South Korean government. The US, Switzerland, and Japan had accepted the price of US$19.50 per pill[61] 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 myelogenic 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 for 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 meant resorting to compulsory licensing in line with the Doha Declaration on TRIPS and Public Health.[62] 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 Korean CML patients were imperiled by unstable supplies and high prices.[63]

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.[64] 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."[65] Indeed, the Korean decision to reject the generic importation option under compulsory license incorporated the very language that USTR Robert Zoellick had been promoting in his efforts to limit the scope of the 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

[61] Daily dosages range from 4 to 8 pills a day.
[62] Ip-health, *supra*, n. 60.
[63] Ip-health, *Text of Korean Decision in Glivec Case* Mar. 10 *at* http://lsits.essential.org/pipermail/ip-health/2003/March (2003).
[64] Benvenisti, Eyal, and Downs, George, "Distributive Politics and International Institutions: the Case of Drugs", 36 *Case Western Reserve J. of Int'*l l. (2004), pp. 21–52.
[65] *Id, at* 29.

extremely dangerous situation in our nation."[66] As James Love of CpTech remarked, "'the US government does not control the price of drugs in its own country but it is telling Korea what they should charge.'"[67] More accurately, the US is telling Korea to do as the US does and let the sellers (Novartis, in this case), set the price.[68] This example highlights the intrusive reach of what Drahos calls the "nodal enforcement pyramid" that global IP-based firms and their governments deploy.[69] Asymmetrical power relations and the political influence of global high-technology 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 substantial challenges in navigating the system to their benefit.

Finally, 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,[70] an ongoing case in the Philippines demonstrates that these tactics persist. Pfizer is suing the Philippine government for parallel importing the Pfizer drug Norvasc for high blood pressure. In the Philippines this product is only available from Pfizer. In the Philippines Norvasc 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.[71] 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 is not only suing the BFAD and Philippine International Trading Corporation (PITC) but is also suing BFAD Director Leticia Barbara Gutierrez and Emilio Polig (a BFAD

[66] IP-health, *supra*, n. 62; *See also* Abbott, Frederick "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health", 99 *A. J. Int*'l L. (2005), pp. 328–336.
[67] Love, quoted in Benvenisti and Downs (2004), *supra*, n. 64.
[68] E-mail from Kenneth Shadlen, Lecturer in Development Studies, the London School of Economics, April 26, 2006, on file with author.
[69] Drahos (2004), *supra*, n. 44.
[70] Bond, Patrick "Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians", *29 Int*'l J. of Health Services (1999), p. 765.
[71] IP-Watch, *Pfizer Fights IP Flexibilities in the Philippines*, April 30 *at* http://www.ip-watch.org (2006).

officer) for damages. Pfizer claims that it is acting to protect its patent and denies that it is a parallel importation case because Pfizer does not believe that the Indian supplier was a Pfizer-authorized source. PITC has filed a countersuit against Pfizer. Stanford alumni and graduate students launched a signatory campaign to oust Pfizer CEO Henry McKinnell from the Stanford Advisory board over Pfizer's ''bullying'' of Philippine government drug regulators.[72]

In attacking portions of the 2006 WHO Commission on Intellectual Property, Innovation, and Public Health (CIPIH) report[73], Eric Noehrenberg of IFPMA argued that the report repeated the ''myth that patents give the power to set prices.''[74] He goes on to state that ''such a misrepresentation ignores the effect of competition between drugs.''[75] However, in the Philippines case it is precisely the *lack* of competition that has caused the problem, and Pfizer actively is seeking 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 precarious 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.[76]

FTA Trips-Plus Provisions: Barriers to Access

In recent years intellectual property protection has been dramatically expanded, notably through the WTO TRIPS but also in bilateral and regional free trade agreements (FTAs). The baseline for property rights has moved quite far in the direction of private

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[72] *Id.*

[73] WHO, *CIPIH Report, at* http://www.who.int/intellectualproperty (2006).

[74] Noehrenberg, Eric, ''Report of the Commission on Intellectual Property Rights, Innovation and Public Health: an Industry Perspective'', 84 *Bulletin of the World Health Organization* (2006), p. 419.

[75] *Id.*

[76] Drahos, Peter with Braithwaite, John, *Information Feudalism: Who Owns the Knowledge Economy*?, (Earthscan, London, 2002), pp. 167–8.

reward over public access. Rights which used to be considered to be privileges or exceptions have superseded obligations of rights holders to the public. To insist that all countries adopt high protectionist standards of protection denies them the opportunity to pursue the public policy strategies that every ''developed'' country enjoyed. Lax intellectual property protection, compulsory licensing, working requirements, keeping certain sectors off-limits in terms of property rights, parallel importing, and discriminating against foreign rights holders were all key features of the developed countries' public policy strategies.[77] Intellectual property rights should be the servant, not the master, of broader public policy goals. However, in the past twenty years intellectual property rights have been elevated from servants to masters – crucial for their own sake.

Focusing on TRIPS and the letter of the law, one can see that TRIPs offers much flexibility for states to tailor their intellectual property policies to suit public policy goals. However, public international law such as TRIPS is embedded in a broader context of asymmetrical power relationships between developed and developing countries, and between producers and consumers of the fruits of intellectual property. This context reduces the amount of leeway that poorer and/or weaker states have in devising regulatory approaches that are most suitable for their individual needs and stages of development.

One of the most important assets for developing country negotiators is peripheral vision to stay abreast of the proliferation of intellectual property policymaking in diverse institutional settings. The US and the EU have been able to exploit resource disparities and shift forums whenever it suits their interests. This holds true of the shift from WIPO to WTO and back again,[78] as well as the shifting between multilateral, bilateral and regional negotiations. Bilateral and regional agreements threaten to undermine any gains that developing countries may bargain for or achieve in multilateral settings. At the end of the Uruguay Round negotiators did not share consensual assessments of TRIPS. Negotiators from the United States and the European Union tended to see TRIPS as a floor – a minimum baseline for intellectual property protection. By

[77] May and Sell, *supra*, n. 43, 107–131.

[78] Sell, Susan K., *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of New York Press, 1998); Drahos and Braithwaite, *supra*, n. 2.

contrast, developing country negotiators saw it more as a ceiling – a maximum standard of protection beyond which they were unwilling and/or unable to go.

Given this perspective, it should come as no surprise that the US and the EU aggressively have been pursuing efforts to ratchet up TRIPS standards, to eliminate TRIPS flexibilities and close TRIPS loopholes. Playing a multi-level, multi-forum governance game, countries like the United States have been able to extract a high price from economically more vulnerable parties eager to gain access to large, affluent markets.[79] Bilateral Investment Treaties, Bilateral Intellectual Property Agreements, and regional FTAs concluded between the US and developing countries, and between the European Union and developing countries invariably have been TRIPS-Plus.[80] According to Dylan Williams, "a recent US Congressional Research Service report states that the United States' main purpose for pursuing bilateral FTAs is to advance US intellectual property protection rather than promoting more free trade."[81]

TRIPS permits countries to exceed TRIPs standards and the US has been pressuring them to do so. It has offered countries WTO-Plus market access in exchange for TRIPs-Plus policies.[82] Particular provisions in these bilateral and regional trade agreements include: (1) data exclusivity provisions; (2) prohibitions of parallel importation; (3) linkage between drug registration and patent protection; (4) highly restrictive conditions for issuing compulsory licenses; (5) expanded subject matter requirements; and (6) patent term extensions. All of these provisions have been crafted by the

[79] Abbott, *supra*, n. 66, pp. 350–354.; Correa, Carlos, "Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses", *26 Mich. J. Int*'l L. (2004) p. 331; Vivas-Eugui, David, *Regional and Bilateral Agreements and a TRIPS-plus World: the Free Trade Area of the Americas (FTAA)*, Quaker United Nations Office, Quaker International Affairs Programme, and International Centre for Trade and Sustainable Development, *at* http://www.quno.org. (2003).

[80] Drahos, Peter, "BITS and BIPS: Bilateralism in Intellectual Property", 4 *Journal of World Intellectual Property* (2001), 6; Duffield, Graham, "Sharing the Benefits of Biodiversity: Is there a Role for the Patent System?", *Journal of World Intellectual Property* (2003).

[81] Williams, Dylan, "World Health: A Lethal Dose of US Politics", June 16, 2006. *Asia Times* Online *at* http://www.atimes.com (2006).

[82] Shadlen, Ken, *Policy Space for Development in the WTO and Beyond: the case of Intellectual Property Rights*, Tufts University, Global Development and Environment Institute, Working Paper No. 05-06, 11 *at* http://ase.tufts.edu/gdae (2005).

brand-name pharmaceutical industry and 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. 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 (10 years for agrochemicals), whether or not it was patented and whether or not the data was disclosed. It also covers chemical entities that are not new.[83] As Musungu and Oh point out, "the first registrant of a new pharmaceutical product may obtain data protection even in the case of old and well known products."[84] 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. 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."[85]

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.[86] As industry lobbyist Mickey Kantor points out, "data exclusivity is an independent intellectual property right, not to be confused with protection of patents."[87] This new right is independent of patent status and therefore presents a huge obstacle to generic competition. The US-CAFTA

[83] Correa, Carlos, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 *Bulletin of the World Health Organization* (2006), p. 399, 401.

[84] Musungu, Sisule and Oh, Cecilia, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines*? CIPIH Study 4C. August. *at* http://who.int.org 1, (2005), pp. 59–60.

[85] Reichman, Jerome H., *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective* 1 (2004). Available at http://www.iprsonline

[86] Shadlen, *supra*, n. 82, 19.

[87] Kantor, Mickey *US Free Trade Agreements and the Public Health* submission to WHO CIPIH, *at* http://www.who.int 1, 5 (2005).

agreement's Article 15.10 is the most extensive version of such provisions. In CAFTA Article 15.10 (a) & (b) fixed term prohibitions "*are distinct from patents*. They prevent marketing approval of drugs that are off-patent (e.g., in either or both the United States and [the CAFTA country]. *A restriction on marketing approval becomes another form of monopoly here granted in ways that the* TRIPS *Agreement does not require*."[88] Would-be generic competitors will hesitate to move forward in this forbidding regulatory framework.

To require the patent owner's consent for marketing approval for a patented item means that it will be nearly impossible to use compulsory licensing as permitted by TRIPS. According to Abbott, "even if a license is granted to a generic producer/importer, the patent owner will be able to prevent marketing of the equivalent medicine (because it will not consent or acquiesce to marketing). The generic product cannot be put on the market on regulatory grounds, regardless of the grant of license with respect to the patent."[89]

Parallel importation is the importation of patented goods from another country. Under TRIPs, countries are free to determine the type of exhaustion regime they want to have. The principle of patent exhaustion refers to the patentee's ability to control the first sale of a product where the product is patented. The US has a national exhaustion regime, which has been incorporated into a number of FTAs. Under the US's national exhaustion regime the patent holder is the only person who has the authority to make the first sale of the product in the US. This prevents the importation of the patented product from another country without the permission of the US patent holder, drastically curbing the opportunities for parallel importation. This policy drove many American senior citizens in the past several years to take buses to Canada to purchase cheaper versions of brand name drugs. By contrast, proponents of access to medicines recommend an international exhaustion regime. Under this TRIPS-compliant alternative regime, the first sale of a patented product *anywhere* exhausts the patent holder's right to block parallel importation. For example using parallel importation,

[88] Abbott, Frederick *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Quaker United Nations Office, Occasional Paper 14, April *at* http://www.quno.org 1, 7 (2004). (emphasis in original).
[89] *Id.* 8.

countries can take advantage of differential pharmaceutical pricing policies in order to obtain cheaper patented goods. If a brand name pharmaceutical company sells a patented product more cheaply in country *x* than country *y*, country *y* could import the drug from country *x*. By mandating *national* exhaustion regimes, the FTAs are TRIPs-plus by eliminating 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 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.[90] This linkage and the data exclusivity provisions have a chilling effect on generic competition and compulsory licensing. In Abbott's view, they are designed to prevent registration and marketing approval of generics and ''appear designed to negate the effective use of compulsory licensing by blocking the marketing of third party medicines during the term of patents.''[91]

TRIPs permits compulsory licensing, albeit with some significant restrictions. The TRIPs amendment adopted in negotiations just before the WTO Hong Kong Ministerial meeting in December 2005 incorporated some cumbersome procedural requirements. However, TRIPs retained far more flexibility to issue such licenses than the bilateral and regional agreements have done. Under these agreements compulsory licensing is restricted to a very limited set of circumstances. For example, in both the US-FTAs with Singapore and Jordan compulsory licenses may not be issued except in the event of ''national emergency or other circumstances of extreme urgency'' (US-Singapore FTA, Article 16.7(6)(b)). Chapter 15 of the US–Morocco FTA limits use of TRIPs flexibilities to particular diseases (HIV/AIDS, malaria and tuberculosis and other epidemics) and to circumstances of ''extreme urgency'' or ''national emergency.'' The US had pushed for these exact limits during the deliberations over Paragraph 6 of the Doha Declaration but was rebuffed. Now it is seeking to incorporate its preferred language in the FTAs with the aim to sharply curtail the possibility of generic

[90] Correa, *supra*, n. 83, 401.
[91] Abbott, *supra*, n. 88, 1,12.

competition and compulsory licensing.[92] Chapter 15.9(2) of the US–Morocco FTA also requires Morocco to give up its right under TRIPs 27.3(b) to exclude plants and animals from patentability, thereby effectively expanding the subject matter available for patent protection.[93]

As Mickey Kantor claims, ''Article 31, the Doha Declaration and the Paragraph 6 compromise are fundamentally 'exceptions' to the intellectual property protections embodied in the TRIPS Agreement….But these exceptions cannot swallow the rule: strong intellectual property protections remain essential to foster innovation and creativity.''[94] Interestingly in the US, which has one of the strongest patent protection regimes in the world, medical R&D spending has doubled between 1995 and 2002; however in this same period, ''the registration of new products has declined, as well as the therapeutic significance of products reaching the market….Pharmaceutical innovation has declined both in quality and quantity.''[95] This fact raises important questions about the correlation that industry asserts between strong patent protection and innovation.

Finally, a number of the FTAs incorporate automatic patent term extensions beyond TRIPs' 20-year term. These extensions are not limited in time, despite the fact that the US limits extensions to compensate for delays in marketing approval to 5 years. Therefore the bilateral and regional agreements are not only TRIPs-Plus but are in fact, *US-Plus*. These agreements provide for automatic extensions for delays in patent examination and marketing approval. This is troubling in developing countries because their patent offices are under-staffed and stretched to the limit. According to Correa, because the grounds for patent term extension:

> Under FTAs are *independent, cumulative*, and *with no maximum period*, nothing seems to prevent a patent from being extended for x years due to a delay in its granting process, and for y more years due to a delay in the marketing approval process…. These mechanisms will have the effect of making the public pay for any administrative delays, and generate increased flow of payments to pharmaceutical companies that can hardly be justified by any additional benefits to patients in developing countries.[96]

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[92] *Id.* 10.
[93] *Id.*
[94] Kantor, *supra*, n. 87, 9.
[95] 't Hoen, Ellen ''Report of the Commission on Intellectual Property Rights, Innovation and Public Health: a Call to Governments'', 84 *Bulletin of the World Health Organization* 421 (2006).
[96] Correa, *supra*, n. 83, 401.

Significantly these provisions inject considerable uncertainty into the calculations of would-be generic competitors and could delay the introduction of competing and affordable products.[97]

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 takes issue with critics who "allege" that TRIPS-plus provisions "extend beyond those expressly set forth in the TRIPS Agreement and thus violate TRIPS."[98] He argues that the provisions are TRIPS-compliant. His rhetoric misses the point. Provisions that "expressly extend beyond those set forth in TRIPS" are *by definition* TRIPS-Plus. He himself states that the "provisions often are more specific and provide greater intellectual property protection."[99] 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 requirements of TRIPS. Critics of TRIPS-Plus provisions question their merits on public health, moral, human rights and economic development grounds.

Resistance to Trips-Plus Trends

In recent years developing countries have begun to challenge the discrepancy between the multilateral rules and the TRIPS-Plus standards proposed in regional and bilateral agreements.[100] In late 2005, Ecuador and Colombia broke off talks with the US over TRIPS-Plus provisions and had refused to agree to TRIPS-Plus standards. However, in late February 2006 the US and Colombia concluded an agreement that includes TRIPS-Plus standards despite the best efforts of some Colombian negotiators to counteract them.[101] In Russia's simultaneous negotiations for its accession to the WTO as well as for a bilateral deal with the United States, Russia's lead negotiator on WTO accession, Maxim Medvedkov, has endorsed TRIPS but has balked at the TRIPS-Plus demands.

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[97] *Id.*
[98] Kantor, *supra*, n. 87, 3.
[99] *Id.*
[100] This resistance is neither limited to medicines nor to the trade arena. See Chon, Margaret "Intellectual Property and the Development Divide", 27 *Cardozo Law Review* (2006), p. 2821.
[101] IP-Watch, *Groups Decry Impact of IP and Health Terms in US Trade Agreements* March 3 *at* http://www.ip-watch.org (2006).

He stated that "'I think we have to draw a line between WTO and bilateral issues.'"[102] This reflects Russia's view of TRIPS as a ceiling and not a floor.

In May 2006 South American Ministers of Health from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela issued an important Declaration on intellectual property, access to medicines and public health.[103] Noting the link between patents and the high cost of medicines, the Ministers endorsed their commitment to the Doha Declaration and expressed their intent to maintain TRIPS flexibilities such as compulsory licensing, parallel importing, and Bolar exceptions (that speed the registration of generic drugs). Furthermore they explicitly rejected TRIPS-plus provisions such as linking patent grants with marketing approval, and expanding the scope of patentability (e.g., patents on plants, animals, and second uses of known formulations).

In June 2006, the Committee on International Trade Law[104] adopted a resolution expressing concern over some WTO Member countries' pursuit of provisions in bilateral and regional agreements "that could not be secured through multilateral negotiations" and urged governments to "refrain from using bilateral and regional trade negotiations and agreements to limit or eliminate flexibilities" in TRIPS "to support the protection of public health and to promote access to medicines for all."[105]

Resistance also has been emerging from WHO activities, and protests over the US–Thai FTA negotiations have become particularly sharp. This section first discusses activities at WHO, then the US-Thai FTA protests. It ends with a discussion of how these two threads intersected with US industry lobbyists' efforts to interfere

[102] IP-Watch, *Official: In WTO Talks US Pushes Russia to Restrictive TRIPS Standard*, October 24 *at* http://www.ip-watch.org (2005).

[103] *Declaratoria de Ministras y Ministros de America del sur Sobre Propiedad Intelectual, Acceso a los Medicamentos y Salud Publica* Geneva, May 23, 2006. I thank Maria Auxiliadora Oliveira for alerting me to the significance of this Declaration, and to Nicoletta Dentico for sending me both the full text and an unofficial English translation (on file with author).

[104] "composed of experts from around the world (including individuals who have served in important positions at the WTO and the European Commission, who are members of national Supreme Courts, who have served as senior trade negotiators and so forth)" Frederick Abbott, *Resolution of the International Law Association on Trade Agreements and Public Health*, Ip-Health Digest, vol. 1, #2088, message 2 June 20, 2006. http://www.cptech.org

[105] *Id.* Resolution No. 3/2006, International Trade Law Committee.

with the WHO and the Thai resistance in early 2006. The intersection between the US-Thai FTA and WHO processes provide a particularly vivid illustration of Drahos' discussion of the murky, deliberately opaque thicket that is industry-driven "nodal governance."[106]

World Health Organization

The WHO is a specialized agency of the UN system. Its mandate is to direct and coordinate authority for health work.[107] The WHO has the largest budget of all the specialized agencies, with an annual budget of "$1.8 billion dollars contributed by its 193 member states."[108] Since TRIPS, the WHO increasingly has been drawn into trade issues, and NGOs have had considerable access to the institution.[109] Even though global pharma has an important voice in the WTO through its powerful OECD member states that contribute significant funding, at times the WHO has been criticized for its "failure to cooperate with the private sector."[110] For instance, in 1998 the US threatened to withdraw its WHO funding.[111]

WHO has set its work in the context of international human rights law, and has adopted access to essential medicines as an element in compliance with the right to health.[112] Under a human rights rubric, intellectual property is recast as "a social product with a social function and not primarily as an economic relationship."[113] According to critics of the access campaigns:

> By advocating these human rights of access, IP skeptics seek to create a conflict with intellectual property rights, which give their owners the right to control and

[106] Drahos, *supra*, n. 44.
[107] Stein, Eric "International Integration and Democracy: No Love at First Sight", 95 *Am. J. Int*'l L. (2001), p. 489, 497.
[108] Volansky, Mark J. Comment, "Achieving Global Health: A Review of the World Health Organization's Response", 10 *Tulsa J. Comp. Int*'l L. (2002), p. 223, 229.
[109] Stein, *supra*, n. 107, 489, 498.
[110] *Id.*
[111] Williams, *supra*, n. 81.
[112] Seuba, Xavier, "A Human Rights Approach to the WHO Model List of Essential Medicines", 84 *Bulletin of the World Health Organization* (2006), p. 405, 405.
[113] Chapman, Audrey, "The Human Rights Implications of Intellectual Property Protection", 5 *J. Int*'l ECON. L. (2002), p. 861, 867.

exclude others…. Since advocates view "human rights obligations" as having "primacy" over economic policies and agreements, then it follows that intellectual property rights are secondary, to be treated as limited exceptions.[114]

The human rights rubric seeks to elevate the rights of *patients* over patents, and to provide avenues for reporting violations of international human rights agreements. In November 2005 the UN Committee on Economic, Social and Cultural Rights issued a General Comment highlighting the fact that intellectual property rights were limited in time and scope, whereas human rights were timeless.[115] While advocates of a human rights framing of access to health acknowledge that it is no panacea,[116] it does offer a broad rubric to mobilize stakeholders working on narrower issues to recognize their mutual interests.

The May 2003 World Health Assembly (WHA) meeting on improving access to essential medicines was particularly volatile. The United States presented a resolution that neglected even to *mention* the Doha Declaration and did little more than assert the value of strong intellectual property protection as a stimulus for innovation.[117] The US proposal further requested the WHO to refer member states to the industry-friendly WTO and WIPO for assistance in implementing TRIPS obligations.[118] Brazil proposed a resolution, supported by Bolivia, Ecuador, Indonesia, Peru, Venezuela, and South Africa on behalf of the members of the WHO African Region. The Brazilian proposal reflected developing

[114] Schultz, Mark and Walker, David, *How Intellectual Property Became Controversial: NGOs and the New International IP Agenda* 6 ENGAGE *at* http://www.ngowatch.org, 82, 84 (2005).

[115] Nygren-Krug, Helena Hogerzeil, Hans *Human Rights; A Potentially Powerful Source for Essential Medicines*, 84 Bulletin of the World Health Organization 5 (2006), 410.

[116] Industry boosters such as the US-based Federalist Society have co-opted this framing to assert that intellectual property rights are "human rights." They have adopted a real property discourse that obscures the very important differences between real property (which is scarce) and intellectual property (in which scarcity is *constructed* by law). http://www.fed-soc.org

[117] Posting of Nathan Ford, Nathan.FORD@london.msf.org, to IP-Health Listserv, *Sparks Fly Over Patents and Vital Drugs at World Health Assembly*, Lancet, May 31, 2003, *available at* http://lists.essential.org/pipermail/ip-health/2003–May/004816.html. (2003).

[118] Posting of Cecilia Oh, ceciliaoh@yahoo.com, to IP-Health Listserv, Third World Network Info. Service, *WHO Adopts Resolution on IPRs and Public Health After Wrangling Over Text*, Third World Network, May 29, 2003, *available at* http://lists.essential.org/pipermail/ip-health/2003–May/004815.html. (2003).

countries' concerns about access to medicines and called for an independent commission to examine the relationship between intellectual property rights, innovation, public goods, and public health. The developing countries sought an international committee much like the UK Commission on Intellectual Property Rights,[119] which was critical of overly strong patent rights as a barrier to access.[120] When it was clear that no one supported the US resolution, the Brazilian, American, and several African delegations worked out a compromise that a WHO committee adopted by consensus.[121] The resolution called for the establishment of a time-limited independent commission, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), and it omitted any reference to TRIPS-Plus obligations in bilateral and regional trade agreements. NGOs bemoaned the fact that the developing countries' proposals had been watered down in the compromise. However, the resolution prominently featured the Doha Declaration and endorsed the NGO/developing country approaches to the medicines issue by emphasizing the neglect of tropical diseases, the Doha Declaration's recognition that pharmaceutical products require special treatment, and the negative effects of patent protection on drug pricing.[122] Further, the resolution underscored the importance of making full use of TRIPS flexibilities. The director-elect of the WHO, Lee Jong-wook, announced measures to make Brazil's AIDS policy the foundation for the WHO efforts in this area. He asked the Brazilian Health Minister to release Paulo Teixeira, head of the administration's AIDS program, "to formulate the new policy for combating AIDS throughout the world, based on Brazil's experience."[123] This represented important recognition of Brazil's leadership role and support for the developing countries' and NGO positions.

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[119] *Id.*

[120] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy, at* http://www.iprcommission.org/papers/text/final_report/reportwebfinal.htm 1, 22 (2002).

[121] World Health Assembly, *Resolution of the World Health Assembly: Intellectual Property Rights, Innovation and Public Health* WHA56.27 *at* http://www.who.int (2003).

[122] WHO, *Intellectual Property Rights, Innovation and Public* Health, 28 May. WHA 56.27 *at* http://www.who.int (2003).

[123] Posting of Mike Palmedo, mpalmedo@cptech.org, to IP-Health Listserv, *WHO to Adopt Brazilian Model to Fight AIDS/HIV*, Fin. Times Ltd., May 21, 2003, *at* http://lists.essential.org/pipermail/ip-health/2003-May/004779.html. (2003).

In April 2006 the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) finally issued its report making numerous recommendations for improving health in developing countries.[124] The report's definition of "innovation" represented a major discursive breakthrough. For the first time, innovation has been defined as including not only the standard "discovery" and "development" components, but also "*delivery*." As Ellen 't Hoen of MSF points out, "the report stresses that innovation is only meaningful when people can have access to the results of the innovation."[125] This is the first time that access has been linked to innovation. It is significant insofar as it changes the debate. Just as today one cannot talk about intellectual property without talking about public health, perhaps several years from now people will begin to assume a necessary relationship between innovation and *access*.

Furthermore, the report explicitly characterizes intellectual property protection as a means and not an end.[126] The report recommends that governments avoid provisions in bilateral trade agreements that could restrict access to medicines.[127] It urges companies to: adopt transparent and consistent pricing policies; reduce prices for developing countries; and avoid filing patents or enforcing them in low-income developing countries in ways that would inhibit access to their products.[128] Overall it highlights how the current patent-based system of drug development is inadequate to serve the needs of the poor.

A former Bush aide and USAID lawyer sharply criticized the CIPIH report for its bias in favor of generic drugs and its criticisms of US FTAs, which he defends as "the best tool to raise economic growth, and therefore health, in the developing world."[129] This focus on macroeconomic growth typically obscures these policies' distributional effects. As Margaret Chon points out:

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[124] CIPIH Report, *at* http://www.who.int/intellectualproperty (2006).

[125] Ellen 't Hoen, "Report of the Commission on Intellectual Property Rights, Innovation and Public Health: a Call to Governments", 84 *Bulletin of the World Health Organization*, (2006), p. 421.

[126] *Id.*

[127] World Health Organization, "CIPIH Report: Main Recommendations", 84 *Bulletin of the World Health Organization* (2006), p. 351 (emphasis added).

[128] *Id.*

[129] Gardner, John, *Healthcare in the Developing World: Obstacles and Opportunities*, Tech Central Station May 9 2006 *at* http://www.tcsdaily.com/article.aspx?id=051906B (2006).

This approach dovetails with the interests of intellectual property industries whose short-term goals of maximizing revenue generation are not necessarily aligned with society's long term dynamic goals of maximizing innovation. While severely problematic even in the domestic welfare generating context, this type of crude welfare calculation can have brutal consequences in the context of intellectual property globalization.[130]

The CIPIH Report explicitly acknowledges the limitations of this prevailing instrumental perspective and calls for new approaches to medical R&D to better serve the poor. While it did not go as far as some health activists would have liked,[131] it is still a significant step forward for WHO in addressing health gaps.

At the WHA in late May 2006, Member States adopted a resolution, "Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action."[132] This resolution called for the establishment of an intergovernmental working group to develop a global framework to meet health needs by setting essential health R&D priorities and devising mechanisms for sustainable funding of R&D to meet public health needs. Kenya and Brazil had first proposed a needs-driven approach to essential health,[133] and exercised notable leadership in keeping this issue on the front burner throughout the deliberations. As James Love stated in praising the resolution, "R&D is too important to be left up to one person (Bill Gates), one country (US NIH/CDC) or private investors only. It is also the beginning of a serious discussion of how we can reconcile incentives to innovate with access."[134] These developments represent significant momentum at the WHO to consider alternative approaches to the TRIPS-Plus zeal of the US and its firms.

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[130] Chon, *supra*, n. 100, 2831.

[131] Correa, Carlos, "the Commission on IPRs, Innovation Public Health – A Critique", 122 *South Bulletin*, 15 April, 198, 198–199 *at* http://www.southcentre.org (2006). Professor Correa was one of the Commissioners.

[132] World Health Organization, *Public Health, Innovation, Essential Health Research an Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, A59/A/Conf. Paper No. 8 27 May 2006 *at* www.who.int (2006).

[133] EB117 R13 *at* www.who.int.org

[134] James Love, *CPTech Statement on WHA Passage of Historic Resolution on: Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, May 27, 2006 *at* http://lists.essential.org/pipermail/ip-health/2006-May/009631.html (2006).

Thailand, FTA Negotiations, The US and WHO

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 US 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.[135] In 2001 Thai activists challenged Bristol-Myers Squibb over its antiretroviral drug didanosine (DDI) because the public US National Institutes of Health developed the drug. That same year the US threatened to impose trade sanctions against Thailand if it pursued compulsory licensing to produce DDI. ''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 the availability of drugs through their pricing policies. This verdict was upheld in January 2004'' and Bristol Myers-Squibb settled out of court, surrendering its version of the drug to the Thai Department of Intellectual Property.[136]

The US has been trying to negotiate a US–Thai FTA and these deliberations became embroiled in a national political crisis. On April 4, 2006 caretaker Prime Minister Thaksin Shinawatra announced his decision to relinquish his claim as Prime Minister.[137] ''After one of the longest anti-government mobilizations in Thailand's history.... anti-government protestors forced Thaksin not to accept''[138] the post. While initially protesters focused on Thaksin, the People's Alliance for Democracy (PAD) expanded its attack to include the US-Thailand FTA negotiations. Prime Minister Thaksin had been conducting these negotiations unilaterally without consulting Parliament.[139] Eager to develop and expand Asian markets for its firms' pharmaceutical products, the US is hoping that a US–Thai FTA can provide a template for similar deals with Malaysia and Indonesia.[140]

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[135] Sell, *supra*, n. 2, 128.
[136] Williams, Dylan C, ''World Health: A Lethal Dose of US Politics'', 16 June 2006, *Asia Times* Online *at* http://www.atimes.com (2006).
[137] Jacques-chai Chomthongdi, *Thaksin*'s Retreat: Chance for Change or Consolidation of Power? 5 April, 2006 *at* http:// www/ftawatch.org (2006).
[138] *Id.*
[139] Williams, *supra*, n. 136.
[140] *Id.*

On January 9th 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 US-FTA negotiations. His op-ed appeared in the midst of the sixth round of US-Thai 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[141] have bargained away reasonable flexibilities and safeguards in the implementation of intellectual property rights provided by the World Trade Organization.[142]

He went on to point out that of 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 extraordinary 79%.[143] 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.''[144]

In late March 2006, the late WHO director-general Lee Jong-wook[145] transferred Dr. Aldis from Bangkok to a research position in New Delhi. An Asia Times Online investigative report into this transfer revealed US 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.''[146] Lee recalled Dr. Aldis after

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[141] Australia, Chile, Morocco, Singapore, Bahrain and Central American countries.

[142] Aldis, William, *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*, 9 January 2006. Bangkok Post *at* http://www.bangkokpost.com/News/09Jan2006_new19.php (2006).

[143] *Id.*

[144] *Id.* The 30 baht scheme refers to the inclusion of HIV treatment in Thailand's 30 baht health care program which is designed to contain costs and make essential medicines affordable to those in need.

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

[146] Williams, *supra*, n. 135.

serving just over 15 months in what is traditionally a four-year posting.[147] 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."[148]

In fact, it appears that Dr. Aldis was being punished for his January op-ed opposing the TRIPS-Plus provisions of the US-Thai FTA proposals. The British medical journal *The Lancet* implied as much in its June article in which it characterized Dr. Aldis' transfer as a direct result of the editorial and "was a clear signal of US influence on WHO."[149] Aldis was critical of the US' 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."[150] During the spring of 2006, 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."[151]

On March 23, 2006, a US ambassador to the UN in Geneva met with Lee privately and expressed concerns about Aldis' editorial. "A follow-up letter 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."[152] The next day Lee contacted the regional WHO New Delhi office and told it of his decision to recall Aldis.[153] A Bangkok-based US official leaked the news of Aldis' transfer. A senior WHO official believes that Lee's decision and the US government's news leak were "specifically designed to engender more self-censorship among other WHO country representatives when they comment publicly

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147 *Id.*
148 *Id.*
149 Benkimoun, Paul, "How Lee Jong-wook Changed WHO", 367 *The Lancet*, June 3, (2006), p. 1806.
150 Williams, *supra*, n. 136.
151 *Id.*
152 *Id.*
153 *Id.*

on the intersection of US trade and WHO public-health policies.''[154] Williams concludes that the Bush administration's tactics of trying to bring UN agencies into line with US commercial and political interests come at the expense of the WHO's ''stated mission, commitments and global credibility as an impartial and apolitical actor.''[155] In the meantime, Suwit Wibulpolprasert, senior adviser to the Thai Public Health Ministry, has requested that WHO provide an explanation for Dr. Aldis' abrupt removal.[156] At the time of this writing[157] this issue has sparked considerable consternation about lack of transparency and suppression of freedom of speech for WHO employees, but remains unresolved.

Conclusion

Contemporary trends are both disturbing and hopeful. The close ties between PhRMA, USTR and campaign contributions mean that US policy will likely remain aggressive. Furthermore, the revolving door that allows former high-level policymakers like Mickey Kantor to turn around and profit as lobbyists also erodes any image of policymakers as disinterested stewards of the ''public interest.'' Inappropriate interference with agencies, like WHO, in pursuit of corporate agendas compromises the integrity of the agencies. These murky and opaque ways of conducting business provide ample opportunity for policies that put profits ahead of people. The recall of Aldis was a particularly ham-fisted example of US interference behind the scenes.

On the other hand, one may hope that revelations of inappropriate interference will provoke enough outrage to lead to new measures to ensure transparency. South American health ministers' unity behind TRIPS flexibilities and against TRIPS-Plus provisions is another hopeful development. They have pledged to be involved

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[154] *Id.*
[155] *Id.*
[156] *String Pulling: Aldis Warned Against Thai–US Free Trade Pact*, The Bangkok Post June 20, 2006 *at* http://www.bangkokpost.com/News/20Jun2006_news03.php (2006).
[157] June 23, 2006.

in trade policymaking; to the extent that they are able to do so they can work to keep access to medicines a priority in trade negotiations. In any event it seems clear that they will not stand by the sidelines and let their governments bargain away TRIPS flexibilities without a fight.

Professor of Political Science and International Affairs
George Washington University
Washington, DC, USA
E-mail: susan.sell@gmail.com