

USTR-2010-003

UNITED STATES TRADE REPRESENTATIVE

IN THE MATTER OF
2010 SPECIAL 301 REVIEW:
IDENTIFICATION OF COUNTRIES UNDER SECTION 182 OF THE TRADE ACT OF 1974

**SUBMISSION OF GLOBAL HEALTH ORGANIZATIONS:
OXFAM AMERICA, HEALTH GAP (GLOBAL ACCESS PROJECT), CENTER FOR
POLICY ANALYSIS ON TRADE AND HEALTH, KNOWLEDGE ECOLOGY
INTERNATIONAL, FORUM ON DEMOCRACY AND TRADE, UNIVERSITIES
ALLIED FOR ESSENTIAL MEDICINES, IP JUSTICE, REDGE - RED PERUANA POR
UNA GLOBALIZACIÓN CON EQUIDAD (PERU) (PERUVIAN NETWORK FOR
GLOBALIZATION WITH EQUITY), FUNDACIÓN MISIÓN SALUD (COLOMBIA),
HEALTH MISSION FOUNDATION, JUSTICE, PEACE & INTEGRITY OF CREATION
MISSIONARY OBLATES, SALUD Y FARMACOS (INTERNATIONAL SOCIETY OF
DRUG BULLETINS)**

Sean Fiil-Flynn (Counsel of Record)
Mike Palmedo
Meredith Jacob
American University Washington College of Law
4801 Massachusetts Ave NW
Washington DC 20016
(202)274-4157

February 16, 2010

SUMMARY	1
ARGUMENT	3
I. USING SPECIAL 301 TO PROMOTE RESTRICTIONS ON PUBLIC HEALTH FLEXIBILITIES IN TRIPS VIOLATES THE DOHA DECLARATION	3
A. <i>TRIPS Flexibilities are Integral to the TRIPS Agreement.....</i>	4
B. <i>Past USTR Efforts to Restrict TRIPS Flexibilities Violated the Doha Declaration.....</i>	6
C. <i>PEPFAR Depends on Access to Generic Medicines.....</i>	10
D. <i>The Administration Needs to Adopt a Policy Guideline Banning USTR from Using Special 301 to Promote TRIPS-plus Policies on Access to Medicines.....</i>	10
II. THE ADMINISTRATION SHOULD UNDERTAKE A REVIEW OF SPECIAL 301 IN LIGHT OF THE MULTILATERAL VALUES OF THE ADMINISTRATION AND THE WORLD TRADE ORGANIZATION.....	11
III. THE 2009 SPECIAL 301 REPORT VIOLATES INTERNATIONAL COMMITMENTS OF THE U.S. AND FAILS TO ADHERE TO BASIC ADMINISTRATIVE JUSTICE NORMS	12
A. <i>The 2009 Report Fails to Fully Endorse and honor the WTO Doha Declaration and WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.....</i>	14
B. <i>The 2009 Report Includes Numerous Listings of Countries for Taking Advantage of TRIPS Flexibilities that Promote Access to Medicines.</i>	15
1. Data exclusivity.....	15
2. Registration and Patent Linkage.....	21
3. Restrictions on Compulsory Licensing	22
4. Patent Extensions	23
5. Patentability criteria	24
6. Disclosure of origin requirements	24
7. Vague definitions of “counterfeit” pharmaceuticals	25
8. Vague Criticisms of Pharmaceutical Patent Policy.....	26
9. Enforcement Requirements	27
C. <i>The 2009 Report Pressures Other Countries to Restrict Nondiscriminatory Pharmaceutical Regulations and Taxes That Have Little to do with Intellectual Property.....</i>	28
D. <i>The 2009 Report Fails to Promote Best Practices in Innovation Policy.....</i>	30
E. <i>USTR Should Continue to Improve Transparency and Due Process Within Special 301</i>	32
1. Adequate Notice and Right of Reply.....	32
2. Neutral Arbiter and Right of Appeal.....	33
3. Objective and Transparent Standards	34
4. Public Interest Representation	34

SUMMARY

This year will be the first Special 301 report written by a United States Trade Representative office overseen by a political appointee of the Obama Administration. We call on the Administration to stop using this process to promote TRIPS-plus policies that endanger access to medicines for millions of people around the world.

USTR's past policy of using the Special 301 Report to promote TRIPS-plus restrictions on access to medicines violates U.S. commitments under the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, the multilateral commitments in the World Trade Organization and World Health Organization, ethical guidelines of the Declaration of Helsinki, express Congressional policy, Obama campaign pledges, the best interests of the PEPFAR program, the interests of global health and international human rights obligations.

We call on the administration to extend the policy guidelines of President Clinton's Executive Order 13155 to all developing countries. Specifically, it should be the policy of the United States that:

- (a) The United States shall not seek -- through Special 301, negotiation, sanction, trade preference, or otherwise -- the revocation or revision of any intellectual property or pharmaceutical market 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, and the August 30 Decision system promoting access to generics for countries with inadequate local capacity to manufacture medicines and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

The Administration should undertake an urgent review of legislative and policy changes necessary to bring Special 301 into compliance with the WTO's ban on unilateral adjudication of trade disputes. Under Special 301, USTR decides for itself what policies violate the TRIPS Agreement. And it has frequently done so under frivolous legal interpretations, such as that Article 39.3 requires data exclusivity when such a proposal was specifically amended out of the Article during TRIPS negotiations.

The U.S. government could use the Special 301 process to pursue pro-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.

At a minimum, the Special 301 program needs serious procedural reforms to provide the full and fair adjudicative process needed to ascertain relevant facts and fairly interpret and implement the statutory requirements. Full administrative justice norms should be afforded during the adjudicative process, including adequate notice and a right of reply, a neutral arbitrator and right of appeal, objective and transparent standards and interpretations of law, and a public interest representation program.

ARGUMENT

I. USING SPECIAL 301 TO PROMOTE RESTRICTIONS ON PUBLIC HEALTH FLEXIBILITIES IN TRIPS VIOLATES THE DOHA DECLARATION

The Special 301 program as enacted by Congress in 1988 requires USTR 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.¹ These standards must be interpreted in light of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, affirming 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.”²

¹ Trade Act of 1974, 19 U.S.C. § 2242(a) (listing identification criteria); § 2242(e) (West 2010) (requiring Trade Representative to publish a list in the Federal Register).

² World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001 WT/MIN(01)/DEC/2, 41 I.L.M. 755, para 4 (2002) [hereinafter Doha Declaration] (*emphasis added*). For a discussion on the legal implications of the Doha Declaration, 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/>.

Consistent with the principle enunciated in Executive Order 13155, the administration should not list any developing country in Special 301 for promoting access to medicines through any non-discriminatory policy that complies with the minimum standards in the TRIPS Agreement.

A. TRIPS Flexibilities are Integral to the TRIPS Agreement

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 is true in the U.S. where a substantial percentage of the working poor and middle class lacks insurance. And it 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.³

In recognition of the unbalanced costs and benefits of intellectual property, particularly with respect to medicines, it is commonly accepted by the world's leading public health organizations and development economists that intellectual property rules for medicines should differ among countries.⁴ Similarly, a one-size-fits-all intellectual property norm was emphatically rejected in the WTO negotiations. The TRIPS agreement contains minimum

³ 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).

⁴ See, e.g., Joseph Stiglitz, *Intellectual-Property Rights and Wrongs*, Project Syndicate (2005) available at <http://www.project-syndicate.org/commentary/stiglitz61/English>; Carsten Fink and Keith E. Maskus (eds.), *Report of the Commission on Intellectual Property Rights Intellectual Property and Development, Lessons from Recent Economic Research*, p. 215 (World Bank and Oxford University 2005); WHO, *Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy*, p. 155 .

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.⁵

Primary among the TRIPS flexibilities supporting access to medicines:

- **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 IP-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 linkage.** Countries 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

⁵ Agreement on Trade Related Aspects of Intellectual Property Rights [hereinafter TRIPS], Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 8, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994). The Agreement states as overriding principles that:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Art. 39.3, thereby avoiding the grant of marketing monopolies for medicines that operate independently of patent status;

- **Freedom of regulation.** Freedom 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).

B. Past USTR Efforts to Restrict TRIPS Flexibilities Violated the Doha Declaration

Past trade agreements and listings in Special 301 have attempted to limit each TRIPS flexibility identified above.⁶ USTR has pressed 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.

TRIPS-plus pressure by USTR on access to medicines has been widely condemned by domestic and international experts and officials.

- In response to global outrage at U.S. use of Special 301 and other pressure on countries to restrict compulsory licenses and other TRIPS flexibilities, President Clinton banned TRIPS-plus pressure in Africa in Executive Order 13155 and WTO member states unanimously adopted the 2001 Doha Declaration, affirming

⁶ 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*, Working Paper available at <http://www.essentialaction.org/access/uploads/tripsplusprovisions.doc>.

“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].”⁷

- The World Health Organization has urged developing countries to “be cautious about enacting legislation that is more stringent than the TRIPS requirements,”⁸ and admonished: “Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.”⁹
- In 2008, after more than 2 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 Property¹⁰. Through the Plan of Action, 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.”¹¹
- Congress supports the Doha Declaration and has frequently criticized TRIPS-plus trade pressure on pharmaceuticals.
 - The Kennedy Amendment to the 2002 Trade Promotion Authority legislation was intended to block TRIPS-plus trade pressure by requiring that trade authority respect the Doha Declaration.
 - In June 2005, the Committee on Government Reform reported that promoting TRIPS-plus provisions on pharmaceuticals are “[c]ontrary to the principles of the Doha Declaration” because they “will significantly

⁷ Doha Declaration, para. 4 (*emphasis added*).

⁸ See WHO, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Doc WHO/EDM/2001.2 (Mar. 2001) at 4-5 (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.”).

⁹ WHO, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Apr. 2006) at 126 [hereinafter 2006 CIPIH Report].

¹⁰ World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the Sixty-first World Health Assembly*, 24 May 2008, WHA61.21, element 5.2.c, [hereinafter Global Strategy and Plan of Action] available at www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

¹¹ Doha Declaration; Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [hereinafter August 2003 Decision], Aug. 30, 2003 available at http://www.wto.org/english/tratop_E/TRIPS_e/implem_para6_e.htm.

impede the ability of developing countries to obtain access to inexpensive, lifesaving medications.”¹²

- 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 requirements for linkage and patent extensions.
- The inclusion of Thailand and Brazil on the 2007 Special 301 watch lists for using compulsory licensing was criticized by dozens of 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 the by the United States.”¹³
- Members of Congress have urged that in Special 301 “countries should not be cited for the use of compulsory licenses or other flexibilities in accordance with international trade rules.”¹⁴
- Soon after the release of the 2007 Special 301 Report, 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 Watch List . . . for exercising the flexibilities on public health provided for in the TRIPS Agreement.”¹⁵
- The UN Special Rapporteur on the Right to Health recently declared that TRIPS-plus trade pressure on developing countries by wealthy countries may constitute a human rights violation.¹⁶

¹² Waxman Report at ii.

¹³ 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>.

¹⁴ 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.

¹⁵ S.Res. 241 and H.Res. 525. 110th Cong. (2007).

¹⁶ The Special Rapporteur, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. doc. A/HRC/11/12 (Mar. 31, 2009). The report finds that “[d]eveloped States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation,” and admonished that “[f]rom a right to health perspective, developing countries and LDCs should be enabled to use TRIPS flexibilities.” The report specifically states that all

- In 2009, 26 global health organizations have adopted a Platform on Trade-Related Intellectual Property and Health Issues, including the principle that the administration should “[f]orbid the use of threats and punitive actions, such as listing in the Special 301 Watch List and/or withdrawal of Generalized System of Preferences benefits, in response to a country’s use of TRIPS safeguards and flexibilities or refusal to adopt TRIPS-plus measures.”¹⁷

Promoting access to affordable drugs through use of TRIPS flexibilities is part of President Obama’s global health platform. President-elect Barack Obama and Vice President-elect Joe Biden pledged to “increase access to affordable drugs” in developing countries, including “access to safe, affordable generic drugs to treat HIV/AIDS.” As 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 pledges support for “the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing

developing countries “should incorporate the flexibility to: (a) Make full use of the transition periods; (b) Define the criteria of patentability; (c) Issue compulsory licences and provide for government use; (d) Adopt the international exhaustion principle, to facilitate parallel importation; (e) Create limited exceptions to patent rights; (f) Allow for opposition and revocation procedures. In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.”

¹⁷ 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>. The signatories included: ACT UP/New York; ACT UP/Philadelphia; ActionAid International USA; Africa Action; African Services Committee; American Medical Student Association (AMSA); American Public Health Association (APHA) Trade and Health Forum; American University, Washington College of Law, Program on Information Justice and Intellectual Property (PIJIP); Center for Policy Analysis on Trade and Health (CPATH) Essential Action; Forum on Democracy & Trade; Global AIDS Alliance; Health GAP (Global Access Project) Interfaith Center on Corporate Responsibility (ICCR); Knowledge Ecology International (KEI); Missionary Oblates of Mary Immaculate; Oxfam America; Peoples Health Movement-USA; Salud y Fármacos; Stop HIV/AIDS in India Initiative (SHAI); Student Global AIDS Campaign (SGAC); TransAfrica Forum; Treatment Action Group (TAG) Universities Allied for Essential Medicines (UAEM); The University Coalitions for Global Health (UCGH) Vermont Global Health Coalition. According to the platform, U.S. trade policy should 1) Promote availability of affordable life-saving medications and protect public health in developing countries; 2) Promote innovation to develop and distribute new, effective medicines that address essential health needs without limiting access to existing or future medical products; 3) Respect the right of all governments to regulate pharmaceutical markets and ensure equitable access; 4) Promote transparency and integrate public health interests into trade policy-making.

public health needs under the WTO's Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS)."¹⁸

C. PEPFAR Depends on Access to Generic Medicines

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.¹⁹ President Bush, in announcing his PEPFAR initiative, directly referenced the low-cost of generic medicines as enabling PEPFAR's scale up.²⁰ FY 2007 some 73% of all antiretroviral drugs delivered by PEPFAR were generics, saving PEPFAR \$64 million.²¹ To obtain the greatest value for the money, to ensure sustainability of treatment and to treat the greatest number of patients at the lowest cost, U.S. trade policy must promote access to affordable medicines through the use of TRIPS flexibilities in developing countries.

D. The Administration Needs to Adopt a Policy Guideline Banning USTR from Using Special 301 to Promote TRIPS-plus Policies on Access to Medicines

This administration should conduct its Special 301 review under the following policy principles:

(a) The United States shall not seek, through listing Special 301 decisions, negotiation or otherwise, the revocation or revision of any intellectual property or pharmaceutical price or competition regulation of any developing country that

¹⁸ Press Release, The Obama-Biden Plan to Combat Global HIV/AIDS, *available at* http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids (accessed on Feb. 11, 2010).

¹⁹ 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/ (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").

²⁰ See Press Release, Increasing the Availability of Safe, Effective, Low-Cost Generic Medications (Jan. 2009) *available at* <http://www.pepfar.gov/press/108120.htm>. (claiming PEPFAR "supports the increased availability of safe, effective, low-cost, and generic antiretroviral drugs (ARVs) in the developing world...").

²¹ 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/.

(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.

II. THE ADMINISTRATION SHOULD UNDERTAKE A REVIEW OF SPECIAL 301 IN LIGHT OF THE MULTILATERAL VALUES OF THE ADMINISTRATION AND THE WORLD TRADE ORGANIZATION

The current use of Special 301 likely violates the WTO accord and contradicts this Administration's policy against promoting unilateral resolution of multilateral disputes.

Enacted at a time when there was no international minimum standard for intellectual property and no effective multilateral dispute mechanism,²² Special 301 authorized a unilateral adjudication of trade disputes involving intellectual property.²³ It is frequently used to unilaterally define and enforce TRIPS, as has been the case with USTR's strained interpretation of TRIPS data protection requirements discussed below. In other circumstances it is used to sanction countries for failing to adhere to intellectual property obligations that do not exist in any trade agreement, as has been the case with the push for patent registration linkage, also discussed below. In either case, such unilateral action in the trade arena violates the multilateral dictates of the WTO.

²² See Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (New Press 2003) at 85 (noting that U.S. trade policy at the time was "decidedly protectionist").

²³ The program is an extension of the Section 301 program, which responded to the lack of effective multilateral enforcement in the General Agreement on Trade Tariffs by authorizing the President (through USTR) to unilaterally impose trade sanctions for any foreign practices that "burden[] or restrict[] United States commerce." The program did not require that the targeted practice violate any trade agreement, and countries were routinely sanctioned for policies that did not violate international standards.

The WTO requires that trade disputes be settled before multilateral dispute settlement panels.²⁴ This requirement bans countries from using sanctions, or the “threat alone” of sanctions, to enforce norms not adjudicated through the multilateral process.²⁵ Special 301’s original purpose was to threaten sanctions for non-compliance with unilaterally defined intellectual property standards. With the advent of the WTO and TRIPS, this purpose is no longer justified or legal.

The administration should undertake a careful review of the current use of Special 301 under its WTO obligations, including expert and independent legal advice from the Justice and State Departments, and work with Congress to propose necessary changes to the program.

III. THE 2009 SPECIAL 301 REPORT VIOLATES INTERNATIONAL COMMITMENTS OF THE U.S. AND FAILS TO ADHERE TO BASIC ADMINISTRATIVE JUSTICE NORMS

Under the Administrative Procedures Act the Special 301 process is an “informal adjudication.”²⁶ There are several notable duties in informal adjudications that bind USTR in decision making. In particular, an informal adjudication must

²⁴ Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 23.2, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) (“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.”); for articulation of the MFN argument against Special 301 Reports, see Jagdish Bhagwati and Hugh T. Patrick (eds.), *Aggressive Unilateralism: America's 301 Trade Policy and the World Trading System*, pp. 113-14 (University of Michigan 1993).

²⁵ Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, ¶ 7.89, WT/DS152/R (Dec. 22, 1999) (stating “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.”).

²⁶ Administrative Procedures Act (APA), 5 U.S.C. § 551(7) (West 2010) (defining “adjudication” as any “agency process for the formulation of an order” which is not a rulemaking process. Rulemaking is forward looking while adjudications determine rights and responsibilities based on past conduct.). The adjudication is “informal” because

- Follow all legal and procedural requirements in its implementing statute,
- provide a brief statement justifying its decision-making,²⁷
- not act arbitrarily or capriciously,²⁸ and
- make decisions in accordance with evidence adduced in the adjudication process (e.g. through a hearing or notice and comment process, as required in the Special 301 statute.)²⁹

Past administration of the Special 301 program violated many of these standards. It failed to implement the legal standards in the statute by defining “adequate and effective intellectual property” in a way that adhered to its commitments to the Doha Declaration and human rights duties to promote access to medicines. The reasons for its decisions have been frequently so vague as to give no explanation for its actions. The report has been arbitrary on its face for the lack of any articulation and application of objective standards that would ensure that like countries are treated alike. And decisions are frequently unsupported by actual evidence but rather simply take industry allegations and opinions as fact. As described more fully below, this state of affairs appears constructed by design through an administrative adjudication that assures industry dominance.

Because public interest groups are required to submit their comments on the same day as the industry complaints they are often responding to, this section of the submission gives specific input on the flaws in the last Special 301 Report rather than any response to the submissions of other parties submitted this year.

the governing statute does not require that the process be “on the record after opportunity for an agency hearing,” which trigger heightened procedural protections. APA §554(a).

²⁷ APA § 555(e).

²⁸ APA § 706(2).

²⁹ *Motor Vehicle Mfrs. Ass'n of US, Inc. v. State Farm Mut. Auto.*, 463 US 29, 43 (1983).

A. The 2009 Report Fails to Fully Endorse and honor the WTO Doha Declaration and WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Public interest groups call on the administration to reverse the past policy of opposition to the plain wording of the Doha Declaration.

The Bush Administration essentially ignored the Doha Declaration, arguing that it could both comply with the Declaration and continue to use Special 301 and trade agreements to pressure developing countries to give up TRIPS flexibilities and raise their pharmaceutical intellectual property standards to U.S. levels.³⁰ The 2009 Special 301 Report continued this trend. While rhetorically expressing support for the Doha Declaration, the section titled “Intellectual Property and Health Policy” carefully avoided endorsement of the specific language in the Doha Declaration, reiterated in the WHO Global Strategy and Plan of Action, affirming countries’ rights to use all TRIPS flexibilities “to the full” and the key Doha Declaration principle that TRIPS “can and should” be interpreted and implemented to promote access to medicines for all. USTR violates these principles when it implements TRIPS through narrow and conservative interpretations of TRIPS flexibilities (e.g. its interpretation of 39.3 to mandate data exclusivity) and through continued pressure on developing countries to adopt more stringent intellectual property standards on medicines than the TRIPS Agreement requires. The 2010 report should change past USTR policy and endorse the WTO Doha Declaration and the WHO Global Strategy and Plan of Action in full.

³⁰ GAO, Rep. to Congressional Requesters, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198 (2007) at 28 [hereinafter GAO Access Report]. (stating “USTR’s view is that IP rights ultimately enhance public health by promoting innovation for new medicines and that therefore this approach is consistent with the Doha Declaration.”).

B. The 2009 Report Includes Numerous Listings of Countries for Taking Advantage of TRIPS Flexibilities that Promote Access to Medicines.

Despite the policy change ushered in with the application of the 2007 New Trade Agreement for America and the change in administrations to one committed to support the Doha Declaration, the 2009 Special 301 Report continued to sanction countries for policies that are clearly permitted by TRIPS. These and all other TRIPS-plus trade pressure on developing countries should be eliminated from the 2010 Report.

1. Data exclusivity

The most common objection in the 2009 report 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.”³¹ Numerous other countries have been listed in Special 301 reports or otherwise pressured to adopt TRIP-plus data exclusivity in recent years.³² In most cases the 2009 Special 301 Report fails to explain what it considers to be inadequate protection of undisclosed data. But the Special 301 Report in the past has been used to press a position that TRIPS Art. 39.3 requires the grant of additional monopoly periods for pharmaceuticals through “data exclusivity,” which appears to motivate the 2009 report as well. This position is unsupported by the text or negotiating history of the TRIPS Agreement, is a clear violation of the Doha Agreement and is bad global health policy.

³¹ United States Trade Representative, 2009 Special 301 Report (Apr. 30, 2009) at 17 [hereinafter 2009 Report]. 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.

³² Guatemala is a key example. *See, e.g.*, Ellen R. Shaffer and Joseph E. Brenner, A Trade Agreement’s Impact On Access To Generic Drugs, *Health Affairs*, 28, 5 (2009): w957-w968 (Aug. 2009) (describing use of Special 301 and other trade pressure for Guatemala to adopt data exclusivity); United States Trade Representative, 2003 Special 301 Report (May 1, 2003) [hereinafter 2003 Report] (listing Guatemala on the watch list after it repealed a law requiring 15 years of data exclusivity); *see also* separate 2010 comment submission by the Center for Policy Analysis on Trade and Health (CPATH) on repeated misuses of 301 Reports to penalize Guatemala for legal measures to provide affordable medicines.

The issue of access to pharmaceutical test data 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 and Good Manufacturing Practice. In this way, the generic firm relies on the original safety and efficacy data that the regulator has already reviewed and approved, rather than repeating costly and ethically troublesome animal and human trials.³³

The TRIPS agreement requires that certain pharmaceutical test data submitted to registration authorities be protected from “unfair commercial use.”³⁴ Article 39.3’s literal scope is relatively narrow.³⁵ Importantly, countries have great leeway in defining what use or reliance on test data may be an “unfair commercial use.” The WHO has advised that most traditional uses of registration data to approve generic medicines do not need to be defined by states as an unfair commercial use of that data:

Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product's similarity to a previously approved first product, is not a proscribed “use” under Article 39.3

³³ 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.”).

³⁴ 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 against unfair commercial use.

³⁵ 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. it the undisclosed data is “the result of significant investment,” proof which could be required.

. . . 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.³⁶

The WHO’s interpretation is consistent with the writings of the leading legal scholars on the TRIPS agreement and public health.³⁷ It is also consistent with the Doha Declaration’s mandate that the TRIPS agreement can and should be interpreted to promote access to medicines.

The practice of providing a form of exclusivity for pharmaceutical test data originates with the Hatch Waxman Act in the U.S. The primary effect of that Act was to implement a fast track for generic approval through reliance on past submitted clinical trial data by originator. But the Act included a political compromise by prohibiting such reliance in the first five years after the registration data is filed. In the EU, data exclusivity periods were later enacted that can run as long as 10 years.³⁸ These periods operate independently of any period of patent exclusivity, and

³⁶ Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement*, South Centre/WHO (2002) at 5 available at <http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf>.

³⁷ *Id.*; Sisule F. Musungu and 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 and 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>.

³⁸ 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. 303-344 (2008).

in the EU have been interpreted to be impervious to compulsory licensing, even in a health emergency.³⁹

Most countries in the world do not follow exclusivity rules, but rather allow generic companies to register products and come on the market through bio-equivalency demonstration at any point.⁴⁰ In such countries, the only marketing monopoly companies receive is through the patent system rather than the registration system. As the WHO has explained, this is the pro-access to medicines approach:

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.⁴¹

USTR has adopted a radical legal interpretation of TRIPS that Article 39.3 requires data exclusivity similar to the U.S. or EU. During the TRIPS negotiating process, the U.S. proposed language for Article 39 requiring that pharmaceutical test data be “reserved for the exclusive use of the registrant for a reasonable period.”⁴² That proposal was specifically amended out of the agreement in negotiation.⁴³ Nevertheless, PhRMA continues to argue that Art. 39.3 requires “a data exclusivity regime which prevents regulatory authorities from prematurely allowing generic producers to rely on or otherwise use the originators proprietary data to gain approval of copies of the originators drug.”⁴⁴ And USTR has adopted this position in past 301 Reports, asserting:

³⁹ 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 to the... periods of 8 year data exclusivity and 10 years marketing protection in case of emergency situation or in case a compulsory patent license has been granted by an EU Member State.”).

⁴⁰ See Musungu and Oh, *supra* note 37 at 65-67 (surveying countries).

⁴¹ See Correa, *supra* note 36 at xi.

⁴² See Correa, *supra* note 36 at 53.

⁴³ Carlos Correa and Abdulqawi Yusuf, *Intellectual Property and International Trade, The TRIPs Agreement*, Kluwer Law International, (London-Cambridge 1998); Daniel Gervais, *TRIPS Agreement - Drafting History and Analysis*, (Sweet & Maxwell. 1998) pp. 182-183.

⁴⁴ 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 (arguing

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.⁴⁵

Elsewhere, USTR has proclaimed that “any other” interpretation of Article 39.3 “would be inconsistent with logic and the negotiating history of the provision.”⁴⁶

The USTR interpretation of 39.3 as requiring data exclusivity is frivolous and would not stand up in any neutral adjudicative forum.⁴⁷ Article 39.3 provides no definition of what kind of protection against unfair commercial use must be provided. The default in international trade agreement interpretation is that undefined terms are subject to local definition by sovereign implementing states. A requirement for data exclusivity was specifically considered and amended out of the text of TRIPS. The Doha Declaration, which is a subsequent agreement by the same members (including the U.S.) and therefore helps define and interpret the TRIPS terms, demands that states interpret TRIPS to promote access to medicines. The ultimate legal conclusion from this is clear: “Countries are not obligated under Article 39.3 to confer exclusive rights on the originator of marketing approval data.”⁴⁸

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

that Thailand cannot meet its Art. 39.3 obligation through the provisions of its Trade Secrets Act 2002, Chapter 3, Section 15, providing for the Preservation of Trade Secrets by Government Entity); *id.* (“the official regulation fails to expressly prohibit the Thai FDA or generic drug applicants, for a fixed period of time, from relying on the originators regulatory data to approve generic versions of the originators product”). PhRMA requests many other TRIPS-Plus measures as grounds for 301 listings and sanctions. *Compare id.* (complaining that “protection applies only to data related to new chemical substances (not to new dosage forms, new indications, composition, etc.)” with WHO, *Data Protection*, (advising that, because article 39.3 only applies to new chemical entities, countries “may exclude applications for second indications, formulations and dosage forms”); 2009 Report at 26.

⁴⁵ 2003 Report at 4-5.

⁴⁶ See Correa, *supra* note 36 at 47 (discussing an unattributed paper for submission in bilateral discussions with Australia) (quoting the Office of the General Counsel, U.S. Trade Representative, 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>).

⁴⁷ See Correa, *supra* note 36 at 5.

⁴⁸ *Id.*

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.⁴⁹

The Bush Administration's press for data exclusivity was subject to vociferous opposition.

- The Waxman Report concluded that the consequences of data exclusivity provisions “are the exact opposite of those intended by the Doha Declaration.”⁵⁰
- 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 a “the central purpose of the Doha Declaration.”⁵¹
- The 2007 New Trade Policy with America negotiated between the Bush Administration and the new Democratic Congress limited data exclusivity provisions in trade agreements.
- 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 built into the TRIPS Agreement, unless such a restriction is required for public health reasons.”

The USTR's use of Special 301 to push its radical interpretation of Article 39.3 on developing countries displays the inadequacy of Special 301 as anything remotely like a neutral adjudicative process and highlights the reason why it violates the WTO. Countries cannot have

⁴⁹ Waxman report at 7.

⁵⁰ *Id.*

⁵¹ 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>.

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.

In the 2010 Special 301 Report, USTR should refrain from listing any country for protection of undisclosed data that complies with any reasonable interpretation of TRIPS Art. 39 (including protection limited to illegal theft of trade secrets).⁵² Where the report identifies any country for inadequate data protection, it should identify the precise problem with the country's laws and refer any dispute about the meaning of Article 39 to WTO dispute resolution rather than unilaterally adjudicating the issue.

2. Registration and Patent Linkage

Another common complaint in the 2009 report involves alleged failures by countries to “implement an effective system to prevent the issuance of marketing approvals for unauthorized copies of patented pharmaceutical products.”⁵³ A nearly identical complaint is raised against twelve countries in the Report.

This issue is commonly referred to as patent/registration “linkage,” referring to the linking of drug approval to patent status. Linking marketing approval for a drug to patent expiration was criticized in the Waxman Report for forcing “the drug regulators in the developing countries to become patent enforcers even though they have no expertise in this area.”⁵⁴

Linkage systems can enable the “evergreening” of patents, whereby patent holders extend their marketing monopolies by filing additional (often invalid) patents and using those filings to halt registration of legitimate generic products. Asking drug regulatory authorities to operate outside of their field of competence, and relieving patent holders of their own obligations to test

⁵² See Correa, *supra* note 36 at 41-47 (explaining that such a minimum provision would satisfy Art. 39 of TRIPS).

⁵³ 2009 Report at 17.

⁵⁴ Waxman Report at 9.

and enforce their alleged patent rights through judicial action, invites this kind of abuse. This brand of “evergreening” has been common in the U.S., where Food and Drug Administration approval is linked to patent status.⁵⁵ 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.⁵⁶

The May 2007 New Trade Policy for America removed the requirement for linkage provisions from then pending agreements. Yet USTR has continued to push for linkage provisions through Special 301. In the 2010 Special 301 Report, USTR should eliminate all requests that any country link their drug approval and patent status.

3. Restrictions on Compulsory Licensing

Compulsory licensing is perhaps the most important flexibility in the TRIPS agreement. 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.”

In 2007 Thailand was elevated to the Priority Watch List (PWL) in large part for its announcement of compulsory licenses for several medicines needed to address critical public health problems. In 2009, Thailand was kept on the PWL and the entry for Thailand continues to

⁵⁵ 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 Washington 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.

⁵⁶ Waxman Report at 9.

note concerns about “the uncertainty created by the previous Government’s policies concerning the issuance of compulsory licenses on patented pharmaceutical products.”⁵⁷

Pressuring countries to refrain from the authorization or use of TRIPS-complaint compulsory licenses is contrary to the WTO Doha Declaration and the WHO Global Strategy Plan of Action. In the 2010 report, USTR should refrain from listing any country for use or authorization in law or policy of TRIPS-compliant compulsory licenses.

4. 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 is three years longer than the period for which the U.S. previously granted patents, and takes into account the known delays in regulatory processes.

Trade agreements negotiated by the Bush Administration frequently required that developing countries grant patent extensions beyond this 20 year period. These provisions were criticized in the Waxman Report, which explained that the “provisions can work to delay access to low-cost generic drugs in developing nations.”⁵⁸

The 2007 New Trade Deal for America removed the requirement for patent extensions in then-pending FTAs. Yet USTR has continued to use Special 301 to pressure countries to adopt patent extensions.⁵⁹ In the 2010 Report, USTR should refrain from singling out any country to promote TRIPS-plus patent extensions.

⁵⁷ 2009 Report at 21.

⁵⁸ Weissman *supra* note 6.

⁵⁹ See 2009 Report (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.”)

5. Patentability criteria

The 2009 Report singles out Brazil for concerns regarding “the decision against granting patents for polymorphs and second-use inventions; and the role of Brazil’s health authority, ANVISA, in the patent application process.”

TRIPS does not require the issuance of second-use patents. It requires patents on new products and processes, but not on new uses.⁶⁰ Second use patents are one method by which pharmaceutical companies can “evergreen” their patent – i.e. by filing a patent for a second use of an existing medicine close to the expiration date of the first patent.

TRIPS leaves it up to countries to define their criteria for what products are sufficiently “new” and involve an “inventive step” so as to qualify for a patent monopoly. Polymorphs are simply new crystalline structures of an existing medicine. Giving patents for polymorphs is not done in many countries (including, e.g., India), and is particularly bad patent policy.

Involvement of health officials in the patenting process is a best practice that should be emulated, not criticized. Health officials may be able to contribute to the analysis of whether a claimed new product is actually new and useful, which lies at the heart of patent analysis. Criticism of such novel institutional arrangements has no place in the Special 301 process.

The 2010 Special 301 Report should halt listing of countries for scope of patentability or patent examination process issues that are not regulated by TRIPS.

6. Disclosure of origin requirements

The 2009 Report entry on China lists objections to China’s disclosure of origin requirements for patent applications. Disclosure of origin provisions are one way to comply with the Convention on Biologic Diversity’s requirement that countries promote equitable benefit

⁶⁰ Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre/WHO (2002) at 23, available at <http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf>.

sharing in their intellectual property laws. Such requirements are not prohibited by TRIPS and they may promote access to medicines by dissuading the patenting of known substances. In the 2010 Special 301 Report, no country should be listed for TRIPS-compliant disclosure of origin requirements in patent statutes.

7. Vague definitions of “counterfeit” pharmaceuticals

The 2009 Report lists 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 infringes a trademark.⁶¹ It is not correctly applied to an allegedly unauthorized generic version of a patented product, or to a substandard medicine that does not violate any trademark protection.

At other times the Report makes accusations of patent law violation with little or no evidence cited. For example, the 2009 report notes concern with the “unauthorized use of bulk active pharmaceutical ingredients” by manufacturers in Brazil, China, and India. 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 industry complaints as fact.

In all references to piracy or “counterfeiting,” the 2010 Report should ensure that the US 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 the proof on which it relies.

⁶¹ TRIPS Art 51, Footnote 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;

8. Vague Criticisms of Pharmaceutical Patent Policy

In several instances it is impossible to tell from the 2009 Report what is being complained about at all.

The entry on Bolivia raises undefined concerns about “the erosion of IP protection for pharmaceutical products.” The entry for Paraguay similarly notes concerns about undefined “shortcomings in Paraguay’s patent regime.” 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* decision,⁶² 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.

We have reviewed the recent amendments to the Philippines patent law and find nothing 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.

⁶² Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114 (Mar. 17, 2000).

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. Such action must be avoided in future Reports.

9. Enforcement Requirements

In several instances in the 2009 Report, USTR presses countries to adopt TRIPS-plus intellectual property enforcement procedures that could limit access to medicines. There are at least 36 countries in the 2009 Report cited for needing to implement tougher criminal or ‘deterrent’ penalties for infringement.

The Report appears to occasionally promote criminal enforcement for patent violations,⁶³ which has been a problem in past FTAs. Criminal penalties for patent infringement relieve right holders of their own private enforcement duties and improperly force countries to expend scarce law enforcement resources on protecting private rights. Criminalizing patent infringement may also deter potential competitors from challenging patents, and therefore increase the amount of invalid patents allowed to monopolize markets.

There are many other instances in the report criticizing the weakness of IP penalties more generally, often saying there is a lack of deterrent effect in the penalties given to unspecified IP infringers. For instance, the passage for Argentina reads: “Civil damages are ineffective and the judiciary is apparently reluctant to impose deterrent-level penalties in criminal cases.”

There are also many vague references to toughening civil penalties. In Spain, for example, the Report states: “rights holders do not have access to important legal tools needed to

⁶³ For example, the Report states about India:

Piracy and counterfeiting, including of pharmaceuticals, remain a serious problem in India. India’s criminal IPR enforcement regime remains weak. Police action against those engaged in manufacturing, distributing, or selling pirated and counterfeit goods, and expeditious judicial dispositions for IPR infringement and imposition of deterrent-level sentences, is needed.

bring meaningful civil infringement suits.” But the Report does not indicate what tools are lacking and therefore it is impossible to engage the comment with an informed response.

There are also problematic passages throughout the Report about the need to give border officials (and others) the ability to instigate raids and confiscate suspected infringing products. Examples include the passages for Canada, 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.⁶⁴ 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. For medicines, wrongful confiscations harm more than economies (which itself threatens social welfare), it directly threatens the lives of people who depend on uninterrupted supplies of the medicines they need.⁶⁵

C. The 2009 Report Pressures Other Countries to Restrict Nondiscriminatory Pharmaceutical Regulations and Taxes That Have Little to do with Intellectual Property

The past USTR began a disturbing expansion of its negotiation topics to include matters at the core of how governments regulate monopolistic pricing practices by essential medicine

⁶⁴ Since late 2008, customs officials in the Netherlands, Germany and France have seized at least 20 shipments of legitimate generic medicines. Of the shipments, 19 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. 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.

⁶⁵ 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.

providers. The 2009 report singles out Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering “unreasonable . . . reference pricing or other potentially unfair reimbursement policies.”

The Report has also been used to pressure countries to change their tax and generic drug promotion policies. Guatemala, for example, was listed in Special 301 for extending tax exemptions and other benefits for generic drugs, including medicines for HIV/AIDS.⁶⁶ In 2009, PhRMA recommended that Guatemala remain on the Special 301 Watch List in 2009 and that the issue related to Decree 16-2003 be “quickly and effectively resolved.”⁶⁷ Guatemala remained on the 2009 Watch List.

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).

Federal agencies (including GSA and VA), U.S. states (particularly through Medicaid) and other country governments are at the forefront of creating policies that can fully respect patent rights while achieving more reasonable pricing of medicines that adequately compensate for incentives to innovate. Contrary to the submissions of the pharmaceutical industry, the problem with global drug pricing is not that the Veterans’ Administration, State Medicaid Programs or the governments of the UK, Australia or Canada pay too little for medicines. The problem is that the world’s poor, including the poor in the U.S., pay too much.

⁶⁶ See Shaffer and Brenner *supra* note 32 (recounting pressure to repeal Decree 16-2003).

⁶⁷ 2009 PhRMA Submission.

USTR should operate Special 301 under the norm that countries must be free to use evidence-based pricing and reimbursement policies, including therapeutic formularies, public and private reimbursement schemes, reference pricing, and other evidence-based regulatory controls on pricing and reimbursement. Congress has not demanded that USTR seek international standards in this area.

The Obama Administration should be treading cautiously in this area, allowing diverse global practices to flourish like a laboratory of states. One thing is clear: global welfare cannot be maximized with both strong patent protection and immunity from price and market regulation as a global constitutional rule.

D. The 2009 Report Fails to Promote Best Practices in Innovation Policy

In the 2009 report, the USTR included a section on “Supporting Pharmaceutical 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.

USTR’s continued advocacy of higher patent protection as the only and best way to serve the global public interest in research and development for new medicines is at odds with the evidence. Exclusive marketing rights have not promoted research and development for diseases and conditions that primarily concern poor people living in developing countries.⁶⁸ As noted by the 2006 WHO report by the Commission on Intellectual Property Rights, Innovation and Health (CIPRH):

Intellectual property rights are important, but as a means not an end. How relevant they are in the promotion of the needed innovation depends on con-text and

⁶⁸ See Margaret Kyle and Anita McGahan, Investments in Pharmaceuticals Before and After TRIPS, NBER Working Paper 15468, *available at* <http://www.nber.org/papers/w15468> (finding that “R&D effort is not associated with the implementation of TRIPS in lower income countries”).

circumstance. We know they are considered a necessary incentive in developed countries where there is both a good technological and scientific infrastructure and a supporting market for new health-care products. But they can do little to stimulate innovation in the absence of a profitable market for the products of innovation, a situation which can clearly apply in the case of products principally for use in developing country markets.

There are steps the Administration could take to encourage global policies that would help global innovation for new medicines:

- Promote a rational innovation policy, including encouragement of countries to fully implement the World Health Assembly resolution 61.21, which contains a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. This includes supporting the WHO in its mandate to implement the entire policy agenda, as well as sufficient financial and human resources to carry it out.
- Recognize and encourage the use of diverse mechanisms that separate and de-link research and development (R&D) incentives from prices, for example through the use of innovation inducement prizes that reward innovations that improve health outcomes and permit open competition for products.
- Promote licensing of all publicly funded biomedical R&D to the developing world, for example by licensing to the UNITAID patent pool publicly-funded IP held by NIH and Universities, and by supporting similar initiatives addressing other health needs, to ensure affordable upstream and downstream access to medical technologies relevant to health needs of developing countries.
- Organize a series of public events where a diverse range of stakeholders can present their proposals. Discussions should include innovation inducement prizes that reward improvements in health outcomes and require open licensing, the use of health-related patent pools, and proposed elements of a WHO biomedical R&D treaty.
- Encourage governments to provide open access to government funded medical research, such as is now required by the NIH Public Access Policy.

- The Special 301 report could be a means of highlighting cases where governments are meeting their R&D commitments, as recommended by the WHO CIPIH Report.⁶⁹

E. USTR Should Continue to Improve Transparency and Due Process Within Special 301

The public interest community appreciates the strides USTR made this year to hold an open public hearing on the Special 301 report for the first time ever. In part out of this appreciation, the public interest community has made great efforts to participate in this process despite none of the organizations receiving any funding specifically for this purpose. In the future, however, much more lasting structural improvements to the 301 process are needed.

USTR claims to review the IP policies of a huge number of countries every year. Yet, USTR has few dedicated staff to this effort, 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 on facts to emerge from an administrative fact finding process.

The Administration has great discretion to decide what procedures to follow in the Special 301 process. It should adopt procedures that best enable it to find truthful facts relevant to the statutory determinations it is required to make.

1. Adequate Notice and Right of Reply

For the great majority of its operation, there has been absolutely no right of reply or specific notice to the accused. Industry complaints and country and NGO replies have been literally due on the same day. The process made a small reform for the 2008 report by allowing a

⁶⁹ See 2006 CIPIH Report at 47 (stating in recommendation 2.1 that “[g]overnments of developed countries should reflect adequately this objective in their research policies. In particular, they should seek to define explicit strategies for R&D and devote a growing proportion of their total health R&D funding to the health needs of developing countries.”).

short reply window for foreign countries. This year, that reply window was *reduced* to just one week, although a hearing was added affording much more opportunity to reply to comments. Nonprofits in support of foreign countries receive no right of written reply to the complaints lodged by industry. Thus, this submission is responding entirely to the 2009 report rather than 2010 complaints.

In the future, the 301 process should be reformed to afford a full and reasonable reply period to foreign countries and public interest supporters. There should also be a period where such parties can comment on a draft of the Report before it is finalized, as is common in many regulatory review processes.

2. Neutral Arbiter and Right of Appeal

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.

The Special 301 adjudication process should be modified to provide for an appeal of legal, policy and factual determinations in the draft report to an independent body outside of the office of the USTR, e.g. 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.

3. Objective and Transparent Standards

As described at length in the analysis of the 2009 Report, the written decisions of the Agency are very difficult to interpret because they are incredibly 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.

4. Public Interest Representation

Commercial industry has organized an entire association, IIPA, with great resources and with a major purpose being the participation in the adjudication process that results in Special 301 listing decisions. On the other side are foreign countries with no real influence in American politics and a diffuse range of public interest organizations, none of which receive any foundation or member funding for participating in such adjudication. This is a recipe for corporate capture of administrative agencies.

To help global health organizations meaningfully participate in the process, participation grants should be established for NGOs to hire professional, legal and research assistance to participate in the process. Such grants are common, for example, in utility rate making determinations where utility companies have great interest and resources to participate but consumers tend to be diffuse and difficult to organize. In California, for example, non-profit organizations can receive the equivalent of attorney fees from the regulatory authority for meaningful participation in the proceedings on behalf of consumers. The Administration could also operate a small grant process that organizations could apply for collectively or individually.