2016

Drugs, Drugs Everywhere but Just Not for the Poor

Srividhya Ragavan
Texas A&M University School of Law, ragavan.sri@law.tamu.edu

Drugs, Drugs Everywhere but Just Not for the Poor

Srividhya Ragavan

Professor of Law, Texas A&M University School of Law

Access to medicines; Compulsory licensing; Developing countries; TRIPS; United States; WIPO

Introduction

In 2009, Ramesh, a highly-paid executive in India, was diagnosed with a rare form of cancer. His hope lay in the compound soranafib tosylate marketed as Nexavar, and the patent in the drug was owned by the German pharmaceutical company, Bayer AG. In India, Nexavar was cleared for marketing in 2007, followed by the grant of a patent in 2008.[1] Although Ramesh's net worth placed him in the top 20 per cent of the annual average income by quintile in India, he was devastated to learn that the treatment regimen for Nexavar cost approximately US $5,000 (INR 2,80,428) per month.[2] The egregious price of Nexavar was nearly five times higher than the median *annual* income in India.[3] In India, individuals earning US $5,000 *per year* would consider themselves fairly well-employed.[4] Thus, Bayer's Nexavar had the distinction of creating have-not out of the haves!

At the time Ramesh was considering his treatment options, India housed approximately 20,000 patients with liver cancer and about 9,000 patients with kidney cancer. So, when Natco, an Indian generic drug company, petitioned the controller general of patents to compel Bayer to issue a licence in its favour, the evidence overwhelmingly favoured Natco. The generic Nexavar from Natco was priced at approximately US $200 (INR 10,000) per month. The controller's order concluding that Bayer's action warranted a compulsory licence was affirmed on appeal by Sridevan J at the Intellectual Property Appellate Board.[5]

The highpoint of the above incident was the United States' visceral reaction following the issuance of the compulsory licence in India. On August 2, 2013, the pharmaceutical industry's lobbying effort translated into a request from the chairman of the US Senate Committee on Finance and the House Committee on Ways and Means to the US International Trade Commission to institute an investigation on India's trade practices,[6] using powers under Tariff Act of 1930 s.1332(g).[7] The Special 301 Report of the Office of the United States Trade Representative (USTR), on which India is usually featured, specifically identified the *Bayer* decision as "concerning" both in the 2012 and 2013 reports.[8]

India was no lone ranger. In fact, the United States established a similar pattern of response in Colombia following the issuance of Resolution 2475 of 2016 on June 17, 2016 by the Minister of Health, Alejandro

[1] "India Grants First Compulsory License to Generic Drug Producer", available at *http://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer* [Accessed October 31, 2016].

[2] Insurance coverage in India broadly covers about 5–20 per cent of the population. Generally, government sponsored schemes have a cap of INR 30,000 (approximately US $500) and is limited to hospitalisation. In addition, domiciliary treatment (medication) is not covered as part of most insurance in India. Email from Professor Surupa Gupta, University of Mary Washington, February 12, 2014.

[3] Mike Palmedo, "Graphics on U.S. Pharmaceutical Exports to India, Patents, the Compulsory License, and Prices", available at *http://infojustice.org/archives/32249* [Accessed October 31, 2016].

[4] Srividhya Ragavan, "Patients Win over Patents", *The Hindu*, March 7, 2013.

[5] *Bayer v Natco* M.P. Nos 74–76 of 2012 and M.P. No.108 of 2012.

[6] International Trade Commission Investigation, Notice for Investigation No.332-543, August 29, 2013 (on issues relating to trade, investment, and industrial policies in India, with particular reference to its effects on the US economy and US jobs).

[7] 19 USC s.1332(g).

[8] 79 Fed. Reg. 421 (January 3, 2014); see also Office of the United States Trade Representative, *Special 301 Report* (2012, 2013).

Gaviria.[9] Resolution 2475 was a declaration by the Government to issue a compulsory licence to lower the price of imatinib, a leukaemia drug, marketed as Glivec. The patent in Glivec was owned by the Swiss pharmaceutical company, Novartis AG.[10] Resolution 2475 was a response to a petition submitted by the Colombian non-governmental organisations to compulsorily license Glivec with a view to reduce the cost of the medication.[11] At that time, Novartis priced 400mg of Glivec at COP 129,000 (approximately US $43).[12] The total annual cost of 400mg of Glivec in Colombia, amounting to US $15,000 per patient per year, represented nearly twice the average annual income of Colombians.

Meanwhile, on August 24, 2016, Colombia celebrated a historic moment when the Colombian Government and the Revolutionary Armed Forces of Colombia (FARC), a guerrilla group, ended an armed conflict that began in 1964.[13] The United States pledged US $450 million in support of the peace plan—Paz Colombia—to provide for programmes to retrain members of FARC and to eradicate the drug trade that has ravaged Colombia.[14]

The US response to Colombia followed a predictable pattern when the USTR, citing Resolution 2475, indicated that Paz Colombia may be at risk![15] The outrageousness of the USTR's response can be best understood considering that it caused the House Democrats to express serious concern over the USTR's actions in a letter addressed to Ambassador Michael Froman, the US Trade Representative.[16] The letter pointed out that the United States would derogate from its obligations as a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) of the World Trade Organization (WTO). TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health 2001 (Doha Declaration)[17] expressly authorise the use of such licences for exactly the same situations for which it was used by Colombia.[18] Interestingly, when the USTR cited India for the *Bayer* decision in the Special 301 Report, it carefully suggested that India's actions will be weighed in the light of the Doha Declaration.[19]

The simple objective for this article is to understand the legitimacy and limitations of US involvement in another country's sovereign actions taken expressly in the public interest, or to protect public health,

[9] Andrew Goldman, "Colombia Issues Public Interest Declaration to Lower Price of Glivec", available at *http://keionline.org/node/2601* [Accessed October 31, 2016]; Ministry of Health and Social Protection Resolution Number 2475 of June 14, 2016, available at *https://www.minsalud.gov.co/Normatividad_Nuevo/Resoluci%C3%B3n%202475%20de%202016.pdf* [Accessed October 31, 2016].

[10] Novartis was involved in a huge dispute in India to patent imatinib mesylate, whose patent would have given the drug new life once the patent on imatinib expires. *Novartis AG v Natco Pharma* Application No.1602/MAS/1998 (2005) (India), available at *http://indiankanoon.org/doc/1352538/* [Accessed October 31, 2016]; Indian Patent Application No.1602/MAS/1998.

[11] Ministro de Salud y Protección Social, "Solicitud de una declaración de interés público en el acceso al medicamento imatinib bajo condiciones de competencia", available at *https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Solicitud-de-una-declaracion-en-el-acceso-al-medicamento-IMATINIB.pdf* [Accessed October 31, 2016].

[12] Knowledge Ecology International, "Background FAQ on Glivec (imatinib) Compulsory License in Colombia", available at *http://keionline.org/colombia-imatinib-FAQ* [Accessed October 31, 2016].

[13] WOLA, "Excerpts from the August 24 Announcement of a Final Peace Accord between the Colombian Government and the FARC: The Joint Communiqué", available at *http://colombiapeace.org/2016/08/25/excerpts-from-the-august-24-announcement-of-a-final-peace-accord-between-the-colombian-government-and-the-farc/* [Accessed October 31, 2016]. The conflict with FARC ended after more than 50 years. Unfortunately, Paz-Columbia was never implemented because the deal was rejected in a referendum. See Sibylla Brodzinsky, "Colombia referendum: voters reject peace deal with Farc guerrillas," The Guardian, available at *https://www.theguardian.com/world/2016/oct/02/colombia-referendum-rejects-peace-deal-with-farc* [Accessed October 31, 2016].

[14] Stephanie Burgos, "Does Colombia Really Have to Choose between Poverty and Public Health", available at *http://politicsofpoverty.oxfamamerica.org/2016/05/does-colombia-really-have-to-choose-between-peace-and-public-health/* [Accessed October 31, 2016].

[15] Andrew Goldman, "15 House Dems Press USTR to Clarify Position on Compulsory Licensing of Cancer Drug Patent in Colombia", available at *http://keionline.org/node/2577* [Accessed October 31, 2016].

[16] The letter was led by Ways and Means Committee Ranking Member Sander Levin (D-Michigan). Letter to Ambassador Michael Froman, available at *https://democrats-waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Colombia%20Compulsory%20License%20Letter.pdf* [Accessed October 31, 2016]; Zach Carter, "Colombia Fears U.S. May Reject Peace Plan to Protect Pharma Profits", *http://www.huffingtonpost.com/entry/colombia-gleevec_us_5733d4ece4b077d4d6f224ee* [Accessed October 31, 2016]; Carolyn Y. Johnson and Karen DeYoung, "Dispute with Swiss Drug Maker Has Colombian Officials Worried about U.S. Peace Funding", available at *https://www.washingtonpost.com/business/economy/dispute-with-swiss-drugmaker-has-colombian-officials-worried-about-us-peace-funding/2016/05/18/6f1903ee-1c5e-11e6-8c7b-6931e66333e7_story.html* [Accessed October 31, 2016].

[17] Doha Declaration on the TRIPS Agreement and Public Health 2001, November 20, 2001, WT/MIN(01)/DEC/2.

[18] Goldman, "15 House Dems Press USTR to Clarify Position on Compulsory Licensing of Cancer Drug Patent in Colombia" available at *http://keionline.org/node/2577* [Accessed October 31, 2016]; Ed Silverman, "House Democrats Blast US Trade Rep for Pressuring Colombia over Novartis", available at *https://www.statnews.com/pharmalot/2016/05/25/novartis-gleevec-patents-cancer/* [Accessed October 31, 2016].

[19] Sean Flynn, Brook K. Baker and Srividhya Ragavan, "Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy", International Trade Commission, 2013, on file with author.

such as the compulsory licensing of pharmaceuticals. The first section takes the example of compulsory licensing as a legitimate sovereign action and delineates its scope in the light of the international trade obligations under TRIPS. The second section discusses the rights and obligations of the USTR vis-à-vis the United States' sovereign trading partners and how international trade obligations intersect with the rights of the USTR. The third section outlines the legality of the USTR's actions in light of the United States' international obligations. The fourth section discusses the question of whether—and if so, how—the other international organisations, particularly the World Intellectual Property Organization (WIPO), can be involved in restoring the legitimacy of sovereign actions taken in the public interest. The article's conclusion outlines the importance of co-ordination amongst international organisations as a critical element to achieve the objectives of the trade and developmental agenda.

International trade obligations and legitimate sovereign actions

Pharmaceuticals and life-saving medications hold a unique significance in the marketplace. Unlike consumer products, where demand is dependent on affordability, the demand for life-saving medications is independent of affordability. Thus, in markets with low per capita income, such as developing countries, high prices sustain or even increase the demand as access becomes limited. As the number infected with a disease increases, productivity of the economy can be adversely affected. Under these circumstances, ensuring access to life-saving medicines becomes an important sovereign responsibility. Discharging judiciously such a responsibility in a manner that would protect public health, preserve economic productivity and maintain socio-economic balance forms a part of the legitimate expectations from any government. The following details how international agreements and national laws are structured to enable a sovereign to discharge the function of protecting public health.

Pharmaceuticals and sovereign actions

Compulsory licensing is an example of a unique tool legitimately deployable by a sovereign government. The term "compulsory licensing" refers to the mandatory licensing of a patented technology used for specific reasons under limited circumstances. Such licences are specifically used to reduce the price of a patented product by forcing the patent holder to license the technology to third parties, thus creating competition. Compulsory licences are unique because they serve to balance the patent owner's right with the societal need for the product. They operate where public interest concerns outweigh the patent holder's rights.[20] Such licences are legitimate, especially in the context of inventions involving pharmaceuticals, food and national security concerns. In the case of pharmaceuticals, the use of compulsory licences represents a legitimate sovereign action for two reasons: first, because the rights to life and health are constitutional guarantees in countries such as Brazil and Colombia, they prompt governmental action to ensure access to medication;[21] secondly, compulsory licences represent the negotiated exclusion to patent rights under international trade agreements, as discussed below.

Article 30 of TRIPS provides for compulsory licences as an outlined exclusion to patent rights. The provision allows countries to determine the grounds for issuing compulsory licences. Furthermore, the Doha Declaration explicitly clarified the determination in art.30 of TRIPS that WTO members may provide

[20] Srividhya Ragavan, "The Jekyll and Hyde Story of International Trade: The Supreme Court in *Phrma v. Walsh* and the TRIPS Agreement" (2004) 38 Rich. L. Rev. 777, 784; Rafael V. Baca, "Compulsory Patent Licensing in Mexico in the 1990's: The Aftermath of NAFTA and the 1991 Industrial Property Law" (1994) 35 IDEA 183, 184–185; David J. Henry, "Multi-National Practice in Determining Provisions in Compulsory Patent Licenses" (1977) 11 Geo. Wash. J. Int'l L. & Econ. 325.

[21] Brazilian Constitution art.196 establishes the right to health. Brazil also established the National Unified Health Care System (*Sistema Único de Saúde*) to guarantee universal health care coverage to all Brazilian citizens. Law 8.080/90 (Brazil). See also Law 8.142/90; Law 1751/2015 (Colombia) (regulating the fundamental right to health).

limited exceptions to the rights conferred by a patent. This declaration represents WTO members' commitment to enable access to medication. It affirms that TRIPS can and should be interpreted

> "in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all".[22]

In so doing, the Doha Declaration emphasises that TRIPS should be a part of the developing country members' efforts to address the public health problems. It adds that, although intellectual property rights are essential for medical innovation, the prices of medication should not impede access in developing nations. Thus, the Doha Declaration establishes the sovereign right and legitimacy of WTO members to protect public health by compulsorily licensing patents and the freedom to determine the grounds of compulsory licensing.

Importantly, the TRIPS compulsory licensing provisions represent a balance that forms the crux of the principles and objectives enshrined in arts 7 and 8 of the TRIPS Agreement. In essence, art.7 outlines that protection and enforcement of intellectual property rights should contribute to technological advancements in a manner conducive to "social and economic" welfare of member states and to the mutual advantage and benefit of producers and users. Article 8 discusses the principles under which the objectives of art.7 will be satisfied. Thus, the "principles" under art.8 recognises members' rights to adopt public interest or public health measures in sectors vital to social, economic and technological development of the WTO member. The narrative in arts 7 and 8 bears wide social and political consequences for developing nations and allows member nations to tailor measures facilitating global trade while also achieving national goals.[23] For instance, poorer nations may be able to use compulsory licences in vital technologies such as life-saving medications to promote downstream innovations otherwise blocked often by rigid definition of intellectual property rights. Such use can also be consistent with TRIPS, especially if the reduced price results in increased volume sales. For example, when Nexavar was subject to a compulsory licence in India, causing a reduction of price, Bayer benefited from increased volume sales of the drug from the lowered price.[24] The increased volume sales offset revenue losses that Bayer feared would ensue from the licence.[25]

Compulsory licence provisions in local laws

Several countries have translated the general prescription in TRIPS into statutory provisions in national laws with a view to be in conformity with international obligations. For instance, s.84 of the Indian patent statute allows the Government to compulsorily license a patent three years after the grant.[26] Applicants seeking compulsory licences should attempt to negotiate a licence with the patent owner (as required under TRIPS) for a minimum period of six months. The grounds for third parties to a compulsory licence are:

- the reasonable requirements of the public with respect to the patented invention have not been satisfied;
- the patented invention is not available to the public at a reasonably affordable price; or
- the patented invention is not worked within the territory of India.

The grounds are fully in accordance with art.5(A) of the Paris Convention for the Protection of Industrial Property 1883. Further, in India, a compulsory licence can be granted under s.92 if there is a national emergency, such as a public health crisis or where the Government intends to use the patent for non-commercial public use.

[22] Doha Declaration on the TRIPS Agreement and Public Health 2001 para.4.
[23] Srividhya Ragavan, *Patents and Trade Disparities in Developing Countries* (Oxford: Oxford University Press, 2012), p.366.
[24] *Bayer Corp v Union of India* M.P. Nos.74–76 of 2012 and No.108 of 2012; OA/35/2012/PT/MUM (Intellectual Property Appellate Board, India).
[25] Sean Flynn, Brook K. Baker and Srividhya Ragavan, "Justifying India's Patent Position to the United States International Trade Commission and the Office of the United States Trade Representative" (2014–2015) 7 Indian J. Intell. Prop. L. 1, 5.
[26] Patents Act of 1970 (as amended by Act 15 of April 4, 2005) s.84.

In Colombia, Law 1751 of 2015 provides that right to health is a fundamental human right.[27] Access to health care is characterised as a mandatory essential public service. The right to health is read to include the right to access to medication, diagnosis, treatment and rehabilitation of every Colombian.[28] Considering this, art.1 directs the Government to establish mechanisms to facilitate health care for Colombians. Further, the right to health was firmly recognised in Decision T/760 of 2008, rendered by the Constitutional Court of Colombia.[29] The decision was a response to a special *tutela* action under which citizens may request a court to determine whether a fundamental right has been violated. Thus, the *tutela* actions represent a special writ to protect fundamental rights of citizens and are automatically subject to discretionary review by the Constitutional Court of Colombia. In T/760, the Constitutional court consolidated 22 petitions to determine whether the individual cases showed systemic regulatory failures resulting in a violation of a fundamental right. The court's judgment established the right to health as a fundamental right and directed competent authorities to adopt necessary measures to fulfil an outlined mandate to meet health care needs.[30] In this regard, the right of the government to compulsorily license patents in the public interest to protect public health falls within Decree 4302 of 2008.[31] A patent can be subject to a compulsory licence by the national office on the grounds that the patent has never been worked in the country or has not been worked for at least a year without legitimate reasons. The existence of the public interest, emergency or national security considerations may also be a good cause for issuing a compulsory licence. Under art.7, if a public interest exigency is established, a Technical Committee should recommend whether a compulsory licence can be granted under art.4. Once the recommendation is made by the Technical Committee, the Superintendencia de Industria y Comercio is legally obligated to process the licence.[32] The procedure for requesting a compulsory licence is outlined in Ch.24 of Decree 1074 of 2015.[33] Under this decree, a request for a compulsory licence should be sent to the National Commission for Medications and Medical Devices to determine if a licence is mandated. The compulsory licensing provisions in Colombian law are subject to Ch.VII of Decision 486 of the Commission of the Andean Community.[34]

The most recent grant of compulsory licensing involved a European patent for an anti-viral compound possessing integrase inhibitor activity, raltegravir.[35] Such compounds are effective as anti-HIV agents to prevent or reduce side effects from reverse transcriptase inhibitors used to treat AIDS.[36] In Germany, Merck marketed raltegravir as Isentress. The patent owner, a Japanese pharmaceutical company, Shionogi & Co Ltd, sought a preliminary injunction preventing Merck from marketing the drug. When an offer to Shionogi to provide a worldwide licence on the patent was rejected, Merck requested a compulsory licence under s.24 of the German Patent Act. The German Federal Court granted Merck's request considering the health consequences to which HIV patients already using Isentress would be subjected.[37] Under s.24 of the German patent statute, a non-exclusive authorisation to commercially use an invention shall be granted on a case-by-case basis by the Federal Patent Court based on public interest considerations established under s.65. The statute does not define the term "public interest" and thus preserves the sovereign discretion

[27] Law 1751/2015 (Colombia).

[28] Law 1751/2015 art.2 (Colombia).

[29] Decision T760 of 2008, July 2008, available at *https://www.escr- net.org/sites/default/files/English_summary_T-760.pdf* [Accessed October 31, 2016].

[30] Decision T760 of 2008, p.4.

[31] Decreto 4302 of 2008, November 13, 2008 (Colombia), available at *http://www.wipo.int/wipolex/en/text.jsp?file_id=190459* [Accessed October 31, 2016].

[32] Decreto 4302/2008 of November 13, 2008 art.2.2.2.24.7 (Colombia); Goldman, "Colombia Issues Public Interest Declaration to Lower Price of Glivec", available at *http://keionline.org/node/2601* [Accessed October 31, 2016].

[33] Ministerio de Comercio, Decreto 1074, Por medio del cual se expide el Decreto Único Reglamentario del Sector Comercio (May 26, 2015).

[34] Andean Community, Decision 486 Establishing the Common Industrial Property Regime, Ch.VII, art.62; James Love and Andrew S. Goldman, "Colombia Asked to Declare Excessive Price for Cancer Drug Contrary to Public Interest", available at *http://www.ip-watch.org/2015/12/03/colombia-asked-to-declare-excessive-price-for-cancer-drug-contrary-to-public-interest-grounds-for-compulsory-license/* [Accessed October 31, 2016].

[35] European Patent No.1,422,218 (DE: (DE 602 42 459.3).

[36] "German Federal Patent Court Issues Compulsory License on Patents for HIV Drug Raltegravir", Email from Priti Radhakrishnan via IP-health Listserv, September 8, 2016.

[37] This decision is subject to appeal.

to determine whether and when such a licence may be granted. Just like in India and Colombia, a compulsory licence may be granted under German law to ensure an adequate supply of the patented product for the German market, even if by only importation.

Statutory provisions that preserve the Government's right to interfere with the private property in patents are not alien to the United States. For instance, the objective of the Bayh-Dole Act is for the government to retain sufficient rights over federally funded inventions to protect the public against non-use or unreasonable use of inventions.[38] Health or safety needs are legitimate grounds under the statute for the federal agency funding the research to exercise the march-in right to compel a licence. The federal government also retains a non-exclusive, non-transferable, royalty-free licence to use the invention. Similarly, under the Judicial Procedure Act, the US Government retains the right to make, use or manufacture a patented product or process "without license" provided the patent holder is duly compensated.[39] The Energy Storage Competitiveness Act is yet another example where the secretary is vested with the discretion to compel the patent owner to negotiate "nonexclusive licenses, and royalties on terms that are reasonable, as determined by the Secretary" in the field of energy storage.[40] Further, the secretary may require that the development of a new invention funded under the enactment be subject to terms deemed necessary by the secretary to "advance the capability of the United States to successfully compete in global energy storage markets".[41] Another example is the Clean Air Act under which a compulsory licensing may be granted upon an application made by the administrator and based on a determination that a patent is not "reasonably available" and thereby hinders the implementation of the objectives of the title.[42]

Unilateral actions and multilateral dispute settlement obligations

The discussion above details how every country uses the support from the international trade regime to statutorily sanction sovereign action to deal with exceptional public interest situations. However, it does not clarify the credence of the US position with reference to the discussion on India and Colombia when these countries exercised the sanctioned rights to compulsorily license medication. The following discussion deals with statutes that authorise the USTR's intrusion into other countries' policies.

Section 182 and the USTR

The United States' intrusion into sovereign policies and legitimate actions in the public interest, such as the granting of compulsory licences in other countries, is authorised under s.182 of the Trade Act of 1974 (Trade Act), commonly referred to as the Special 301 provision.[43] This provision authorises the USTR to identify countries that are perceived to deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to US industries or entities that rely on intellectual property protection to compile the Special 301 Report. The USTR forms a part of the executive office of the president and is the agency tasked with negotiating trade agreements and conducting unilateral reviews of policies of other sovereign countries as part of the responsibilities to enforce US trade policy, including intellectual property policy. Thus, the USTR identifies the "act, policy, or practice" of foreign countries that, in its opinion, burdens or restricts US commerce by denying adequate intellectual property protection. Similarly, the USTR identifies a country as denying market access when access to that foreign national market is affected or denied for US industries. The term "market access" is construed broadly to cover

[38] 35 USC s.200.
[39] 28 USC s.1498.
[40] 42 USC s.17231(h).
[41] 42 USC s.17231(h)(7).
[42] 42 USC s.7608.
[43] 19 USC s.2242.

any subject matter and without giving any accord or deference to the circumstances that caused the policy. For instance, when India's National Manufacturing Policy discussed promoting green technologies as part of its environmental protection programme, it was identified as an area of concern by the USTR in its 2013 Special 301 Report because of its potential to affect US investments into India (and because of the possibility of the compulsory licence prevailing in protected technologies)![44]

Once identified, the USTR designates the countries within specific groups before the Special 301 Report is submitted to the House and the Senate.[45] The most egregious identified violators are featured as Priority Foreign Countries, serious offenders are featured in the Priority Watch List, and the less serious offenders are included in the Watch List. A *priority* designation for a country by the USTR results in the greatest scrutiny of the sovereign nation followed by an investigation and threat of either unilateral sanctions,[46] the denial of benefit under the Generalised System of Preferences (GSP), or both.[47] Over the years, the USTR has clearly increased the number of countries that are put on the Priority Watch List.

Multilateral dispute settlement

Amidst the above, the establishment of the WTO and the US commitment to the multilateral dispute settlement process remains a significant event. The significance is derived from the fact that the WTO provides a forum—the Dispute Settlement Body (DSB)—to adjudicate and enforce trade related grievances of individual members. The enforcement mechanism borrows its basic features from the General Agreement on Tariffs and Trade 1994 (GATT).[48] The establishment of the DSB necessitates member states to strictly observe and implement trade obligations, part of which is the dispute settlement process. Thus, all disputes between member states involving compliance with any of the WTO agreements, including TRIPS, are subject to the integrated dispute settlement process of the WTO.

Article 23 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 (DSU) specifically outlines the redress mechanism for members with respect to any violation, nullification or impediment of benefits preventing the attainment of trade agreement objectives. Article 23(2)(a) outlines that the DSU procedures remain the unitary mechanism that can be used for findings that lead to the "suspension of concessions or other obligations" under GATT. Numerous WTO disputes have reiterated the preference for settlement of disputes using multilateral forum as opposed to sovereign nations unilaterally taking action against other trading partners. For example, in "Canada—Aircraft Credits and Guarantees", the panel observed that "Members shall resolve all disputes through the multilateral dispute system, to the exclusion of unilateral self-help".[49] Similarly, in "United States—Import Measure on Certain EC Products", the panel noted that the general obligation in art.23(1) required members to seek redress of any violation only within the WTO institutional framework and pursuant to the rules and procedures of the DSU.[50] Further, art.23(2) prohibits unilateral redress preventing members from making determinations on violations, nullification or impairment of benefits, except through recourse to the DSB.[51]

In short, the DSU's emphasis on the multilateral dispute settlement process is meant to prevent unilateral resolution of disputes by countries with more trade muscles to flex. The strength of the DSU is the DSB's juridical nature wherein a panel is constituted to hear both parties if consultations fail.[52] The process also

[44] Office of the United States Trade Representative, *2013 Special 301 Report* (2013).
[45] 19 USC s.2411.
[46] 19 USC s.2411(d)(3)(VB)(ii).
[47] 19 USC s.2462(c). The GSP programme provides preferential tariff, including duty-free entry, to goods from developing and least developed countries with the objective of promoting economic growth.
[48] Adrian Otten and Hannu Wager, "Compliance with TRIPS: The Emerging World View", 29 Vand. J. Transnat'l L. 391, 411–413 (1996).
[49] "Canada—Aircraft Credits and Guarantees", Report of the Panel, January 28, 2002, WT/DS222/R, para.7.170.
[50] "United States—Import Measure on Certain EC Products", Report of the Panel, January 10, 2001, WT/DS165/R, para VI.20 (opining that art.23(1) of DSU prohibits "unilateral redress" and the prohibition is more directly provided for under art.23(2)).
[51] "United States—Import Measure on Certain EC Products", Report of the Appellate Body, December 11, 2000, WT/DS165/AB/R, para.111.
[52] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 arts 6, 7, 12.

provides for an appeal by either party, in which case the DSB will not adopt the panel report.[53] Appeals from the panel's opinions are heard by an appellate body whose findings, once adopted by the DSB, are final.[54] Importantly, the DSB is authorised to take action against non-complying parties.[55]

The structure of the DSB's process enables countries, including the United States, to commit to multilateral dispute settlement. Considering that imposing unilateral threats would violate the US obligations to the WTO, the Trade Act states that the USTR is not required to take action in any case in which the DSB has adopted a report or in a ruling that US rights under a trade agreement have not been violated or denied, nor have the benefits due to the United States under a trade agreement been nullified.[56] This and perhaps the DSB's ruling on the US Special 301 process, discussed below, explains why the USTR has hesitated to designate a trading partner with Priority Foreign Country status, a status, which, if proven in an investigation, would lead to unilateral sanction by the United States.

Scrutiny of the US Special 301 process

When the US Congress failed to repeal s.301 in the Uruguay Round Agreements Act of 1994, which was the WTO implementation legislation, the European Union requested consultation as required under the DSU with the United States.[57] When initial consultations failed, a panel was established.[58] The European Union claimed that

> "by imposing specific, strict time limits within which unilateral determinations must be made and trade sanctions must be taken, Sections 306 and 305 of the Trade Act of 1974"

violated the US commitment to the WTO to resolve multilateral disputes through the DSB's process.[59] Thus, the legality of the Special 301 process came under scrutiny by the DSB in "United States—Sections 301–310 of the Trade Act of 1974" to determine whether it violated the US obligations under art.23(1) and 23(2) of the DSU. The panel opined that the statutory language of s.304 constituted a serious threat to multilateral dispute resolution. Nevertheless, a "Statement of Administrative Action" (SAA) from the US administrative authorities, the Panel held, alleviated the concerns.[60] The SAA was treated as an "authoritative expression" by the United States on the subject of reconciling its domestic laws with the country's international trade obligations.[61] The SAA was effectively a pledge by the United States promising that the USTR will:

- invoke DSU dispute settlement procedures, as required under current law; or
- base any s.301 determination of violation or denial of US rights under a relevant WTO agreement on a panel or Appellate Body findings adopted by the DSB.[62]

Considering the SAA, the panel held that the Special 301–310 provisions did not violate the United States' international trade obligations so long as the country does not repudiate or remove its SAA undertakings.

[53] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 art.16. The DSB may also unanimously reject the proposed resolution.

[54] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 art.17.

[55] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 art.22.

[56] 19 USC s.2411(2)(A).

[57] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 art.6; "United States—Sections 301–310 of the Trade Act of 1974", European Communities' Request for the Establishment of a Panel Pursuant to Article 6 of the DSU, December 22, 1999, WT/DS152/11.

[58] "United States—Sections 301–310 of the Trade Act of 1974", Report of the Panel, December 22, 1999, WT/DS152/R, para.4.8. The European Communities asserted that its own WTO implementation mechanism conformed in letter and spirit with art.23 of the DSU. Trade Barriers Regulation, Council Regulation 3286/94 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization [1994] OJ L349/71.

[59] "United States—Sections 301–310 of the Trade Act of 1974", Report of the Panel, December 22, 1999, WT/DS152/R, para.1.3, 1.4.

[60] H.R. Doc. No.103-316, p.1029.

[61] H.R. Doc. No.103-316, p.364.

[62] H.R. Doc. No.103-316, pp.365–366.

However, the panel noted that even a *mere threat of trade sanction* could be perceived as a threat to the WTO. The panel report notes that the threat alone can enable a member to exert undue leverage. It can

> "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".[63]

Does the United States exert undue unilateral pressure?

The validity of US actions relating to other countries exercising sovereign rights is the focus of the discussion below. This discussion is important considering that poorer nations find the Special 301 process a yearly intrusion by the United States into sovereign actions. Some of these nations may even consider taking the United States to the DSB to determine whether the USTR's actions amount to a threat violating the spirit of art.23 of the DSU and the SAA, in light of the prescriptions and limitations outlined in art.23 as well as the limitations imposed by "United States—Sections 301–310 of the Trade Act of 1974".

The USTR's actions can be construed as amounting to unilateral threats over sovereign nations for the following reasons:

Historic pattern

The United States, historically and to date, has regularly exerted pressure on its trading partners. For example, Chile and Thailand have featured on the Priority Watch List since 2007; China, Russia, Venezuela and Argentina have featured on the Priority Watch List since 2006; Bolivia, Belarus, Peru, Romania, the Philippines, Costa Rica, Colombia, Turkmenistan, Uzbekistan and Vietnam have all been regularly featured on the Watch List.[64] Another great example, India, has featured in every Special 301 process since its first inception in 1989, even after it has fully complied with TRIPS. Such yearly badgering of trading partners amount to a clear, unequivocal and unilateral threat to adjudicate issues outside the multilateral forum such as through the DSB.

Unfair pressure

The USTR regularly designates trading partners as having inadequate intellectual property protection "notwithstanding the fact that the foreign country may be in compliance" with specific trade and intellectual property obligations.[65] For example, despite full compliance with TRIPS after 2005, India in 2013 alone was designated as a notorious market, was threatened that its status would be elevated to a Priority Foreign Country which entailed a loss of trade benefits, was subjected to an out-of-cycle review and was taunted in two successive Special 301 reports (in 2012 and 2013) for granting a compulsory licence to Bayer's egregiously priced Nexavar. Thus, the USTR unfairly determines practices that are in compliance with trade obligations as "an unjustifiable burden amounting to inadequate [intellectual property] protection and unduly restrictive of US commerce". It is unfair because the pressure from the USTR's imposition causes trading partners to reconsider a nationally favourable policy to instead institute a policy that is friendly to US domestic economic interests.

[63] "United States—Sections 301–310 of the Trade Act of 1974", Report of the Panel, December 22, 1999, WT/DS152/R, para.7.89.
[64] "Special 301 Report", available at *https://en.wikipedia.org/wiki/Special_301_Report* [Accessed October 31, 2016].
[65] 19 USC s.2411(d)(3)(VB)(ii).

The United States unilaterally threatens to punish trading partners

The Trade Act retains the right of the USTR to enforce retaliatory punitive trade-related measures. Notably under the Act, the USTR, based on the identification in the Special 301 Report, is authorised to "suspend, withdraw, or prevent the application of benefits of trade agreement concessions" as well as "impose duties or other import restrictions on the goods" for such time as the USTR determines appropriate.[66] For instance, in 2013, the Special 301 Report cited the *Bayer* decision in India to suggest that the United States would withdraw GSP benefits and impose sanctions on India.[67] In reality, no country can alter GSP or other benefits that accrue to a trading partner unless the trading partner falls within an applicable exception. Altering the GSP benefits for any one country would affect the WTO's most favoured nation clause which requires that tariff treatments provided to one member be extended to all, subject to limited exceptions.[68] Further, the WTO Appellate Body in "European Communities—Conditions for the Granting of Tariff Preferences to Developing Countries" stressed that GSP criteria must be tailored to the needs *of developing countries* to strike down an EU programme that, like Special 301, was justified by domestic economic interests rather than the "non-reciprocal" development interests of other countries.[69]

USTR uses public law to further private interests

The USTR's scrutiny is an undue threat because it is based on domestic and self-claimed interests of private organisations. In fact, the USTR's Special 301 Report is largely dependent on representations from private companies. Susan Sell highlights that most countries included on the Priority Watch List and Watch List between 1996 and 2000 were requested by the Pharmaceutical Research Manufacturers of America or the International Intellectual Property Alliance.[70] In fact, the Special 301 process has been criticised by Peter Drahos as "a public law devoted to the service of private corporate interests".[71] It is an example of an US administrative body wielding questionable legal powers to unduly influence sovereign governments to protect private interests. American trade lobbyists regularly "boast" about how they "fixed" other countries' intellectual property laws.[72] Such methods reek of the use of undue threat by a country that regularly flexes its muscles while preaching against it in public.

Lack of deference

The unilateral, univocal Special 301 determinations of the USTR have never historically been given any deference to public policy, public health or similar human rights, based on constitutional limitations or other compelling conditions. For example, in 2013, Ukraine's status was elevated to Priority Foreign Country for intellectual property law violations, and the status was sustained in 2014 despite the fact that the country suffered the consequences of Russian invasion several times![73] In 2015, the USTR downgraded Ukraine to the Priority Watch List with the following note:

[66] 19 USC s.2171.

[67] 19 USC s.2242.

[68] General Agreement on Tariffs and Trade 1947 art.1; "Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries", Decision of 28 November 1979, WTO Doc. L/4903.

[69] "European Communities—Conditions for the Granting of Tariff Preferences to Developing Countries", Report of the Appellate Body, April 7, 2004, WT/DS246/AB/R, para.163.

[70] Susan K. Sell, Private Power, *Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003), pp.126–129.

[71] Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002), p.89.

[72] Drahos with Braithwaite, *Information Feudalism* (2002), p.87 (detailing a lobbyist noting, "Jamaica had no intellectual property law, but they wrote one (with our help). Similarly the Dominican Republic. I sat down with their lawyer and together we wrote their copyright law.").

[73] But the USTR determined that no action will be taken considering the political unrest in Ukraine. Office of the United States Trade Representative, *2014 Special 301 Report* (2014), p.30.

> "[T]he United States appreciates that the Ministry of Internal Affairs' Cybercrime Division and Economic Crimes Division have both been willing to work closely with the U.S. Department of Justice on online piracy and that Ukrainian enforcement personnel have participated in training and engagement on this issue, including a workshop on Combating Digital Piracy by the Commercial Law Development Program of the United States Department of Commerce."[74]

Thus, the United States uses the Special 301 process and the USTR to impose its version of intellectual property policies in complete disregard of the targeted country's local political and economic realities.

Traditionally, the WTO and the DSB have failed to position themselves to appreciate local realities that genuinely impede intellectual property implementation requiring legitimate sovereign intrusions. For example, in stark contrast to the deference that the SAA received, the DSB—both the WTO panel and the Appellate Body—in "India—Patent Protection for Pharmaceutical and Agricultural Chemical Products" refused to accept India's rationale that administrative orders are treated as a legally tenable tool to implement certain aspects of the statute in question.[75] This dispute is a great example of how the DSB has tended to easily ignore domestic systems and refuse to consider domestic rationales in determining perceived derogations from international obligations.[76] Deference to domestic lawmakers' wisdom has been difficult to generate at the WTO, particularly the DSB, when the wisdom is from a developing country.

Trade Facilitation and Trade Enforcement Act of 2015 increases scrutiny

That the USTR will be relentless in exerting pressure is clear from the terms of the Trade Facilitation and Trade Enforcement Act of 2015. Under the Act, the position of "Chief Innovation and Intellectual Property Negotiator" has been created within the USTR specifically to increase the level of scrutiny over other countries and to

> "take appropriate actions to address acts, policies, and practices of foreign governments that have a significant adverse impact on the value of United States innovation".[77]

The statute creates a Trade Enforcement Trust to fund enforcement actions against foreign countries.

In reality, the deference that the DSB panel extended to the SAA undertakings is exceptional. The DSB's reliance on the SAA of a powerful member has been detrimental to less powerful nations. It has left an impression of a system that has merely worked to reinforce the balance of power inequities. In any event, the DSU has been consistently criticised for lacking important paradigms required to appreciate the complexities involved in establishing an intellectual property regime.[78] The DSU's inability to appreciate local realities and over-reliance on the TRIPS negotiations during which the balance of powers were even more skewed than what exists currently, are all internal barriers that have impeded the WTO from achieving the spirit of the overall objectives. They have also created the dire need for other international organisations such as WIPO, the World Health Organization (WHO) and the United Nations to provide the required humane angle to balance the trade agenda.

[74] Office of the United States Trade Representative, *2015 Special 301 Report* (2015), p.56.

[75] "India—Patent Protection for Pharmaceutical and Agricultural Chemical Products", Report of the Panel, September 5, 1997, WT/DS50/6; "India—Patent Protection for Pharmaceutical and Agricultural Chemical Products", Report of the Appellate Body, December 19, 1997, WT/DS50/AB/R.

[76] Ragavan, *Patents and Trade Disparities in Developing Countries* (2012), p.366.

[77] 19 USC s.4301.

[78] Thomas Cottier, "The Agreement on Trade-Related Aspects of Intellectual Property Rights" in P.F.J. Macrory, A.E. Appleton and M.G. Plummer (eds), *The World Trade Organization: Legal and Political Analysis* (New York: Springer, 2005) Vol.1, p.1063.

WIPO's Role

WIPO is closely linked to TRIPS in the trade regime. The incorporation of the WIPO treaties into TRIPS has created a link between the WTO and WIPO with a common objective. The following discussion expounds the link between the two organisations to determine whether there is scope for larger involvement.

The DSB has periodically consulted WIPO and sought inputs. For instance, in "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights",[79] WIPO responded to the Panel's request and submitted factual information from the official records of the various diplomatic conferences regarding the interpretation of arts 5(1), 5(2) and 17 of the Berne Convention for the Protection of Literary and Artistic Works 1886.[80] Yet, the involvement has been limited to seeking factual information. Further, the DSB has traditionally provided limited deference to WIPO even in instances where it has sought input.[81] In "United States—Section 211 Omnibus Appropriations Act of 1998", for instance, the Appellate Body mentions the response of the Director-General of WIPO to a request for information by the DSU Panel.[82] But, the report notes that "the Panel did not discuss this … [and] the Panel seems to have taken [a different] view".[83] WIPO also has limited powers to intervene in the DSB's process when inputs are not sought except by filing an amicus brief. Unfortunately, most amicus briefs, while accepted, are not taken into account.[84] The need is for a platform for institutional involvement of international organisations.

WIPO's adoption of the Development Agenda in 2007 sets the right forum and provides an opportunity to assume leadership in these matters. The evolution of WIPO as a negotiator for the developing nations with the WTO will contribute to the restoration of the rather relatively weaker image of WIPO in the post-WTO era. The Committee on Development and Intellectual Property which was established by the WIPO General Assembly in 2008 has the objective of implementing the Development Agenda recommendations.[85] These recommendations set the right tenor for WIPO to work on issues relating to development in the intellectual property context.[86] For example, Recommendation 40 requests WIPO "to intensify its cooperation on intellectual property-related issues with United Nations agencies", including the WHO and other relevant international organisations, especially the WTO. Similarly, Recommendation 45 outlines that intellectual property enforcement should be contextualised within "broader societal interests and especially development-oriented concerns" outlined in art.7 of TRIPS. Unfortunately, there is no specific mention on issues relating to intellectual property and access to life-saving medications, but the recommendations are commendable for outlining larger public interest concerns and for implicating the work of the United Nations, the WTO and the WHO. In turn, the WHO's specific objective on the trade and health diplomacy agenda includes a commitment to support countries on implications of international trade and trade agreements on health. The WHO also hopes to build the capacity of countries to negotiate the support of collective action to address global health challenges, with which WIPO should be involved. The newly released report of the UN Secretary-General's High-Level Panel on Access to Medicines also

[79] "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights", Report of the Panel, January 26, 2009, WT/DS362/R.

[80] "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights", Report of the Panel, January 26, 2009, WT/DS362/R, p.4.

[81] These cases include "United States—Section 211 Omnibus Appropriations Act of 1998", Report of the Panel, August 6, 2001, WT/DS176/R; "United States—Section 110(5) of the U.S. Copyright Act", Report of the Panel, June 15, 2000, WT/DS160/R; "China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights", Report of the Panel, January 26, 2009, WT/DS362/R; and "European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs", Report of the Panel, March 15, 2005, WT/DS174/R. Thomas Cottier and Marina Foltea, "Global Governance in Intellectual Property Protection: Does the Decision-making Forum Matter?" (2012) 3 WIPO J. 139, 158.

[82] Understanding on Rules and Procedures Governing the Settlement of Disputes 1994 art.13.

[83] "United States—Section 211 Omnibus Appropriations Act of 1998", Report of the Appellate Body, January 2, 2002, WT/DS176/AB/R, para.189.

[84] E.g. "Mexico—Tax Measures on Soft Drinks and Other Beverages", Report of the Appellate Body, October 7, 2006, WT/DS308/AB/R.

[85] WIPO, "Committee on Development and Intellectual Property", available at *http://www.wipo.int/policy/en/cdip/* [Accessed October 31, 2016].

[86] WIPO, "The 45 Adopted Recommendations under the WIPO Development Agenda", available at *http://www.wipo.int/ip-development/en/agenda/recommendations.html* [Accessed October 31, 2016].

calls on WTO members to "commit" at the highest political levels, to the letter and spirit of the Doha Declaration and refrain from actions that limit the use of TRIPS flexibilities.[87]

Greater coordination among international organisations would streamline objectives to ensure that trade and intellectual property objectives be not achieved at the cost of human lives and human rights. WIPO's commitment to the intellectual property and development agenda, the United Nations' involvement in this area, sets the right platform to create concrete steps in this area. At a general level, systems to incentivise research should be streamlined to achieve a balance between innovation and access. As public funding for research increases, the terms for private returns and incentives from publicly funded research deserves closer scrutiny. For poorer nations, the term access should be defined to include investments into research to treat diseases that disproportionately prevails in and affects poorer nations.

Conclusion

International organisations have an obligation to carefully act on behalf of all its members. Such an obligation entails a careful consideration of local realities to generate co-operation to international efforts at harmonisation. Neither international organisations nor individual member states can afford to be blind to global effects from local crisis in other nations. The outbreak of Ebola in one part of the world, for example, affected other parts of the world. Airlines, diversion of resources for screening and tourism are just samples of industries that are immediately affected. Similarly, national economies affect global trade when a loss of labour productivity ensues from a deteriorating public health, which, in turn, can affect unrelated industries vital to international trade. Prioritising harmonisation at the cost of local economic, political or social crisis is a misguided policy. So is allowing a powerful member to dominate and interfere unduly with sovereign legitimate actions of other countries. Tools like compulsory licensing are critical to restore national economies and to prevent a country's deteriorations from affecting global trade. Global responsibilities of developed nations should include an expectation to not unduly and unilaterally impose itself on sovereign actions of other countries, especially to please local private actors.

[87] United Nations Secretary-General's High-Level Panel on Access to Medicines, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies* (2016).