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Special 301 of the Trade Act of 1974 and Global Access to Medicine

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SPECIAL 301 OF THE TRADE ACT OF 1974 AND GLOBAL ACCESS TO MEDICINES

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ABSTRACT

Since its inception in 1988, the United States Trade Representative's "Special 301" adjudication of foreign intellectual property law standards has been used to promote policies restricting access to affordable medications around the world. President-elect Obama released a platform promising to "break the stranglehold that a few big drug and insurance companies have on these life-saving drugs" and pledged support for "the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing public health needs." The 2009 and 2010 Special 301 reports, however, indicate that the Obama Administration has not yet implemented this pledge into administration trade policy. Although the 2010 Report shows some improvement, the Obama Administration continues using Special 301 to pressure developing countries to adopt escalating intellectual property rules that are not required by any international agreement and that will negatively impact access to medicines.

Keywords: Access to medicine; TRIPS; World Trade Organization; Special 301; United States Trade Representative; Human Rights; generic medicines; public health; Doha Declaration; data exclusivity; linkage; patents; intellectual property; Obama Administration

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One of the less heralded rituals of spring in Washington, D.C., is the unveiling of the U.S. Trade Representative’s Special 301 Report on the last day of April each year. For over two decades the report has functioned as one of the primary sticks for the U.S.’s “carrot and stick” approach to

international intellectual property policy. The report weighs countries' compliance with intellectual property standards and enforcements efforts—both those embedded in existing treaties and those the U.S. would like to see adopted. It threatens and rewards countries via inclusion on or delisting from its annual 'Watch List' ("WL") and 'Priority Watch List' ("PWL"), and has the power to implement unilateral trade sanctions when U.S. demands are not met. The construction of the report requires the administration to take decisions on which countries it views as having "adequate" intellectual property protection. The report is thus a key expression of the trade policy of the U.S. in intellectual property matters.

This article examines the history and current use of the Special 301 program to restrict access to generic medicines in developing countries, including in the two reports (in 2009 and 2010) released under the Obama Administration. The news for access to medicines advocates is not good on the whole. Both Obama Administration reports continue the previous administration's policies of using Special 301 to promote "TRIPS-plus"[2] policies that endanger access to medicines for millions of people around the world. These policies violate not only the Obama Administration's pledges to promote access to affordable medications in developing countries, but also U.S. commitments and duties under World Trade Organization's dispute settlement understanding, the 2001 Doha Declaration on the TRIPS Agreement and Public Health, numerous World Health Organization resolutions, express Congressional policy, the best interests of the President's Emergency Plan for AIDS Relief, the interests of global health and international human rights obligations.

There is a glimmer of hope. The 2009 and 2010 Reports reflect small

[2] i.e. policies that go beyond the minimum standards required by the World Trade Organization agreement on Trade Related Aspects of Intellectual Property Rights.

moves toward a more complete embrace of the Doha Declaration on TRIPS and Public Health and a gradual de-escalation of some issues that threaten access to medicines. But on the whole, the most recent Special 301 Reports signal more continuity than change in U.S. policy on trade and access to medicines.

A. Legal and Statutory Background

The Special 301 program takes its name from, and builds upon the administrative structure of, Section 301 of the Trade Act of 1974. That Act was passed at a time of large and growing trade deficits, increasing flight of manufacturing activities abroad, the rise of Japan as an industrial giant, skyrocketing foreign debt and economic crises caused by dependency on foreign oil imports, all of which fueled a mood in U.S. policy circles that was "decidedly protectionist."[3] U.S. export industries attached considerable blame for the U.S. economic woes on the weak enforcement regimes in the General Agreement on Tariffs and Trade (GATT), and the accompanying inability of the U.S. to enforce free trade commitments abroad.[4] Section 301 of the Trade Act of 1974 was a key element of the response. The program authorized the President to impose economic sanctions on countries that "burden or restrict United States commerce."[5] Notably, the law did not

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[3] PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 85 (2003).

[4] *See generally* AGGRESSIVE UNILATERALISM 18-26 (Jagdish Bhagwati & Hugh T. Patrick eds., 1993); Drahos & Braithwaite, *supra*; Andreas F. Lowenfeld, International Economic Law 46 (1st ed. 2002) (discussing weak GATT enforcement rules); SUSAN SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003) (discussing the general history of the creation of the WTO).

[5] 19 USC 2411(a)-(c) (describing authorized sanctions as including suspension of trade agreements, the imposition of tariffs or restrictions on imported goods, and the withdrawal

require that the alleged foreign conduct violate any trade agreement with the United States to be subject to sanction under the Act.[6]

At the urging of the pharmaceutical and copyright industries, Section 301 was amended in 1984 and 1988 to expand the policy into intellectual property. The 1984 amendment established "adequate and effective protection of intellectual property rights" as grounds for 301 investigation and sanctions.[7] In 1988, the statute was amended again to create the new intellectual property-focused "Special 301" program.

Under Special 301, the USTR is required to annually publish in the Federal Register a list of countries that deny "adequate and effective protection of intellectual property" or "deny fair and equitable market access for U.S. firms that rely on intellectual property," and then designate among those countries the subset of worst actors to be designated "priority foreign countries."[8] These requirements resulted in the well-known 'Watch List' and 'Priority Watch List,' which serve as warning mechanisms to countries perceived as out of compliance with USTR's preferences on IP policy. Designation as a 'Priority Foreign Country,' triggers a 30-day countdown during which targeted countries must "(enter) into good faith negotiations" or "(make) significant progress in bilateral or multilateral negotiations" or face sanctions determinations under the Section 301 process.[9] Priority foreign country determinations are reserved for countries

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of Generalized System of Preferences ("GSP") benefits for developing countries).

[6] *See* LESLIE ALAN GLICK, GUIDE TO UNITED STATES CUSTOMS AND TRADE LAWS AFTER THE CUSTOMS MODERNIZATION ACT 150 (3rd Ed. 2008).

[7] 19 U.S.C. § 2411(d)(3)(B)(i)(II).

[8] 19 U.S.C. § 2242(a) (listing identification criteria); *see also*, § 2242(e) (requiring Trade Representative to publish a list in the Federal Register).

[9] 19 U.S.C. § 2242(b)(1)(C) (specifying that "In identifying priority foreign countries under subsection (a)(2) of this section, the Trade Representative shall only identify those

"that have the most onerous or egregious acts, policies, or practices,"[10] that "have the greatest adverse impact (actual or potential) on the relevant United States products,"[11] and for which "there is a factual basis for the denial of fair and equitable market access as a result."[12]

Special 301 findings are, by intent and definition, unilateral findings by the U.S. and subject to U.S. standards.[13] As in the original Section 301, foreign practices and policies do not have to contravene any trade agreement with the United States to be found "unreasonable."[14] Nor must the U.S. take into account a country's level of economic development in determining what is fair or unfair—a sharp departure from GATT rules promoting differential treatment for developing countries.[15]

1. 1984-1994

The first use of Section 301 unilateral sanction authority in an intellectual property case followed the 1984 amendments listing a lack of adequate intellectual property protection as a potential ground for a 301 action. The Reagan Administration made quick use of the new powers by

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foreign countries that are *not entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations.*" (emphasis added)).

[10] 19 USC 2242(b)(1)(A)

[11] 19 USC 2242(b)(1)(B)

[12] 19 USC 2242(b)(3)

[13] *See* LESLIE ALAN GLICK, GUIDE TO UNITED STATES CUSTOMS AND TRADE LAWS AFTER THE CUSTOMS MODERNIZATION ACT 150-51 (3rd Ed. 2008) (explaining the "great deal of discretion" USTR has to define infringements).

[14] Id.

[15] See Hesham Youssef, *Special and Differential Treatment for Developing Countries in the WTO*, SOUTH CENTRE TRADE-RELATED AGENDA, DEVELOPMENT AND EQUITY (T.R.A.D.E.) WORKING PAPERS No. 2 (1999), available at http://www.southcentre.org/index.php?option=com_content&view=article&id=283%3Aspecial-and-differential-treatment-for-developing-countries-in-the-wto&Itemid=1&lang=en

launching investigations of two industrializing nations with histories of infant-industry protection: Korea and Brazil. Each case ultimately led to new intellectual property laws being passed in the targeted countries, marking the strategy as a huge success in industry perception.

A 1985 action against Brazil pressed for changes in Brazil's informatics policy. The U.S. alleged that Brazil failed to adequately protect copyrights in computer software, as part of a broader attack on Brazil's national import substitution policy favoring domestically produced computers and software. At the time, there was no bilateral or multilateral agreement binding Brazil to grant copyrights on software. But the U.S. threats were successful in pressuring Brazil to alter its policy in 1988, when Brazil amended its copyright law to include computer software protection and pledged to phase out its local purchasing preferences.[16]

A second complaint in 1987 concerned Brazil's lack of pharmaceutical product patent protection. At least 50 other countries denied patents for pharmaceuticals at the same time period,[17] and Brazil was not required to grant pharmaceutical patents by any bilateral or multilateral commitment binding it.[18] Nevertheless, the U.S. carried forward its 301 complaint and used its unilateral authority to impose trade sanctions on Brazil until it

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[16] THOMAS BAYARD & KIMBERLY ELLIOT, *RECIPROCITY AND RETALIATION IN US TRADE POLICY* 189 (1994).

[17] *See* Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents, Developing a Public Health Perspective*, WHO, ICTSD, UNCTAD WORKING PAPER (January 2007) (noting that at least 50 countries lacked pharmaceutical patents prior to the initiation of the Uruguay round of trade negotiations in 1986).

[18] *See generally* Kumariah Balasubramaniam, *Pharmaceutical Patents in Developing Countries: Policy Options*, 22 ECON. & POLITICAL WEEKLY 103-120 (1987) (explaining lack of international obligations on scope of patents at the time).

changed its law.[19] Brazil responded with a GATT suit challenging the legality of the unilateral retaliation.[20] The GATT complaint was never adjudicated, however, because the U.S. blocked the formation of a dispute settlement panel. Sanctions were ultimately lifted in 1990 when a new Brazilian president promised to revise its law to provide pharmaceutical patents.[21]

A 1985 301 case against Korea also included complaints about Korea's lack of patent protection for pharmaceuticals. That complaint ultimately ended with a bilateral agreement with the US on intellectual property. The agreement required Korea to amend its copyright and patent laws, creating what one negotiator described as a "blueprint for other agreements," including TRIPS.[22]

The Special 301 program creating watch lists for intellectual property was created in 1988, during the Uruguay Round of GATT negotiations that ultimately produced the TRIPS agreement. During those early years, the US government used Special 301 to pressure countries to accept TRIPS and to punish dissenters.[23] The US placed many of the leading countries opposing

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[19] *See* Bayard & Elliott, *supra,* at187-193. (noting that U.S. imposed duties on imported Brazilian goods cost Brazil approximately $39 million); *see also* § 19 USC 2411(a)(3) (stating that penalties under Section 301are supposed to "be devised so as to affect goods or services of the foreign country in an amount that is equivalent in value to the burden or restriction being imposed by that country on United States commerce.").

[20] Id.

[21] *See id.*; *Brazil-U.S. Dispute Set For GATT*, N.Y. TIMES, Feb. 22, 1989, *available at* http://www.nytimes.com/1989/02/22/business/brazil-us-dispute-set-for-gatt.html.

[22] Drahos & Braithwaite, *supra* , at 103.

[23] *See* Donald Harris, *The Honeymoon is Over: The US-China WTO Intellectual Property Complaint*, 32 FORDHAM INT'L L.J. 96, 101 (2008) [hereinafter Harris I]; *see also* Donald Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 735 (2006) [hereinafter Harris II] (explaining that in 1992, US

TRIPS in the first Special 301 Report in 1989, including Brazil, India, Argentina, and Egypt.[24] Two years later, India, China and Thailand became the first countries to grace the Priority Foreign Countries listing, triggering section 301 investigations. Brazil was sanctioned with a loss of GSP benefits in 1988; Thailand lost them in 1989; and India in 1992—all on matters related to pharmaceutical patents. None of the countries were in derogation of any multilateral or bilateral commitment with the U.S.

Through these years, the credible threat of sanction appeared to be the driving policy choice motivating the program. Foreign countries had a great deal to lose from US sanctions that limited access to the broad US market. And because 301 sanctions were determined unilaterally, there was little countries could do to influence the process and resist its negative determination. Accepting the regime shift of intellectual property matters into the multilateral World Trade Organization (WTO) became one strategy of developing countries to get rid of Special 301's unilateral threats and sanctions.[25] But that strategy failed.

2. 1994-2008

The passage of the WTO's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)[26] secured most of the substantive goals on intellectual property policy that the USTR had pursued in the 1980s. Through TRIPS, the WTO included a broad array of minimum intellectual

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suspended India's GSP benefits (valued at $60 million). India's resolves was weakened in opposing the TRIPS, in light of a pragmatic issue of retaining good trade relations with the US).

[24] *See* Harris II, *supra* , at 735.

[25] *See* Bayard & Elliot, at 207.

[26] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, Annex 1C, art. 8, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

property standards for every member, including product and process patents in every field of technology. And perhaps most importantly, it resolved longstanding U.S. complaints about the lack of enforcement procedures in GATT by establishing a formal and binding dispute resolution process which could authorize trade sanctions for violations.[27] The dispute settlement provision came with a prohibition on the kind of unilateral adjudication previously effected under Section 301 and Special 301. Article 23.2 of the WTO agreement provides: "Members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this understanding."[28] It was thus thought by many developing countries that the enactment of TRIPS would spell the demise of Special 301.

The creation of the WTO did not end Special 301. Instead, Congress amended the Trade Act to specify that "[a] foreign country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations" of TRIPS.[29] Although the legality of this continuation of Special 301 under the WTO is open to question, as described below, continue it did.

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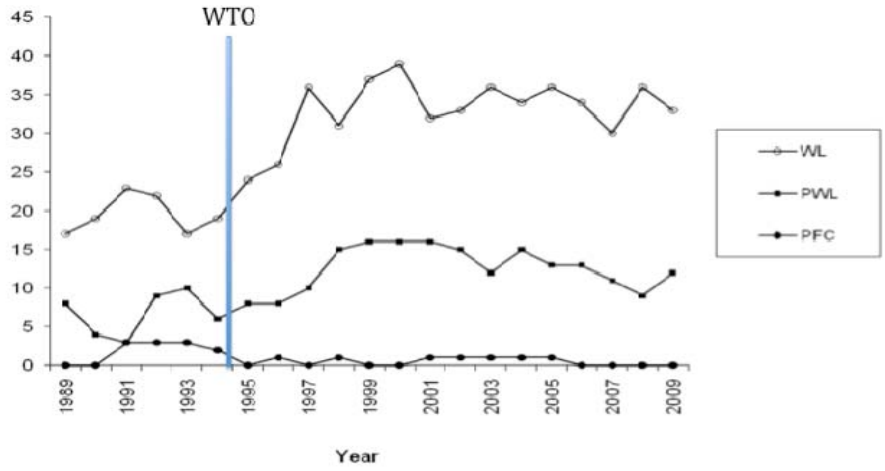
[27] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

[28] DSU Article 23(2) 23.2(a), Annex 2, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

[29] Trade Act of 1974, 19 U.S.C. § 2242(d)(4).



The above chart shows the number of countries placed on the Watch List, Priority Watch List, and Priority Foreign Country listings before and after the establishment of the WTO.[30] What is notable is that the number of countries identified on Special 301 watch lists steadily *increased* in the post-WTO years while the number of countries designated as PFCs, and therefore under the most immediate threat of economic sanctions, dropped off dramatically. Only three countries were designated as PFCs after 1994: China in 1996, Paraguay in 1998, and Ukraine in 2001-05. Of these, only Paraguay was a member of the WTO in the year it was listed as a PFC.[31]

The increasing use of watch lists and decreasing use of PFC designations reflect a shift in the primary mechanism of coercion under Special 301. Whereas in the pre-1994 period the US appeared to be relying on a credible threat of sanctions as its main tool to promote compliance with its wishes, after the WTO the main tool of persuasion was "to give countries the feeling that their behavior on intellectual property was the subject of

[30] Research by Mike Palmedo, American University Washington College of Law Program on Information Justice and Intellectual Property (2010).

[31] Argentina (WTO member since 1995) was identified as PFC in 1994 (prior to WTO establishment), but US sanctions against Argentina became effective in 1996 (50% GSP reduction).

constant surveillance."[32] For this purpose, it was more important to list many countries as subject to the watchful gaze of USTR than it was to actually impose sanctions.

3. Special 301 as a Violation of the WTO Dispute Settlement Understanding

The reduction of PFC determinations likely reflected concerns about the legality of unilaterally imposing economic sanctions on foreign countries within the WTO framework. Indeed, in 1999, a WTO Dispute Settlement Panel reviewed the use of Section 301 in non-IP cases and held that the U.S. could not use 301 to impose unilateral trade sanctions without going through the WTO dispute settlement process.[33] Similarly, unilateral sanctions imposed under Special 301 would appear to be a clear violation of the WTO agreement.

The continued use of Special 301 watch lists after the establishment of the WTO evidences a conclusion by the U.S. that watch lists do not implicate the multilateral dispute resolution mandate. This conclusion is far from clear, however. By its plain terms, the dispute settlement understanding is not limited to a ban on unilateral imposition of economic sanctions, but rather extends to a prohibition of any member making "a determination to the effect that a violation has occurred."[34] Under U.S. law, the Special 301 process is an administrative adjudication – it is a rule bound procedure for determining whether other country laws are consistent with a statutory standard.[35] The statutory standard includes determinations as to

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[32] Drahos & Braithwaite, *supra*, at 100.

[33] Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, ¶ 7.89, WT/DS152/R (Dec. 22, 1999) [hereinafter Section 301 Panel Report].

[34] DSU, *supra*.

[35] *See* Administrative Procedures Act 5 U.S.C. §551(7) (defining "adjudication" as any "agency process for the formulation of an order" determining rights and responsibilities

whether foreign country laws "violate provisions of international law or international agreements to which both the United States and the foreign country are parties."[36] In the results of Special 301 adjudications, USTR frequently determines that countries are in violation of U.S. interpretations of the TRIPS agreement, for example in failing to adopt "data exclusivity" regulations as the means for implementation of TRIPS Article 39.3. As such, the process appears to violate the WTO dispute settlement understand both facially and as applied.

There is also basis in WTO jurisprudence for seeing the Watch Lists themselves as trade barriers. In the 1999 dispute settlement decision on Section 301, the WTO panel explained that the "threat alone" of unilateral sanctions outside the dispute settlement process risks undermining the basic principle of WTO legitimacy:

> Members faced with a threat of unilateral action, especially when it emanates from an economically powerful Member, may in effect be forced to give in to the demands imposed by the Member exerting the threat... To put it differently, merely carrying a big stick is, in many cases, as effective a means to having one's way as actually using the stick. The threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."[37]

This language in the panel decision appears to be a shot across the bow

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based on past conduct). The adjudication is "informal" because the governing statute does not require that the process be "on the record after opportunity for an agency hearing," which would trigger heightened procedural protections. Id. at §554(a)

[36] 19 U.S.C. § 2242(d)(3).

[37] Section 301 Panel Report, *supra*.

of the Special 301 Watch Lists, but no member has brought a challenge against the program in the WTO yet.

B. Special 301 and Access to Medicines

1. Use of Special 301 to Promote TRIPS-Plus Policies

During the negotiation of the TRIPS agreement, concerns about its impact on access to medicines were a primary issue for many countries. Pharmaceutical patents grant monopoly rights to patent holders, allowing them to charge much higher prices than would be possible in a competitive environment. That effect is justified by the assertion that a portion of those excess profits would be directed toward research and development of new medicines. But increased prices also limit access to affordable medications. This effect is most pronounced in developing countries with high income inequality where monopolies on medicines predictably lead to profit maximizing pricing that will exclude the great majority from access while providing miniscule incentive for future innovation.[38]

In recognition of the unbalanced costs and benefits of intellectual property, particularly with respect to medicines, it is commonly accepted that intellectual property rules for medicines should differ among countries.[39] A one-size-fits-all intellectual property norm was emphatically

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[38] Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184 (2009).

[39] *See, e.g.*, *Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy*, 155 (2002); *Report of the Commission on Intellectual Property Rights Intellectual Property and Development, Lessons from Recent Economic Research*, 215 (Carsten Fink & Keith E.Maskus eds., 2005); Joseph Stiglitz, *Intellectual-Property Rights and Wrongs, available at* http://www.project-syndicate.org/commentary/stiglitz61/English.

rejected in the WTO negotiations. TRIPS contains minimum standards for patents and other forms of intellectual property for all countries. But the agreement contains important flexibilities that can and should be used to tailor the contours of intellectual property protection to public health and other public interests.[40] Primary among the TRIPS flexibilities supporting access to medicines are:

- **Compulsory licenses.** TRIPS protects the authority to grant a compulsory license or government use order for any patented product for any reason, subject only to the procedural and adequate compensation requirements of Art. 31;
- **Scope of patentability.** Countries have freedom to define the scope of patentable subject matter through legislative or policy definitions of the criteria that inventions be "new," "involve an inventive step," and are "capable of industrial application," (Art. 27), including by rejecting patents for minor improvements or new uses of known products;
- **Parallel importation.** Countries may define "exhaustion of rights" for intellectual property to allow parallel importation of intellectual property protected products between countries;
- **20 year patents.** Countries may limit patents to 20 years (Art. 28), with no extensions for new uses of existing products or for problems of regulatory delay;
- **Freedom from patent-registration "linkage."** Countries

[40] *See* TRIPS, *supra*, Art.8 (expressing the overriding principles that countries remain free to "adopt measures necessary to protect public health" and to take measures "to prevent the abuse of intellectual property rights").

are not required to implement any "linkage" between the drug registration and assertions of patent protection, which can permit improper use of the registration system by patent holders to delay legitimate generic entry into a market;

- **Flexible data protection.** Countries are not required to adopt U.S. or EU-style "data exclusivity" as the form of protection for undisclosed information under Art. 39.3, thereby avoiding the grant of marketing monopolies for medicines that operate independently of patent status;
- **Freedom of regulation.** Countries remain free to use other regulatory systems, including competition policies, reimbursement formularies and price regulations, to restrain excessive pricing by patent holders, in particular "to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development." (Art. 8).

In the post-TRIPS years, Special 301 was used to press countries to limit every one of the access to medicines flexibilities noted above. The trend began in the Clinton Administration when, soon after the passage of TRIPS, the U.S. used Special 301 to pressure South Africa to give up statutory authorization for parallel importation and Brazil to restrict the grounds for which it authorized compulsory licenses.[41] In each case, the countries were attempting to use these flexibilities to promote access to generic AIDS drugs. These measures were in large part responsible for an outpouring of international outrage. Health advocates in the U.S., South Africa and Brazil took the streets and, in the U.S., protested at Gore

[41] *See* Section 301 Panel Report, *supra*.

presidential campaign rallies.[42] The pressure led the Clinton Administration to announce a new policy on access to medicines in December 1999.

The new policy of the Clinton Administration included an executive order banning TRIPS-plus pharmaceuticals pressure on any Sub-Saharan African country.[43] It also included a notable change in the Special 301 program. The 2000 Special 301 report explained:

> The Administration has made clear that the final choice of what policies to employ [to promote access to medicines] is one for each government to make on its own. Should a government avail itself of the flexibility the WTO TRIPS agreement provides to address a health care crisis, the United States will raise no objection.[44]

For a short moment in U.S. trade policy, it appeared that access to medicines advocates had obtained a significant victory over the use of Special 301 to promote restrictions on access to medicines. But the Administration soon changed hands.

One of the Bush Administration's first acts on international intellectual property policy was to assent to the 2001 Doha Declaration on the TRIPS

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[42] See ELLEN F. M. 'T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH (2009); Susan Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481 (2002); Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069 (1996).

[43] Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 10, 2000).

[44] Press Release, Office of the United States Trade Representative, USTR Releases Super 301, Special 301 and Title VII Reports (May 1, 2000) *available at*, http://hongkong.usconsulate.gov/uploads/images/YXuL_DZ9fkSv3SDt1zgbMg/usinfo_301_00-30.pdf.

Agreement and Public Health.[45] That declaration, instigated by the African Group in response to the Clinton administration's use of Special 301 and other trade pressure in South Africa and Brazil, affirmed the "the right of WTO Members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibility" to "promote access to medicines for all."[46] But Bush's USTR soon turned face on that commitment, vigorously pursuing trade agreements and trade pressure aimed at promoting TRIPS-plus policies on pharmaceuticals in developing countries.[47] Special 301 was used to press countries to limit grounds for compulsory licenses, restrict freedom to define the scope of patentability, prohibit parallel importation, extend patents beyond 20 years, implement "linkage" between drug registration and assertions of patent protection, adopt U.S. or EU-style "data exclusivity" rules, and do away with evidence-based formularies and other price and competition restrictions on pharmaceutical monopoly power. The administration justified these pressures in spite of its international commitments with the assertion that "IP rights ultimately enhance public health . . . and that therefore this approach is consistent with the Doha

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[45] *See* t'Hoen *supra*, *see also* Sell, *supra*, Weissman, *A Long Strange Trips, supra.*

[46] World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 755, ¶ 4 (2002) [hereinafter Doha Declaration] (*emphasis added*); *see* Carlos Correa, *Implications of the Doha Declaration on the Trips Agreement and Public Health*, Health Economics and Drugs Series, No. 012, WHO (2002) *available at* http://apps.who.int/medicinedocs/en/d/Js2301e/ (discussing the legal implications of the Doha Declaration).

[47] *See* United States House of Representatives, Committee On Government Reform – Minority Staff, Special Investigations Division, Trade Agreements and Access To Medications Under The Bush Administration, Prepared For Rep. Henry A. Waxman [hereinafter Waxman Report] (June 2005); Robert Weissman, *TRIPS-Plus Provisions in Trade Agreements: Consequences for Public Health* (Essential Action, Working Paper), *available at* http://www.essentialaction.org/access/uploads/tripsplusprovisions.doc.

Declaration."[48]

2. Public Health Criticism of TRIPS-Plus Policies

TRIPS-plus pressure to restrict access to medicines in the Bush Administration was widely condemned by domestic and international experts and officials.

a. The World Health Organization

The World Health Organization (WHO) has long urged developing countries to "be cautious about enacting legislation that is more stringent than the TRIPS requirements."[49] Its 2006 major report on *Intellectual Property Rights, Innovation and Public Health* admonished that "Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries."[50] In 2008, after more than two years of negotiation, all the WHO Member States, including the U.S., adopted by consensus the historic resolution WHA 61.21 containing a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.[51] Through the Plan of Acton,

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[48] U.S. Government Accountability Office, *Report to Congressional Requesters: U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, Publication No. GAO-07-1198 at 28 (2007) [hereinafter GAO Access Report] (quoting administration officials).

[49] *See* WHO, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO/EDM/2001.2 at 4-5 (Mar. 2001) (stating "Poorer populations in developing countries should not be expected to pay the same price as do the wealthy for newer essential drugs. TRIPS-compliant mechanisms can be used to lower drug prices.").

[50] WHO, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, at 145 (Apr. 2006) [hereinafter 2006 CIPIH Report]

[51] WHO, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the Sixty-first World Health Assembly*, WHA61.21, element 5.2.c, (May 24, 2008) [hereinafter Global Strategy and Plan of Action] *available at* www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

the U.S. agreed "to take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference and the WTO decision of 30 August 2003."[52]

b. UN Human Rights Bodies

U.S. trade pressure on medicines attracted the attention of UN human rights bodies. Promoting access to affordable medicines for the poor is a widely recognized human rights duty emanating from the recognition of civil and political as well as social and economic rights that bind the United States.[53] Health and social policies which increase mortality and morbidity implicate the right to life in Article 6(1) of the International Covenant on Civil and Political Rights[54] as well as Articles 22 and 25.1 of the Universal Declaration of Human Rights.[55] States are bound to protect the rights to life and health not only of their own citizens, but also of the citizens of other countries affected by their foreign policy, trade and assistance programs.[56]

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[52] *Id.*

[53] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health, ¶ 2, E/C.12/2000/4 (Aug. 11, 2000).

[54] *See* The Right to Life, U.N. GAOR Human Rights Comm., 37th Sess., Supp. No. 40, at Gen. Comment No. 6, ¶ 5, U.N. Doc. A/37/40 (1982); Concluding Observations of the Human Rights Committee: Peru, ¶¶ 13, 15, U.N. Doc. CCPR/C/79/Add.72 (1996).

[55] Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948) [hereinafter Universal Declaration of Human Rights] (noting that Art. 22 protects "the economic, social and cultural rights indispensable for his dignity and the free development of his personality"; Art. 25 protects "the right to a standard of living adequate for the health of himself and of his family, including . . . medical care and necessary social services.").

[56] *See id.* at arts. 22, 28 (requiring "national effort and international cooperation" and noting that "[e]veryone is entitled to a social and international order in which the rights and

UN human rights officials and bodies have repeatedly affirmed that the globalization of intellectual property rights can only be squared with human rights concerns if countries are permitted and encouraged to utilize the full scope of intellectual property exceptions and limitations provided for in the TRIPS agreement.[57] Examining the human rights duties of states to take advantage of TRIPS flexibilities to promote access to medicines has been a frequent subject of human rights treaty monitoring bodies.[58] Such reviews

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freedoms set forth in this Declaration can be fully realized."); *see also* U.N. Charter arts. 55-56 (calling on members to take "joint and several action" to promote "a higher standard of living," "solutions of international economic, social health and related problems," and "universal respect for, and observance of, human rights"); *see* CONSTITUTION OF THE WORLD HEALTH ORGANIZATION, Preamble (July 22, 1946), 62 Stat. 2679, 14 U.N.T.S. 185 (declaring the "health of all peoples" as "dependent upon the fullest co-operation of individuals and States").

[57] *See* U.N. Human Rights Council [UNHRC], *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶ 27, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (*prepared by* Anand Grover); UNHRC, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶ 63, U.N. Doc. A/63/263 (Aug. 11, 2008); U.N. Econ. & Soc. Council [ECOSOC], Human Rights and Intellectual Property: *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, 27th Sess., ¶ 12, U.N Doc. E/C.12/2001/15 (Dec. 14, 2001); ECOSOC, Sub-Comm. on the Promotion and Protection of Human Rights, *Report of the High Commissioner: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, ¶¶ 27-28, E/CN.4/Sub.2/2001/13 (June 27, 2001). *Cf.* UNHCR, Commission on Human Rights Resolution: *Access to medication in the context of pandemics such as HIV/AIDS, Tuberculosis and Malaria*, E/CN.4/2003/29 (Apr. 22, 2003).

[58] *See* UNHCR, Comm. On the Rights of the Child, *Concluding Observations: Thailand*, ¶ 58(f), CRC/C/THA/CO/2 (March 17, 2006) (admonishing Thailand to "[e]nsure that regional and other free trade agreements do not have a negative impact on the enjoyment of the right to health"); UNHCR, Comm. On the Rights of the Child,

have included analysis of the duties of wealthy countries to promote the use of TRIPS flexibilities in their trade and assistance relations with poor countries.[59] This body of human rights law was summarized by Special Rapporteur Paul Hunt as meaning that "that no rich State should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement. In other words, developed States should not encourage a developing country to accept 'TRIPS-plus' standards."[60]

c. U.S. Congress

Members of Congress frequently criticized the Bush Administration's TRIPS-plus trade pressure on pharmaceuticals. The Kennedy Amendment

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Concluding Observations: *Peru*, ¶¶ 48-49, CRC/C/PER/CO/3 (March 14, 2006); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Ecuador*, *Concluding Observations*, ¶ 21, CRC/C/15/Add.262 (Sept. 13, 2005); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Nicaragua*, ¶ 16, CRC/C/15/Add.265 (Sept. 21, 2005); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Philippines*, ¶ 59, CRC/C/15/Add.259 (June 3, 2005) (recommending that the State use "all the flexibilities reaffirmed by the Doha Declaration . . . to ensure access to affordable medicines"); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Chile*, ¶ 59, E/C.12/1/Add.105 (Nov. 26, 2004) (encouraging Chile "to provide greater access to generic medicine making use of the flexibility clauses permitted in [TRIPS]"); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Ecuador*, ¶ 55, E/C.12/1/Add.100 (June 7, 2004) ("strongly urges the State party . . . to make extensive use of the flexibility clauses permitted in [TRIPS] in order to ensure access to generic medicine"); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Botswana*, ¶ 20, CRC/C/15/Add.242 (Nov. 3, 2004); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *El Salvador*, ¶¶ 47-48, CRC/C/15/Add.232 (June 30, 2004); UNHCR, Comm. On the Rights of the Child, *Concluding Observations*: *Uganda*,, CCPR/CO/80/UGA (May 4, 2004).

[59] *See* Denmark, Summary Record, E/C.12/2004/SR.37, ¶ 7 (16 November 2004).

[60] Paul Hunt, *Report to the General Assembly*, ¶ 63, A/61/338 (13 September 2006).

to the 2002 Trade Promotion Authority legislation, requiring trade policy to respect the Doha Declaration, was intended to block TRIPS-plus trade pressure on medicines.[61] In June 2005, the Committee on Government Reform reported that TRIPS-plus provisions on pharmaceuticals are "[c]ontrary to the principles of the Doha Declaration," because they "will significantly impede the ability of developing countries to obtain access to inexpensive, lifesaving medications."[62]

In the end of 2006, control of Congress shifted to the Democratic Party. The inclusion of Thailand and Brazil on the 2007 Special 301 watch lists for using compulsory licensing was criticized by dozens of Democratic Members of Congress for sending "a troubling message" to the "whole world . . . that the exercise of recognized public health flexibilities in trade obligations is frowned on by the United States."[63] Soon after, in May 2007, a bipartisan group of congressional leaders and the Bush Administration negotiated a "New Trade Policy for America," which limited pending trade agreement provisions on data exclusivity and excluded from the agreements requirements for linkage and patent extensions.[64] The same year, resolutions were introduced in the Senate and House calling on the USTR to "honor" the Doha Declaration's affirmation of the rights "to use 'to the full' the flexibilities" in TRIPS and "not place countries on the 'Special 301' Priority

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[61] *See* Consumer Project on Technology, *Trade Promotion Authority and HIV/AIDS*, *available at*, http://www.cptech.org/ip/health/trade/kennedy.html

[62] Waxman Report, *supra*, at ii.

[63] Letter from Rep. Henry Waxman, United States House of Representatives, et. al. to The Honorable Susan Schwab, United States Trade Representative (Jun. 20, 2007), *available at* http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=153595.

[64] http://waysandmeans.house.gov/Media/eNewsLetter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf; www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf

Watch List . . . for exercising the flexibilities on public health provided for in the TRIPS Agreement."[65]

d. The interest of PEPFAR

TRIPS-plus trade pressures on access to medicines have always stood in uneasy tension with U.S. foreign aid goals to increase treatment of people with AIDS in developing countries. The U.S. is a major purchaser of antiretroviral and other medicines for people living with HIV/AIDS through the President's Emergency Plan for AIDS Relief (PEPFAR).[66] In 2007, 73% of all antiretroviral drugs delivered by PEPFAR were generics, saving PEPFAR $64 million.[67] President Bush, in announcing his PEPFAR initiative, directly referenced the low-cost of generic medicines as enabling PEPFAR's scale up,[68] even while his USTR was annually producing 301

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[65] S.Res. 241, 110th Cong. (2007); H.Res. 525, 110th Cong. (2007). *See also* Letter from Rep. Henry Waxman, United States House of Representatives, et. al. to The Honorable Susan Schwab, United States Trade Representative (Apr. 9, 2008), *available at* http://waxman.house.gov/UploadedFiles/letter_special_301__04-09-08.pdf (urging that in Special 301 "countries should not be cited for the use of compulsory licenses or other flexibilities in accordance with international trade rules").

[66] *See* Press Release, The White House, Presidential Statement on the Global Health Initiative (May 5, 2009), *available at* http://www.whitehouse.gov/the_press_office/Statement-by-the-President-on-Global-Health-Initiative/ (last visited Jul. 1, 2010) (describing the President's global AIDS program as guided by the principle that "[t]he world is interconnected, and that demands an integrated approach to global health" that supports "the health and dignity of people everywhere").

[67] OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE, THE POWER OF PARTNERSHIPS: FOURTH ANNUAL REPORT TO CONGRESS ON PEPFAR (Feb. 2008), *available at* http://www.pepfar.gov/press/fourth_annual_report/ (last visited Jul. 1, 2010).

[68] *See* Press Release, President's Emergency Plan for AIDS Relief, Increasing the Availability of Safe, Effective, Low-Cost Generic Medications (Jan. 2009), *available at*

reports and trade agreements working counter to this goal.

C. Special 301 in the Obama Administration

The Obama campaign for the presidency reached out to access to medicines campaigners to join the broad coalition he was building to gain the presidency. In response to their concerns, he declared that his presidency would "break the stranglehold that a few big drug and insurance companies have on these life-saving drugs," and pledged support for "the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing public health needs under the WTO's Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS)."[69] The Obama administration has now produced two Special 301 reports cataloguing its policies on intellectual property and access to medicines. As detailed below, the administration receives low marks on its commitments thus far.

1. Procedural reform

The most notable change in Special 301 under the Obama administration may be in the area of procedural reform. But even here, the change has been extremely modest.

USTR reviews the IP policies of a huge number of countries every year. The 2010 report states that the laws and policies of 77 countries were reviewed through "extensive research and analysis."[70] The bulk of the work

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http://www.pepfar.gov/press/108120.htm (last visited Jul. 1, 2010) (claiming PEPFAR "supports the increased availability of safe, effective, low-cost, and generic antiretroviral drugs (ARVs) in the developing world…").

[69] Press Release, The Office of the President – Elect, The Obama-Biden Plan to Combat Global HIV/AIDS, *available at* http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids (last visited Jul. 1, 2010).

[70] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE

is done in a roughly four month window between January and April of each year. During that period, a great number of technical factual and legal determinations must be made, including the statutory mandates that the review distinguish countries "that have the most onerous or egregious acts, policies, or practices,"[71] that "have the greatest adverse impact (actual or potential) on the relevant United States products,"[72] and for which "there is a factual basis for the denial of fair and equitable market access as a result."[73] USTR has few dedicated staff to this effort,[74] and lacks the necessary legal, economic, and other experts to independently research and analyze the world's intellectual property policies and their economic effect on US trade interests. The agency therefore relies largely on an administrative comment process to provide the factual material required.[75]

Construction of the Special 301 report has always attracted a great deal of attention from the brand name pharmaceutical industry. The Pharmaceutical Research and Manufacturers of America (PhRMA) annually submits hundreds of pages of detailed allegations about the intellectual property and pharmaceutical policies of countries around the globe and delineates those it wishes to be targeted for threats of sanctions. PhRMA regularly targets countries for the failure to enact U.S.-style intellectual property and data protection standards or for having reimbursement

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PRESIDENT, 2010 SPECIAL 301 REPORT, at 3 (Apr. 30, 2010) [hereinafter 2010 Special 301 Report].

[71] Trade Act of 1974, 19 U.S.C. § 2242(b)(1)(A).

[72] 19 U.S.C. § 2242(b)(1)(B)

[73] 19 U.S.C. § 2242(b)(3)

[74] USTR Office of Intellectual Property and Innovation has a total of 8 staff, as verified over a phone inquiry on October 9, 2009.

[75] Drahos & Braithwaite, *supra*, at 94 (describing USTR's "symbiotic" reliance on industry submissions).

formularies that consider cost or promote generic medicines. PhRMA generally gets its way. Of the 48 countries PhRMA requested to be included in watch lists in 2008, 36, or 75%, of the requests were honored by USTR. For the most part, PhRMA findings and recommendations simply pass through into USTR's Special 301 Report.

In the past, it was exceedingly rare for pharmaceutical policy interests other than PhRMA to make their voice heard in the Special 301 process. Part of this has been by design. Reflecting a desire at the time to increase industry input into trade policy, the Special 301 statute requires USTR to "take into account information from such sources as may be available to the Trade Representative and such information as may be submitted to the Trade Representative by interested persons."[76] Although "interested persons" may include targeted countries or non-governmental organizations, in practice, USTR has sought and received input almost exclusively from industry. This too appears to be by design. For example, the 2009 request for comments focuses on requests for information on "problems experienced," rather than for all information needed to reach a balanced decision.

If the goal of the comment period was to solicit a full record of differing views and information to adjudicate between them, then one would expect an adversarial process in which notice and opportunities to be heard would be structured for targeted countries and their allies (e.g. "friend of the court" submissions from public interest organizations) to respond. Yet, until 2008, the process effectively made replies to the industry complaints impossible, as all comments were due on the same day. Presently, countries (but not non-state parties allied to them) are given two weeks of additional time to submit comments after industry submissions are received. That change

[76] 19 U.S.C. § 2242(b)(2)(B)

appears to have led to a dramatic increase of country submissions in the process – from a norm of 3 or 4 per year to over 20 in 2009 and 2010.

In 2010, for the first time, the USTR held an open public hearing (limited to participants physically present in the U.S.) as part of its report preparation process. The hearing was a response to the requests of global health groups that the Obama Administration change previous policies and processes that affect access to medicines. As shown in the table below, this small step toward more openness dramatically changed the range of parties participating in the process. In previous years there were never more than 60 submissions to USTR about Special 301, half of which were generally industry submissions and the other half (in recent years) from foreign countries. But in 2010 the number of submissions ballooned to over 500, nearly 90% of which were from individuals or public interest organizations opposed to the current direction of U.S. trade policy.[77] In the open hearing, the large majority of participants were representing public health organizations requesting change in administration policy that negatively impacts access to medicines.

[77] *See* Submissions Concerning Special 301, www.regulation.gov (choose "Read Comments" then enter "USTR 2010-0003" in "Keyword or ID").

	2007	2008	2009	2010
Companies and industry groups	21	19	30	37
Countries on previous 301 lists	4	3	24	25
Individuals and small businesses	0	2	1	441
Nonprofits	1	0	0	26

Although the process improved in 2010, the hearing procedure implemented by USTR remains severely flawed from an administrative justice standpoint. In a regular regulatory review process, a draft regulation or report is released and comments are requested on its contents. After the comments, the agency is normally compelled to explain its decision between opposing comments, thus demonstrating that any choices between opposing views have some rational basis. The 301 process lacks these basic procedural norms. Comments are invited on a notice, not a draft. And the final report that was issued in 2010 failed to respond to any of the factual and legal disputes before it. State and public health advocates submitted a list of 13 legal and factual disputes that they requested responses to. These included assertions that Special 301 violates the WTO Agreement, that USTR's interpretation of TRIPS article 39.3 as requiring data exclusivity is legally erroneous, that TRIPS-plus pressure on access to medicines violates U.S. international commitments, and that the Special 301 statute does not authorize the pursuit of substantive restrictions on nondiscriminatory reimbursement, competition or pricing policies. USTR's 2010 report does

not respond to any of these allegations of unlawful administrative action.

One of the hallmarks of a just and fair administrative process is an avenue for appealing questions of law, policy, and erroneous findings of fact to an independent authority. Indeed, this procedural protection is being demanded by USTR for pharmaceutical pricing programs abroad, but is not given in the Special 301 process that is used to make such demands. Administrative options for such an appeal could be established to a body housed in the State Department's Office of General Counsel or the Justice Department's Office of Legal Counsel. For example, questions about interpretation of whether Special 301 violates the WTO agreement, international human rights obligations, and the Doha Declaration involve important questions of international law that should not be determined by USTR itself.

As described at length in the analysis of the 2009 and 2010 Reports below, the written decisions of USTR are exceedingly vague. One of the marks of a non-arbitrary administrative process is that there are set standards being applied, which can then be appealed to the proper policy and legal authorities. But it is difficult to know what standards are being applied in many places in the Special 301 Report because there are no citations to offending laws or policies, no quotation of them and no clear recitation of the specific standard being applied.

2. Continuation of Restrictions on Access to Medicines

The changes in the substance of the Special 301 report on access to medicines issues have been similarly modest.

To further the administration's campaign and policy pledges to promote access to medicines and global health, a broad coalition of public health advocates pressed the administration to adopt a limiting principle in its trade policy to "[f]orbid the use of threats and punitive actions . . . in response to a country's use of TRIPS safeguards and flexibilities or refusal to adopt

TRIPS-plus measures."[78] In a submission to USTR in the 2010 Special 301 process, a coalition of global health groups pressed the Administration to put this principle into effect through an extension of President Clinton's Executive Order 13155 to all developing countries. The submission argued that the policy of the United States should be:

> (a) The United States shall not seek, through Special 301 listing decisions, negotiation or otherwise, the revocation or revision of any intellectual property or pharmaceutical price or competition regulation of any developing country that
>
> (1) promotes access to affordable pharmaceuticals or medical technologies; and
>
> (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 511(d)(15)), the Doha Declaration on the TRIPS Agreement and Public Health, the August 30 Decision system promoting access to generics for countries with inadequate local capacity to manufacture medicines, and the WHA Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

These principles have not been embraced by the Obama Administration yet. The 2009 and 2010 reports continue to press developing and other countries to adopt access to medicines limiting policies in excess of those required by TRIPS and in excess of the restrictions placed on the Bush Administration's trade negotiations by the May 2007 New Trade Policy for America.

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[78] ESSENTIAL ACTION, U.S. CIVIL SOCIETY PLATFORM ON TRADE-RELATED INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES ISSUES (2009), *available at* http://www.essentialaction.org/access/uploads/IP-MedsPlatformMay2009.pdf (last visited Jul. 1, 2010).

a. Incomplete Embrace of the Doha Declaration

The use of Special 301 to pressure countries to adopt TRIPS-plus intellectual property rules and other policies that limit access to affordable medicines has always stood in uneasy tension with the U.S. commitment to the Doha Declaration on TRIPS and Public Health.

The Bush Administration Special 301 reports rhetorically embraced the Doha Declaration while avoiding its affirming of the rights of countries to use TRIPS flexibilities "to the full" or the commitment that TRIPS "can and should" be interpreted and implemented to promote access to medicines for all public health problems. In the first Special 301 report after the Doha declaration, the U.S. limited its embrace of the Doha declaration to situations to "address a major health crisis, like the HIV/AIDS crisis in sub-Saharan Africa."[79] By 2008, the Bush Administration's stance had moderated somewhat, recognizing the application of the Doha Declaration to "serious public health problems," rather than only to "crises."

The Obama Administration's statements on the Doha Declaration are slightly broader. The 2009 Report eliminates the qualification "serious" from the public health problems Doha was meant to address, explaining: the "United States respects a country's right to protect public health, in particular, to promote access to medicines for all."[80] For the first time, the Report explicitly mentions support for use of compulsory licenses, stating: "the United States respects our trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement."[81] The same language is included in the 2010 report.[82] These

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[79] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE PRESIDENT, 2002 SPECIAL 301 REPORT, at 5 (2002) [hereinafter 2002 Special 301 Report].

[80] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE PRESIDENT, 2009 SPECIAL 301 REPORT, at 6 (2009) [hereinafter 2009 Special 301 Report]..

[81] *Id.*

are much broader categories of public interest concerns than the US has previously endorsed. But the Administration still appears intent on avoiding the Doha Declaration's affirming of the rights to use TRIPS flexibilities "to the full" and the instruction that TRIPS "can and should" be interpreted and implemented to promote public health and access to medicines. A strong endorsement of these principles would stand in stark contrast to the many TRIPS-plus pressures on medicines issues included in the reports.

b. Data exclusivity

The most common objection in the 2009 and 2010 Reports related to pharmaceutical policy is a complaint about "lack of protection [in a particular country] against unfair commercial use of undisclosed test and other data."[83] In 2010, fifteen countries were cited for lack of adequate pharmaceutical data protection (Algeria, Argentina, Brazil, Chile, Dominican Republic, Egypt, India, Indonesia, Lebanon, Malaysia, Mexico, Pakistan, Paraguay, Turkey, and Vietnam). This number of citations is down from 21 countries similarly cited in 2009.

The vague complaints about lack of data protection, which most commonly merely restate the TRIPS article 39.3 requirement, is best interpreted as a demand for a new form of pharmaceutical marketing monopoly known as "data exclusivity." The issue arises because of

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[82] 2010 Special 301 Report, *supra*, at 12-13.

[83] 2009 Special 301 Report, *supra*, at 17 (noting that each of the ten countries on the Priority Watch List is targeted for such a complaint as are ten of the Watch List countries and Paraguay, identified as a Section 306 monitoring case. In all but one of the entries (Israel), this vague language complaining of unidentified "lack of protection" is used nearly verbatim with no explanation of what specifically is inadequate in the country's laws. For the Israel submission, the report specifically states that USTR considers five years of data exclusivity to be required, rather than the "effective period" of three to four years provided in Israel's law).

requirements that manufacturers must prove the safety, efficacy, and quality of medicines through clinical trials or other data. When a generic manufacturer subsequently attempts to obtain marketing approval for a therapeutically equivalent medicine, it is normally required to prove only bioequivalence to the already approved drug. In this way, the generic firm relies on the original safety and efficacy data. "Data exclusivity" rules delineate a time period in which a generic firm may not rely on the originator's data, thus requiring that the generic product either remain off the market or repeat costly and ethically troublesome clinical trials.[84]

The TRIPS agreement requires that certain pharmaceutical test data submitted to registration authorities be protected from "unfair commercial use."[85] Article 39.3's literal scope is relatively narrow.[86] Importantly,

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[84] *See* World Medical Association, *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*, 18th WMA General Assemb. Art. 20 (Jun. 1964) (stating "[p]hysicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results." Repetition of clinical trials on human subjects would therefore violate international ethical standards for clinical trials, which forbid doctors to continue experiments on humans "when there is conclusive proof of positive and beneficial results."); *see also* Global Strategy and Plan of Action (committing to "[p]romote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines.").

[85] TRIPS Art. 39.3 specifically states:

> Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data

countries have great leeway in defining what use or reliance on test data may be "unfair" or "commercial."[87] A World Health Organization paper advises that "[c]ountries are not obligated under Article 39.3 to confer exclusive rights on the originator of marketing approval data,"[88] and most traditional uses of registration data "to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3." [89]

> Countries can meet their obligations to protect against "unfair commercial use" under Article 39.3 by barring "dishonest" uses of test data. This would require, for example, proscribing situations in which a competitor obtains the results of testing data through fraud, breach of confidence or other "dishonest" practices, and uses them to submit an application for marketing approval for its own benefit. It would also apply in cases where the government provides access to undisclosed testing data in order to provide an advantage to a firm which did not produce them or share their cost.[90]

The practice of providing a form of exclusivity for pharmaceutical test

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against unfair commercial use.

[86] Test data must be protected only if: (1) national authorities require its submission; (2) it is undisclosed, not already public, (as many clinical trial results in the U.S. are by virtue of state and local clinical trial registry laws); and (3) it concerns a new chemical entity, i.e., the undisclosed data is "the result of significant investment," proof which could be required.

[87] *See* Correa, *supra*, at 41-47.

[88] *See* Correa, *supra* at *x.*

[89] Correa, *supra* at 5.

[90] Correa, *supra* at 5. *See also* Sisule F. Musungu & Cecilia Oh, *The Use of TRIPS By Developing Countries: Can they Promote Access to Medicine?*, Commission on Intellectual Property Rights, Innovation and Public Health, Study 4C, 65-67 (Aug. 2005); Judit Rius-Sanjuan, James Love & Robert Weissman, *Protection of Pharmaceutical Test Data: A Policy Proposal*, Consumer Project on Technology (Nov. 2006), *available at* http://www.cptech.org/ip/health/data/CPTech-Test-Data.pdf.

data originates with the Hatch Waxman Act in the U.S. The Act included a political compromise by providing an avenue for generic firms to register based on originator safety and efficacy data, but prohibiting such reliance in the first five years after the data is filed. In the EU, data exclusivity periods were later enacted that can run as long as eleven years.[91] These periods operate independently of any period of patent exclusivity, and in the EU have been interpreted to be impervious to compulsory licensing, even in a health emergency.[92]

Most countries in the world do not follow exclusivity rules.[93] In such countries, the only marketing monopoly companies receive is through the patent system rather than the registration system.[94]

USTR has adopted a legal interpretation of TRIPS that Article 39.3 requires data exclusivity similar to the U.S. or EU. This interpretation is in

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[91] In the U.S., the data originator obtains five years of data exclusivity for a new chemical entity and an additional three years for marketing approvals of new uses, new formulations, or new dosages that require the submission of new clinical trial data. In Europe, the data originator obtains ten years of data exclusivity and can obtain an additional, one-time-only one-year extension for registering a significant improvement. *See, e.g.,* Brook Baker, *Ending Drug Registration Apartheid – Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 303-44 (2008).

[92] European Commission Directorate General for Enterprise and Industry, Letter from Martin Teberger, Head of Unit for Consumer Goods to the European Generic Pharmaceuticals Association (Feb. 20, 2006), *available at* wcl.american.edu/pijip/go/eu02202006 (stating "[t]he European pharmaceutical legislation does not foresee any exception . . . in case of emergency situation or in case a compulsory patent license has been granted by an EU Member State").

[93] *See* Musungu & Oh, *supra* at 65-67 (surveying countries).

[94] *Cf.* Correa, *supra*, at *xi* ("This approach emphasizes that the registration of products should not erect barriers to otherwise legitimate competition. It holds, instead, that the registration system should promote price competition and access to more affordable medicines.").

direct conflict with the negotiating history of the TRIPS agreement, during which the U.S. proposal to require that pharmaceutical test data be "reserved for the exclusive use of the registrant for a reasonable period"[95] was amended out of the final text.[96] Despite this rejection of a data exclusivity requirement by TRIPS negotiators, both PhRMA and the USTR have argued that Art. 39.3 of TRIPS requires countries to implement data exclusivity regimes.[97]

Data exclusivity can have particularly harmful effects in developing countries. In many developing countries, drug companies lack patents because they were never sought or granted. In such circumstances, data exclusivity grants a marketing monopoly in the absence of patent protection. Another problem is that companies often register their products in developing countries very late, focusing instead on the wealthy markets.

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[95] *See* Correa, *supra* at 53.

[96] CARLOS CORREA & ABDULQAWI YUSUF, INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE, THE TRIPS AGREEMENT (1998); DANIEL GERVAIS, TRIPS AGREEMENT - DRAFTING HISTORY AND ANALYSIS, 182-183 (1998)..

[97] *See* Pharmaceutical Research and Manufacturers of America (PhRMA) *Special 301 Submission 2009* [hereinafter 2009 PhRMA Submission], *available at* http://www.ipophil.gov.ph/ipenforcement/phrma_submission.pdf (stating that TRIPS requires "a data exclusivity regime which prevents regulatory authorities from prematurely allowing generic producers to rely on or otherwise use the originator's proprietary data to gain approval of copies of the originator's drug," and cannot be met through); USTR 2003 Special 301 Report at 4-5 ("the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity during which second-comers may not rely on the data that the innovative company has created to obtain approval for their copies of the product"). Elsewhere, USTR has proclaimed that "any other" interpretation of Article 39.3 "would be inconsistent with logic and the negotiating history of the provision." Office of the General Counsel, USTR, The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3 (May 1995), available at http://apps.who.int/medicinedocs/en/d/Jh3009ae/11.html).

When this is the case, data exclusivity can extend monopoly periods past the point at which the medicine is subject to full competition in the U.S.[98]

The Bush Administration's press for data exclusivity was subject to vociferous opposition. One congressional report concluded that the consequences of data exclusivity provisions "are the exact opposite of those intended by the Doha Declaration."[99] Members of the House of Representatives criticized USTR's pressure on Guatemala and other CAFTA members to adopt data exclusivity, explaining that the pressure "interferes directly" with "the central purpose of the Doha Declaration."[100] The 2007 New Trade Policy for America limited data exclusivity provisions in pending trade agreements, requiring that exclusivity "not preclude FTA countries from taking measures to protect public health" and that exclusivity periods run concurrently with exclusivity in the U.S. The World Health Organization's 2006 Report of the Commission on Intellectual Property Rights, Innovation and Public Health "recommends that developing countries should not impose restrictions for the use of, or reliance on, data from pharmaceutical development tests in ways that would exclude fair competition or impede the use of flexibilities" in TRIPS.[101]

The USTR's use of Special 301 to push its interpretation of Article 39.3

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[98] Waxman Report, *supra*, at 7.

[99] *Id.*

[100] Letter from Members of the House Ways and Means Committee, United States House of Representatives, to Robert Zoellick, President of the World Bank (Jan. 26, 2005), *available at* http://www.cpath.org/sitebuildercontent/sitebuilderfiles/congressguatemalatest-data-secrecy-letter1-05.pdf.

[101] World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health. *Public Health, Innovation and Intellectual Property Rights.* (2006) at 126.

on developing countries displays the inadequacy of Special 301 as a just and neutral adjudicative process and highlights the reason why it violates the WTO. Countries cannot have the right to list and sanction other countries for violating their own interpretation of the WTO accord. The proper route for pressing TRIPS complaints is through dispute resolution.

c. Registration and Patent Linkage

The 2010 report indicates a policy change in the Obama administration on the issue of linkage.

"Linkage" refers to requirements that FDA-like marketing authorities not register generic copies of medicines for which there is a patent claimed by a supplier. This is an added enforcement process favored by patent holders. It permits them to use patent claims to block marketing of products without the need to sue the alleged infringer in courts to enforce the patent rights. The rule in the US has led to "ever-greening" - where marketing monopolies are extended with new (often baseless) applications for patents that may be used to prohibit marketing approval of generics unless and until the generic firm successfully challenges the patent in court.[102] Evergreening problems are likely to be more pronounced in developing countries that lack the rigorous patent examination process and other regulatory resources and

[102] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, (2002). *See also* Robert Weissman, *The Evergreen Patent System: Pharmaceutical Company Tactics to Extend Patent Protections*, MULTINATIONAL MONITOR, June 2002; Marc Kaufman, *Drug Firms' Deals Allowing Exclusivity -- Makers of Generics Being Paid to Drop Patent Challenges, FTC Review Finds*, THE WASH. POST, Apr. 25, 2006; Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 -- A Report by the Bureau of Competition* (2006), *available at* www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

expertise of the U.S.[103] TRIPS does not require countries to implement linkage rules.

The 2007 New Trade Policy for America called on the USTR to "eliminate [the] requirement that a drug regulatory agency withhold approval of a generic until it can certify that no patent will be violated if the generic were marketed," calling instead for the U.S. to work to "strengthen and expedite judicial processes in countries to ensure patent rights of innovative companies are respected." Nevertheless, USTR continued to demand linkage rules through Special 301.

In 2009, a lack of linkage was the second most cited medicines-related complaint in Special 301 (after data exclusivity). The complaint was normally framed as an alleged failure by countries to "implement an effective system to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products."[104] A nearly identical complaint was raised against twelve countries in the 2009 report.

In 2010, the number of countries cited for similar problems was reduced to eight – Chile, Pakistan, Columbia, Dominican Republic, Ecuador, Egypt, Malaysia and Mexico. Of these, Chile, Columbia and the Dominican Republic are signatories to free trade agreements with the US that already require linkage. The other countries have no outside obligations to enforce linkage rules.

Perhaps more importantly, the language used to define the complaint shifted. Instead of requesting a "system to prevent the issuance of marketing approvals," as in 2009, the 2010 report asks for "an effective system to address patent issues expeditiously in connection with applications to

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[103] Waxman Report, *supra*, at 9.

[104] 2009 Special 301 Report, *supra*, at 17.

market pharmaceutical products."[105] To be consistent with the 2007 New Trade Policy, such a system could be an effective court adjudication process for the enforcement of patent rights. But so interpreted, the 301 complaint becomes incredibly vague. Are we to interpret the 2010 Report as meaning that the eight countries identified have no system to effectively resolve patent infringement claims? As is the norm in the Special 301 report, the complaint is so vague and without citation or explanation as to leave the reader with very little idea as to what is in fact being complained about.

d. Restrictions on Compulsory Licensing

Compulsory licensing is perhaps the most important flexibility in the TRIPS agreement. Despite the express mention of respect for the rights of countries to issue compulsory licenses in the 2010 report, the Obama Administration is continuing to use Special 301 to pressure countries to reduce the use of this important tool to promote public health.

A compulsory license is a government-issued license to one or more competitors permitting entry in the market upon payment of adequate royalties to the patent holder. The Doha Declaration affirms the broad right of all countries to use compulsory licenses to promote access to medicines, stating that each country "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

The Obama Administration is continuing to use Special 301 to pressure Thailand over its use of compulsory licenses. In 2007, Thailand was elevated to the Priority Watch List (PWL) in large part for its announcement of compulsory licenses for excessively priced medicines needed to treat AIDS and heart disease. The official U.S. complaint was not about the license per se, but rather an alleged failure of Thai government to "engage openly and transparently with the companies that developed the

[105] 2010 Special 301 Report, *supra*, at 30.

drugs that are at issue."[106] In 2009, Thailand was kept on the PWL, noting concerns about "the uncertainty created by the previous Government's policies concerning the issuance of compulsory licenses on patented pharmaceutical products."[107] Thailand remained on the 2010 PWL as well. Although use of the words "compulsory license" was eliminated from the entry, the issue was clearly indicated through the call for Thailand "to engage in a meaningful and transparent manner with all relevant stakeholders, including owners of intellectual property rights, as it considers ways to address Thailand's public health challenges."[108]

Other countries were also targeted for pressure on the use of compulsory licenses in the 2010 report. China was singled out for complaints about "the possible use of compulsory licensing for essential patents included in national standards," and for concerns about "the scope of and procedures related to compulsory licensing."[109] And the report noted that "the United States will continue to monitor recent developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador."[110]

e. Patent Extensions

Under TRIPS, WTO members are required to grant patents for a period of 20 years from the time the patent is filed. This period takes into account the known delays in regulatory processes. But the U.S. has long used Special 301 to pressure countries to extend patent terms for delays in

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[106] Letter from U.S. Ambassador Ralph L. Boyce to His Excellency, General Surayud Chulanont, Prime Minister of the Kingdom of Thailand, July 20, 2007, available at http://lists.essential.org/pipermail/ip-health/2007-August/011610.html

[107] 2009 Special 301 Report, *supra*, at 21.

[108] 2010 Special 301 Report, *supra*, at 28.

[109] 2010 Special 301 Report, *supra*, at 21-22.

[110] 2010 Special 301 Report, *supra*, at 31.

granting patents or marketing approvals for medicines. In response to the public health concerns with such extensions,[111] the 2007 New Trade Policy demanded that the U.S. "[e]liminate [the] requirement that an FTA country extend the term of a patent on a pharmaceutical product for delays in the patent and regulatory approval process," and instead "ensure expeditious patent and regulatory approval."[112] In 2009 and 2010, no developing country was targeted for a failure to grant patent extensions to compensate for regulatory delays. But Israel was cited for lack of patent extensions in both reports.[113]

f. Patentability criteria

One of the key flexibilities in the TRIPS agreement is the ability of a country to decide for itself what inventions qualify for patents for being sufficiently "new," involving an "inventive step" and being "capable of industrial application."[114] In pharmaceuticals, the definition of these terms can determine whether a country grants patents for new uses or formulations of existing products that are already known. The grant of such patents is controversial between countries and among experts and there are no provisions in TRIPS restricting country flexibility in making these basic policy decisions.

The 2009 and 2010 Reports single out Brazil, India and Philippines for

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[111] See Waxman Report, *supra*, at 8 (criticizing patent extensions which "can work to delay access to low-cost generic drugs in developing nations").

[112] New Trade Policy for America, p.2, available at http://waysandmeans.house.gov/Media/eNewsLetter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf

[113] *See* 2009 Special 301 Report, *supra* (requesting Israel "amend its laws to increase the effective patent term extension given to pharmaceutical products to compensate for delays in the regulatory approval process.")

[114] TRIPS, *supra*, Art. 27(1).

laws that ban patents on polymorphs (i.e. new forms) and new uses of known inventions.[115] These complaints press countries to grant patents on a larger range of inventions than TRIPS requires and thereby would limit access to affordable medicines in each country. In the case of India, the claim is particularly troublesome because that country is the largest supplier of generic medicines in the world. The more patents India grants, the less possibility there will be to find a source of generic supply for other countries.

g. Vague definitions of "counterfeit" pharmaceuticals

The 2009 and 2010 Reports list concerns about "counterfeit" pharmaceuticals in several countries. But it is unclear what definition of "counterfeit" is being used. Under TRIPS, "counterfeit" has a particular meaning. It means a product that willfully deceives consumers by using an identical mark to the originator.[116] It is not correctly applied to an allegedly unauthorized generic version of a patented product or to lesser forms of trademark infringement that do not use identical marks.

The reports frequently allege concerns with "unauthorized use of bulk active pharmaceutical ingredients" by manufacturers in Brazil, China, and India. But the reports fail to identify who determined that these uses were unauthorized? The proper mechanism for enforcing a patent and determining if a particular use is in fact a violation is through civil litigation. The USTR cites no such litigation. It appears to be simply taking

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[115] See 2010 Report, *supra*, at 26 (India), 29 (Brazil), 36 (Philippines).

[116] TRIPS, *supra*, Art, 51 n.14. "For the purposes of this Agreement: (a) 'counterfeit trademark goods' shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

industry complaints as fact.

In all references to "counterfeit" medicines, USTR should ensure that the U.S. position respects the legitimacy of generic medicines and clearly distinguishes generic equivalents from actual trademark counterfeits. And when it makes accusations about violations of patent law, such as targeting "unauthorized uses" of patents, it should back those claims up with proof.

h. Vague Criticisms of Pharmaceutical Patent Policy

The 2009 and 2010 reports make many vague allegations that a patent law in a particular country is "weak" or otherwise deficient, with little indication as to what specifically is wrong with the country's system.[117] It is impossible to engage with comments that are so vague. Basic due process concerns mandate that countries listed on watch lists have notice for the grounds for their listing so that they can challenge the factual and legal basis for USTR's claims.

The 2009 Report lists the Philippines on the Watch List and comments:

> The United States is troubled by the amendments to the patent provisions in the Philippines Intellectual Property Law only as they apply to pharmaceuticals. The amendment significantly weakens patent protection for pharmaceutical products.

There is no citation to the law or what part of it USTR opposes. There is no ban in TRIPS from having patent law requirements that apply specifically to pharmaceuticals. As the WTO panel noted in the *Canada – Patent Protection* decision,[118] TRIPS only bans unjustified discrimination by field of technology, not mere differentiation. And the Doha Declaration

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[117] See 2010 Special 301 Report, *supra*, at 24 (Algeria cited for "weak" patents); 26 (India cited for needing "stronger" protection). See 2009 Report at 31 (citing "shortcomings in Paraguay's patent regime").

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

specifically requires countries to promote access to medicines for all. There is nothing in the recent amendments to the Philippines patent law that violates the TRIPS agreement. The new law puts in place model TRIPS-compliant compulsory licensing and government use provisions, excludes minor new uses or new forms of existing medicines from patent protection, authorizes TRIPS-compliant parallel importation, and adopts recognized limitations to patent rights, such as limitations for experimental use.

USTR should identify with specificity the provisions it opposes so that more informed response can be made to its allegations. This appears to be an instance where USTR is sanctioning a country for putting in place all of the TRIPS flexibilities protected by the Doha Declaration.

i. Enforcement Requirements

In many instances in the 2009 and 2010 Reports, USTR presses countries to adopt TRIPS-plus intellectual property enforcement procedures that could limit access to medicines. Particularly troubling are the many vague complaints about the need to give border officials (and others) the ability to confiscate suspected infringing products without court orders or other procedural checks. These allegations are not specifically limited to trademark counterfeit or commercial-scale copyright infringements. Examples include the passages for Canada, Thailand, Belarus, Malaysia, Mexico, Tajikistan, Turkmenistan, and Uzbekistan. Seizures of legitimate medicines by border officials have become a massive problem for access to medicines around the globe, particularly through the so-called "Dutch seizure" cases in Europe.[119] The U.S. should not be encouraging border

[119] Since late 2008, customs officials in the Netherlands, Germany and France have seized at least twenty shipments of legitimate generic medicines. Of the shipments, nineteen were legally manufactured and exported from India and intended for developing countries where they could be legally imported. Patents did not exist on the medicines in either the country of origin or destination. These shipments were seized as a result of

officials to confiscate products that allegedly violate patents. Patent violations cannot be identified by sight by border officials or police. The reason we enforce patents through complex civil proceedings is that such proceedings are necessary to avoid wrongful confiscations. For medicines, wrongful confiscations harm more than economies (which itself threatens social welfare), they directly threaten the lives of people who depend on uninterrupted supplies of the medicines.[120]

j. Restrictions on evidence-based reimbursement programs

In the 2009 and 2010 Reports, the USTR included sections on "Supporting Pharmaceutical [and Medical Device] Innovation" that promotes only one narrow pro-innovation policy: convincing other countries to abandon regulatory and reimbursement programs that restrain the high cost of patented prescription drugs. The Reports single out all OECD members and specifically mention Finland, France, Italy, Japan, Korea, Canada, Germany, New Zealand, Taiwan, and Poland for administering "unreasonable . . . reference pricing or other potentially unfair

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national implementation of an EU regulation that empowers border officials to classify and seize medicines as counterfeits if the customs official determines (often at the direction of pharmaceutical companies) that the medicines violate territorial patents of the relevant EU country. The IP standards of the EU countries have been applied to medicines in-transit even though these medicines are not intended for domestic consumption in the EU. Medicines that were seized included a cardiovascular disease medicine (Losartan) intended for Brazil and a key anti-retroviral medicine (Abacavir) purchased by the Clinton Foundation and intended for Nigeria. Without modifying or eliminating the EU regulation (or worse, expanding the regulation through new trade agreements), medicines supplied through U.S. foreign assistance programs - such as PEPFAR – could be similarly affected.

[120] In the case of AIDS and other illnesses, an interruption in supply of medicines can lead to drug resistance – which harms not only the patient but the greater society effort to combat the disease.

reimbursement policies."[121]

As in other areas, the use of Special 301 to target reimbursement programs appears linked to a broader international regulatory agenda. Two Free Trade Agreements negotiated under the Bush Administration – with Australia and Korea – included chapters imposing restrictions on pharmaceutical reimbursement programs. During and after the negotiation of these agreements, U.S. state officials repeatedly warned USTR and Congress that the norms adopted in these agreements, if applied to U.S. state governments, would cripple Medicaid programs.[122] This is because

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[121] 2010 Special 301 Report, *supra*, at 14; 2009 Special 301 Report, *supra*, at 7-8.

[122] *See* Vermont State Senate Resolution 2006 J.R.S. 50 (urging USTR to "pursue an exchange of Interpretive notes" with Australia to formally ensure state Medicaid programs would not be covered by Annex 2(c)); Letter from Liz Figueroa and Sheila Kuehl, California State Senators, to USTR(Feb. 16, 2005); Letter from National Legislative Association on Prescription Drugs, to USTR (May 26, 2005) (warning about the dangers of the free trade agreement and asked for a binding interpretation that it did not cover U.S. state programs); Letter from Washington Governor Christine Gregoire, (Mar. 13, 2006) (expressing concerns over the FTA); Letter from Four Washington State Legislators to the Washington State Congressional Delegation (Mar. 2, 2006); Letter from Meg Burton Cahill, Arizona State Senator, and Kevin Ryan, Connecticut State Representative, to Members of the House Ways and Means Committee Subcommittee on Trade (Mar. 18, 2007) (stating that legislators are "extremely troubled by, and strongly oppose, USTR's efforts to alter public reimbursement formularies in the Korea FTA"); National Legislative Association on Prescription Drug Prices, Testimony before the Subcommittee on Trade of the House Committee on Ways and Means, (Mar. 20, 2007) (warning that the language applied to Medicaid programs would "give pharmaceutical companies rights to block and delay implementation of the most important and proven medicine cost-control tools available."); Letter from Ginny Lyons, Vermont State Senator, and Kathleen Keenan, Vermont State Representative, to Senators Patrick Leahy and Bernard Sanders, and Representative Peter Welsh, (Apr. 18, 2007) (asserting that "Vermont uses a similar 'positive list' approach [as Korea]").

Medicaid programs rely on preferred drug lists to exact lower prices from pharmaceutical companies, which operate very similarly to the formularies and other programs targeted by the US in other countries.

TRIPS does not restrict how countries regulate the market power of companies that is created by patents. Patents on medicines create particularly strong and socially harmful market power because people will pay anything they can for life-savings drugs, there often are literally no substitutes if a truly innovative medicine is under patent, and the burdens of lack of access fall almost exclusively on the poorest people (or, in the U.S., the uninsured).

U.S. state officials appeared at the 2010 Special 301 hearing to "oppose the recent and disturbing use of the Special 301 Report to discipline effective and non-discriminatory pharmaceutical pricing policies."[123] Referring to Ambassador Kirk's expressed "support" for broadening a discussion of a proposal by Pfizer for a new international trade agreement to "discipline" pharmaceutical reimbursement programs in the U.S. and abroad,[124] the elected state officials explained that U.S. state reimbursement

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[123] Testimony of Sean Fiil-Flynn on behalf of the Forum on Democracy and Trade, before the interagency hearing for the 2010 Special 301 Review. (March 3, 2010) *Available at http://www.wcl.american.edu/pijip/go/forum03032010*

[124] *See* Testimony of Jeff Kindler, Pfizer CEO, before the Senate Finance Committee (Jul. 15, 2008), *available at* http://media.pfizer.com/files/news/kindler_testimony_sfc_071508.pdf (last visited on Feb. 17, 2010). *See also*, A Discussion with Prof. John Barton, sponsored by PIJIP (Feb. 19, 2009) *available at* wcl.american.edu/pijip/go/barton (last visited on Feb. 17, 2010) (stating that the Pfizer proposal includes as "a trade goal the achievement of a sector-specific trade agreement" that would ensure that high prices in wealthy countries subsidize lower prices for some populations in poor countries. In the rich countries like the U.S., the agreement would impose internationally binding restrictions on regulatory authority that would "ensure that pricing and reimbursement policies recognize and reward innovation, and to

programs "follow the same basic policies and principles of foreign countries that USTR seeks to discipline." The officials warned: "Reciprocal enforcement of USTR standards to state programs would obliterate the effectiveness of Medicaid pricing programs and threaten the administration's policy goal of reducing the cost of healthcare in this country."[125]

The concerns of state officials protesting the use of 301 to criticize reimbursement policies had minimal effect. The 2010 report, as in 2009, continues to target "unfair" reimbursement policies without describing what is unfair about them or how these programs differ from what states now do to reduce drug prices. There is nothing in the 301 statute that authorizes USTR to pressure or sanction other countries for their pharmaceutical reimbursement policies. There is nothing in the report that backtracks from Ambassador Kirk's expressed support for a new international trade agreement that would "discipline" pharmaceutical pricing programs in developed countries such as the U.S.

D. Conclusion

The continuation of the Special 301 program to threaten and sanction

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set disciplines on government practices that undermine incentives for innovation." The proposal would also demand that wealthy country aid programs limit use of generic drugs and pay high prices even for distribution in developing countries with no patent protections on the drugs).

[125] 2010 Special 301 Submission of Groups Representing State Governments, available at http://www.wcl.american.edu/pijip/go/blog-post/pijip-represents-public-health-and-states-in-submissions-to-the-united-states-trade-representative. *See also,* Letter from Governor Baldacci to Secretary Sebelius and Ambassador Kirk (Apr. 26, 2010) available at http://www.wcl.american.edu/pijip/go/blog-post/governor-baldacci-writes-sebelius-on-special-301 (calling on the administration to "reverse the previous administration's support for using trade policy to restrict governmental powers to control medicine prices").

countries for TRIPS-plus intellectual property and pharmaceutical regulation policies stands in stark contrast to the principles that the Obama Administration states that it espouses. Failure to change course and embrace the cause of access to medicines in Special 301 and in the administration's trade policies could trigger legal disputes by countries in the WTO and by affected people in international human rights forums.

Global health groups have developed the outlines of a trade and access to medicines agenda that needs to be expanded into a broader campaign.

First, the Obama Administration should take Executive Order 13155 as a starting point and apply its principles to all developing countries. No developing country anywhere in the world should be pressed by the U.S. to adopt an intellectual property or pharmaceutical regulation policy in excess of those required by the WTO accords if the effect will be to raise prices of needed medicines in that country.

Second, the Administration should undertake an urgent review of legislative and policy changes necessary to bring Special 301 into compliance with the WTO. Special 301 was created for the explicit purpose of unilaterally adjudicating and sanctioning other countries for violation of U.S.-determined standards on intellectual property. This purpose cannot survive the WTO's ban on unilateral adjudication of trade disputes.

Third, the U.S. government should use trade policy to pursue more equitable innovation policies. For example, it could encourage our trading partners to invest more in public sector R&D, including open source projects, and could highlight best practices to promote access to knowledge, such as the NIH policies to provide open access to published scholarly and scientific research when the research benefited from government funding.