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# Special 301 and Access to Medicine in the Obama Administration

## **Keywords**

genericmedicine, Trade-Related Aspects of IntellectualProperty Rights TRIPS, pharmaceutical

# Special 301 and Access to Medicine in the Obama Administration<sup>1</sup>

by Sean M. Flynn<sup>2</sup>

## I. INTRODUCTION

This article examines the history and current use of the Special 301 program to restrict access to generic medicines in developing countries, specifically the 2009 and 2010 reports released under the Obama Administration. The news for access to medicines advocates is not good overall. Both reports continue the previous Administration's policies of using Special 301 to promote Trade-Related Aspects of Intellectual Property Rights ("TRIPS") policies ("TRIPS-plus") endangering access to medicines for millions of people worldwide. These policies violate not only the Obama Administration's pledges to promote access to affordable medications in developing countries, but also U.S. commitments under the 2001 World Trade Organization ("WTO") Doha Declaration on the TRIPS Agreement and Public Health, numerous World Health Organization resolutions, and express Congressional policy. Although the reports reflect small moves toward a more complete embrace of the Doha Declaration and a de-escalation of some issues threatening access to medicines, the most recent Special 301 Reports signal more continuity than change in U.S. policy on trade and access to medicines.

## II. 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 ("Act"). That Act was passed at a time of large and growing trade deficits, increasing flight of manufacturing activities abroad, skyrocketing foreign debt, and economic crisis caused by dependency on foreign oil imports, all of which fueled a mood in U.S. policy circles that was decidedly "protectionist."<sup>3</sup> U.S. export industries attached

considerable blame 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.<sup>4</sup> Section 301 was a key element of the response.

Section 301 authorizes the President to impose economic sanctions on countries that "burden or restrict United States commerce."<sup>5</sup> Notably, the law does not require that the alleged conduct violate any trade agreement with the U.S. to be subject to sanction under the Act.<sup>6</sup>

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. In 1988, the statute was amended again to create the new intellectual property-focused "Special 301" program.

Under Special 301, the United States Trade Representative ("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."<sup>7</sup> These requirements resulted in USTR's creation of a "Watch List" and "Priority Watch List," which serve

1. This is an abbreviated version of a forthcoming article to be published in the next issue of the Journal on Generic Medicine. Special thanks are due to Prudence Cho for her stellar editing assistance. Remaining errors are mine.

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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., 1990); DRAHOS & BRAITHWAITE, *supra* note 3; 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 U.S.C. § 2411(a)(c) (2010) (describing authorized sanctions as including suspension of trade agreements, the imposition of tariffs or restrictions on imported goods, and the withdrawal 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. § 2242(a) (2010) (listing identification criteria); see also, § 2242(e) (2010) (requiring Trade Representative to publish a list in the Federal Register).

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.<sup>8</sup>

Special 301 findings are, by intent and definition, unilateral findings by the U.S. and subject only to U.S. standards. As in the original Section 301, foreign practices and policies do not have to contravene any trade agreement with the United States to be subject to listing on watch lists or for sanction determinations.<sup>9</sup> 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 special and differential treatment for developing countries.<sup>10</sup>

### III. SPECIAL 301 AND ACCESS TO MEDICINES

During the TRIPS Agreement negotiations, 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.

The increased prices that patents permit to promote social benefits from research and development also create social costs by limiting access to affordable medications. Economists call this social cost "deadweight loss," and it refers the number of people who would have been able to purchase the medicine at a lower competitive price who are unable to purchase the medicine at the higher monopoly price.

The deadweight loss effect is most pronounced

and harmful in developing countries with high income inequality. In such markets, the nature of demand—with a small number of very wealthy people and a large number of the very poor—predictably leads to profit maximizing pricing that will exclude the great majority from access while providing miniscule incentives for future innovation.<sup>11</sup>

Recognizing 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.<sup>12</sup> The WTO agreement on TRIPS harmonizes global patent and other intellectual property standards to a minimum level. But the agreement permits a great deal of differentiation between countries through provisions allowing flexibility in defining rights and the exceptions and limitations of them.<sup>13</sup> Primary among TRIPS flexibilities supporting access to medicines are the freedom to grant compulsory licenses for any purpose; freedom to define the scope of patentability through definitions of novelty and inventiveness standards; liberty to permit parallel importation of protected goods from any country; permission to limit patent terms to twenty-years without extension; absence of any requirement to adopt U.S.-style patent-registration "linkage" systems (where registration authorities are required to check patent status before approving the safety profile of a drug); a flexible requirement to protect undisclosed data that does not require U.S. or EU-style "data exclusivity" that grants originator firms a limited marketing monopoly even in absence of a patent; and complete freedom to regulate the prices and other sales terms of any patented good, including through price controls or completion duties.

### IV. SPECIAL 301 IN THE OBAMA ADMINISTRATION

The cause of promoting access to affordable

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8. 19 U.S.C. § 2242(b)(1)(C) (2010) (specifying that "In identifying priority foreign countries under subsection (a)(2) of this section, the Trade Representative shall only identify those foreign countries that are *not entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations.*" (emphasis added)).

9. See GLICK, *supra* note 6, at 150 (explaining the "great deal of discretion" USTR has to define infringements).

10. See Hesham Youssef, *Special and Differential Treatment for Developing Countries in the WTO*, (South Centre, T.R.A.D.E. Working Papers 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](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).

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11. 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).

12. See, e.g., *Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy*, 155 (2002); *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>.

13. See Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 8, Apr. 15, 1994, WTO [hereinafter TRIPS] (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").

medicines in developing countries has occasionally become a high-profile political issue. When the Clinton Administration pressed South Africa and Brazil to halt the use of TRIPS flexibilities to promote affordable AIDS medications in their public treatment programs, U.S. AIDS activists protested at the campaign rallies of Vice President Gore, who was running for president. A policy change ensued, and since then Democratic presidential candidates (more than Republicans) have attempted to reach out to global health advocates in their campaigns.

The Bush Administration was largely hostile to access to medicine concerns and favorable to the interests of the brand name pharmaceutical industry. Special 301 was a central vehicle for the Administration's efforts to impose ever-higher intellectual property standards around the world with little regard for their effect on the affordability of potentially life saving treatments. 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 twenty 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 Declaration."<sup>14</sup>

The Obama presidential campaign recognized the access to medicine issue as part of its campaign's global health platform. Obama 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."<sup>15</sup>

The Obama Administration has now produced two Special 301 reports cataloguing its policies on

intellectual property and access to medicines. With no free trade agreements yet negotiated in its term,<sup>16</sup> these reports are key indications of the Administration's accomplishments on its promises to change the previous hostility to access to medicine concerns. As detailed below, the Administration receives low marks on its commitments thus far.

#### A. 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 large number of countries every year. The 2010 report states that the laws and policies of seventy-seven countries were reviewed through "extensive research and analysis."<sup>17</sup> USTR has few dedicated staff to this effort,<sup>18</sup> 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.<sup>19</sup>

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. PhRMA regularly targets countries failing to enact U.S.-style intellectual property and data protection standards or having reimbursement formularies that consider cost or promote generic medicines. Of the forty-eight countries PhRMA requested to be included in watch lists in 2008, thirty-six, or 75%, of the requests were honored by USTR.

In the past, it was exceedingly rare for

14. U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION (2007) [hereinafter GAO ACCESS REPORT] (quoting Administration officials).

15. Press Release, The Office of the President - Elect, The Obama-Biden Plan to Combat Global HIV/AIDS, [http://change.gov/pages/the\\_obama\\_biden\\_plan\\_to\\_combat\\_global\\_hiv\\_aids](http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids) (Oct. 29, 2010, 12:08 EST).

16. See STAFF OF SPECIAL INVESTIGATIONS DIVISION, U.S. HOUSE OF REPRESENTATIVES COMM. ON GOV'T REFORM, TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION: PREPARED FOR HENRY WAXMAN (2005) [hereinafter WAXMAN REPORT] (for analysis of the impact of Bush Administration FTAs on access to medicine concerns); 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>.

17. OFFICE OF THE U.S. TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE PRESIDENT, 2010 SPECIAL 301 REPORT, at 3 (Apr. 30, 2010) [hereinafter 2010 SPECIAL 301 REPORT].

18. OFFICE OF THE U.S. TRADE REPRESENTATIVE, Office of Intellectual Property and Innovation has a total of 8 staff, as verified over a phone inquiry on October 9, 2009.

19. DRAHOS & BRATHWAITE, *supra* note 3, at 94 (describing USTR's "symbiotic" reliance on industry submissions).

pharmaceutical policy interests other than PhRMA to make their voices 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 . . . submitted to the Trade Representative by interested persons.”<sup>20</sup> Although “interested persons” may include targeted countries or non-governmental organizations, in practice, USTR has sought and received input almost exclusively from industry.

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 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 party allies) are given two weeks of additional time to submit comments after industry submissions are received. That change appears to have led to a dramatic increase of country submissions in the process, from a norm of three or four per year to over twenty 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 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.<sup>21</sup>

Although the process improved in 2010, the hearing procedure implemented by USTR remains severely flawed from an administrative justice standpoint. In a normal 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 Special 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.

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 being given in the Special 301 process that is used to make such demands. The Special 301 adjudication process lacks any defined means for the appeal of legal, policy, and factual determinations in the draft report to an independent body.

#### *B. Continuation of Restrictions on Access to Medicines*

The change in Special 301 procedure in the Obama Administration has been similarly modest. A comparison of the 2009 and 2010 Special 301 reports shows some gradual change in the direction of promoting access to medicines and respecting the Doha Declaration. Both 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 negotiation of the May 2007 New Trade Policy for America.

##### *1. Incomplete Embrace of the Doha Declaration*

The Bush Administration Special 301 reports rhetorically embraced the Doha Declaration, while avoiding its affirmation 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.”<sup>22</sup> By 2008, the Bush Administration’s stance had moderated somewhat, recognizing the application of the Doha Declaration to “serious public health problems.”

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 that the “United States respects a country’s right to protect public health, in particular, to promote access to medicines for all.”<sup>23</sup> For the first time, the report

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20. 19 U.S.C. § 2242(b)(2)(B) (2010).

21. See Submissions Concerning Special 301, [www.regulation.gov](http://www.regulation.gov) (choose “Read Comments” then enter “USTR 2010-0003” in “Keyword or ID”).

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22. OFFICE OF THE U.S. TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE PRESIDENT, 2002 SPECIAL 301 REPORT 5 (2002) [hereinafter 2002 SPECIAL 301 REPORT].

23. OFFICE OF THE U.S. TRADE REPRESENTATIVE, EXECUTIVE

explicitly mentions support for use of compulsory licenses.<sup>24</sup> The same language is included in the 2010 report.<sup>25</sup> These are much broader categories of public interest concerns than the U.S. 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.

## 2. Data Exclusivity

The most common objection in the 2009 and 2010 reports related to pharmaceutical policy is a complaint about "lack of protection . . . against unfair commercial use of undisclosed test and other data."<sup>26</sup> 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 twenty one countries similarly cited in 2009.

The vague complaints about lack of data protection are best interpreted as a demand for a new form of pharmaceutical marketing monopoly known as "data exclusivity." The issue arises because of 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 safety and efficacy data to approve a competing product, thus requiring that the generic product either remain off the market or repeat costly clinical trials.<sup>27</sup>

The TRIPS Agreement requires that certain

pharmaceutical test data submitted to registration authorities be protected from "unfair commercial use."<sup>28</sup> Article 39.3's literal scope is relatively narrow.<sup>29</sup> Importantly, countries have great leeway in defining what use or reliance on test data may be "unfair" or "commercial."<sup>30</sup> 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,"<sup>31</sup> 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."<sup>32</sup>

The practice of providing a form of exclusivity for pharmaceutical test 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.<sup>33</sup> 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.<sup>34</sup> Most countries in the world do not follow exclusivity rules.<sup>35</sup> In such countries, the only marketing monopoly companies receive is through the patent system rather than the registration system.<sup>36</sup>

USTR has adopted a legal interpretation of TRIPS

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OFFICE OF THE PRESIDENT, 2009 SPECIAL 301 REPORT, at 6 (2009) [hereinafter 2009 SPECIAL 301 REPORT].

24. *Id.*

25. 2010 SPECIAL 301 REPORT, *supra* note 17, at 12-13.

26. 2009 SPECIAL 301 REPORT, *supra* note 23, at 17.

27. See World Medical Association ("WMA"), *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*, 18th WMA Gen. Assemb. Art. 20 (Oct. 2008); see also WHO, *The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPQA)*, 61st World Health Assemb. (2008).

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28. TRIPS, *supra* note 13, at art. 39.3.

29. 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.

30. See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement*, South Centre/WHO (2002) at 41-47, available at <http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf> (explaining that such a minimum provision would satisfy art. 39 of TRIPS).

31. *Id.* at x.

32. *Id.*

33. 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).

34. Letter from Martin Teberger, Head of Unit for Consumer Goods to the Eur, Generic Pharms. Ass'n. to Greg Perry, Eur. Generic Med. Ass'n., (Feb. 20, 2006) (available at [wcl.american.edu/pijip/go/eu02202006](http://wcl.american.edu/pijip/go/eu02202006)).

35. Sisule F. Musungu & Cecilia Oh, *The Use of TRIPS By Developing Countries: Can they Promote Access to Medicine?*, Comm'n on Intellectual Prop. Rights, Innovation and Public Health, Study 4C, 65-67 (Aug. 2005).

36. Cf. Correa, *supra* note 30 at xi.

that Article 39.3 requires data exclusivity similar to the U.S. or EU. This interpretation is in direct conflict with the negotiating history of the TRIPS agreement, during which the U.S. proposal to include language in Article 39 requiring that pharmaceutical test data be “reserved for the exclusive use of the registrant for a reasonable period”<sup>37</sup> was rejected and amended out of the final text.<sup>38</sup> Despite this rejection of a data exclusivity requirement by TRIPS negotiators, both PhRMA and the USTR have argued that Article 39.3 of TRIPS requires countries to implement data exclusivity regimes.<sup>39</sup>

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. 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.<sup>40</sup>

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

### 3. 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.<sup>41</sup> Evergreening problems are likely to be more pronounced in developing countries that lack the rigorous patent examination process and other regulatory resources and expertise of the U.S.<sup>42</sup> TRIPS does not require countries to implement linkage rules.

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.”<sup>43</sup> A nearly identical complaint was raised against twelve countries in the 2009 report.

In 2010, the number of countries cited for lacking linkage requirements decreased 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 U.S. 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 also 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 market pharmaceutical products.”<sup>44</sup> Such a system could be an effective court

37. See Coireta, *supra* note 30 at 53.

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

39. See Pharmaceutical Research and Manufacturers of America (“PhRMA”) *Special 301 Submission 2009*, available at [http://www.ipophil.gov.ph/ipenforcement/phrma\\_submission.pdf](http://www.ipophil.gov.ph/ipenforcement/phrma_submission.pdf) [hereinafter 2009 PhRMA Submission].

40. See STAFF OF SPECIAL INVESTIGATIONS DIVISION, U.S. HOUSE OF REPRESENTATIVES COMM. ON GOV’T REFORM, TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION: PREPARED FOR HENRY WAXMAN 7 (2005) [hereinafter Waxman Report].

41. FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002). See also Robert Weissman, *Victory and Betrayal: 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; FED. TRADE COMM’N, *AGREEMENTS FILED WITH THE FED. TRADE COMM’N 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/fy2005drugsettlementsreport.pdf](http://www.ftc.gov/os/2006/04/fy2005drugsettlementsreport.pdf).

42. WAXMAN REPORT, *supra* note 16, at 9.

43. 2009 Special 301 Report, *supra* note 23, at 30.

44. 2010 Special 301 Report, *supra* note 17, at 30.



adjudication process for the enforcement of patent rights. But so interpreted, the complaint becomes incredibly vague, leaving the reader with very little idea as to what is in fact being complained about.

#### 4. 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 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 the alleged failure of Thai government to “engage openly and transparently with the companies that developed the drugs that are at issue.”<sup>45</sup> In 2009, Thailand was kept on the PWL, noting “the uncertainty created by the previous Government’s policies concerning the issuance of compulsory licenses on patented pharmaceutical products.”<sup>46</sup> Thailand remained on the 2010 PWL as well. Although the words “compulsory license” were eliminated from the entry, the issue was indicated through a 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.”<sup>47</sup>

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45. Letter from Ralph L. Boyce, U.S. Ambassador, to Gen. 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>).

46. 2009 SPECIAL 301 REPORT, *supra* note 23, at 21.

47. 2010 SPECIAL 301 REPORT, *supra* note 17, at 28.

#### 5. Patent Extensions

Under TRIPS, WTO members are required to grant patents for a period of twenty 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 granting patents or marketing approvals for medicines. In response to the public health concerns with such extensions,<sup>48</sup> the Bush Administration’s 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.”<sup>49</sup> 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.<sup>50</sup>

#### 6. 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.”<sup>51</sup> 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 their similar laws that ban patents on polymorphs (i.e. new forms) and new uses of known inventions.<sup>52</sup> These complaints press countries to grant patents on a larger range of inventions than TRIPS requires and thereby limit access to affordable medicines in each country. In the case of India, the claim is particularly troublesome because it is the largest

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48. See Waxman Report, *supra* note 16, at 8 (criticizing patent extensions which “can work to delay access to low-cost generic drugs in developing nations”).

49. New Trade Policy for America, available at <http://waysandmeans.house.gov/Media/eNewsLetter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf> (last visited Oct. 29, 2010).

50. See 2009 Special 301 Report, *supra* note 43.

51. TRIPS, *supra* note 13, at art. 27(1).

52. See 2010 Special 301 Report, *supra* note 17, at 26 (India), 29 (Brazil), 36 (Philippines).

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.

### 7. *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 the particular meaning of a product that willfully deceives consumers by using an identical mark to the originator.<sup>53</sup> 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 fail to identify who determined that these uses were unauthorized. Civil litigation is the proper mechanism for enforcing a patent and determining if a particular use is in fact a violation. Yet, USTR cites no such litigation and appears to be simply taking 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 support those claims with proof.

### 8. *Vague Criticisms of Pharmaceutical Patent Policy*

The 2009 and 2010 reports make many vague allegations that a particular country’s patent law is “weak” or otherwise deficient, with little indication as to what is specifically wrong with its system.<sup>54</sup>

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,<sup>55</sup> TRIPS only bans unjustified discrimination by field of technology, not mere differentiation. And the Doha Declaration 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 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.

### 9. *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 instigate raids and confiscate suspected infringing products. These allegations are not specifically limited to trademark counterfeit or commercial copyright infringements. 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.<sup>56</sup> The U.S. should not be encouraging border 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. Wrongful confiscations of medicines harm more than economies (which itself threatens social welfare), they directly threaten the lives

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55. WTO, *Canada — Patent Protection of Pharmaceutical Products*, WT/DS114 (Mar. 17, 2000).

56. 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 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.

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53. TRIPS, *supra* note 13, at art. 51 n. 14.

54. See 2010 SPECIAL 301 REPORT, *supra* note 17, at 24 (Algeria cited for “weak” patents); 26 (India cited for needing “stronger” protection). See 2009 SPECIAL 301 REPORT, *supra* note 23, at 34 (citing “shortcomings in Paraguay’s patent regime”).

of people who depend on uninterrupted supplies of the medicines.<sup>57</sup>

#### *10. Restrictions on Evidence-Based Reimbursement Programs*

In the 2009 and 2010 reports, the USTR included sections on “Supporting Pharmaceutical [and Medical Device] Innovation” that promote 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 Organization for Economic Co-operation and Development (“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 reimbursement policies.”<sup>58</sup>

TRIPS does not restrict how countries regulate the market power of companies 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 are often 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).

As in other areas, the use of Special 301 to target reimbursement programs appears linked to a broader international regulatory agenda. The free trade agreements negotiated with Australia and Korea under the Bush Administration 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.<sup>59</sup> This is because 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 U.S. in other countries.

The concerns of state officials protesting the use of Special 301 to criticize reimbursement policies

abroad that are similar to those used by U.S. Medicaid programs 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 Special 301 statute that authorizes USTR to pressure or sanction other countries for their pharmaceutical reimbursement policies.

#### IV. CONCLUSION

The continuation of the Special 301 program to threaten and sanction 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. Global health groups have developed the outlines of a trade and access to medicines agenda that needs to be expanded into a broader campaign. The first step should be to expand President Clinton’s Executive Order 13155 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.

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57. 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.

58. 2010 Special 301 Report, *supra* note 17, at 14; 2009 Special 301 Report, *supra* note 23, at 7-8.

59. See S.J. Res. 50 (Vt. 2006) (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)).