

14 United States

Unilateral Norm Setting Using Special 301

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Introduction

Every year since 1989, the Office of the United States Trade Representative (USTR) has released the Special 301 Report, which identifies countries that “deny adequate and effective protection of intellectual property (IP) rights or deny fair and equitable market access to U.S. persons who rely on IP protection.”¹ USTR is obligated to publish the report annually under the Trade Act.² The report classifies countries according to the seriousness of their alleged shortcomings. USTR designates countries it finds to “have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products” as Priority Foreign Countries (PFCs).³ Designation of a country as a PFC triggers a Trade Act investigation, which, in turn, can lead to sanctions.⁴ A country may also be placed on a “Priority Watch List” (PWL) or “Watch List” (WL), which indicates that the United States will further engage with it regarding the policy or policies at issue. Countries on the PWL or WL are usually the subject of further diplomatic and trade pressures to change their domestic policies.⁵ Some countries, even if removed from these lists, may feature in the reports for being monitored under Section 306, and some receive Out-Of-Cycle Reviews, which are more detailed reviews of the IP or market access policies.

The Omnibus Trade and Competitiveness Act of 1988 created the Special 301 Review. At the time, the Guaranteed Agreement on Tariffs and Trade (GATT)

* The author wishes to thank Sri Ragavan (Texas A&M University Law School) and Jonathan Kimball (Association for Affordable Medicines) for their comments.

1 Office of the United States Trade Representative, *Request for Comments and Notice of a Public Hearing Regarding the 2020 Special 301 Review*, FEDERAL REGISTER (Dec. 23, 2019), <https://www.federalregister.gov/documents/2019/12/23/2019-27572/request-for-comments-and-notice-of-a-public-hearing-regarding-the-2020-special-301-review>.

2 See 19 U.S.C. § 2242.

3 OFFICE OF THE U.S. TRADE REP., 2020 SPECIAL 301 REPORT, 88 (2020), <https://ustr.gov/> [hereinafter 2020 Special 301 Report].

4 19 U.S.C. § 2411. See also Congressional Research Service, *Section 301 of the Trade Act of 1974* (Apr. 20, 2020).

5 2020 SPECIAL 301 REPORT, *supra* note 3.

loosely governed global trade, but it lacked IP rules and had only weak enforcement provisions. The Uruguay Round of trade negotiations was underway, and the United States wanted to include an agreement on IP that would be subject to stronger enforcement measures, but many countries in the Global South opposed this. Special 301 served two purposes – it threatened countries the United States accused of lacking adequate IP protections with trade sanctions, and it made a multilateral IP framework seem more appealing than facing unilateral pressure from the United States.⁶ However, the establishment of the WTO did not end unilateral pressure through Special 301. The US legislation passed to join the WTO in 1994 added text to the Special 301 provision clarifying that “a country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations” of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).⁷ The Special 301 Report has since become a tool used to coerce countries to strengthen IP rights beyond the level required by TRIPS.

To conduct its annual review, USTR leads a Special 301 Subcommittee of an interagency team called the Trade Policy Staff Committee. This group solicits comments from interested parties. Most of the comments are submitted by IP-owning firms and industry groups that ask to have certain countries included for various alleged IP deficiencies. Since 2010, it has hosted a public hearing to gather additional information to inform the report. Although the process by which the Committee receives input is clear, there is a lack of concrete criteria to determine (a) which countries are identified in the report, and (b) which countries are placed on the PWL rather than the WL.⁸ However, it is clear that industry input drives much of the process. The Pharmaceutical Research and Manufacturers Association (PhRMA) submits detailed comments each year. Many of the countries PhRMA asks to have included in the report on an annual basis are regularly included in it.

This chapter reviews USTR’s Special 301 Reports from 2009 to 2020, with a focus on countries identified by PhRMA in its Special 301 comments. It examines (a) trends in the identification and listing of countries; (b) the qualities of the countries included; and (c) the particular reasons for inclusion in the Special 301 Reports. Thus, this chapter focuses on the Special 301 listings that apply to IP and health care to examine how USTR’s actions threaten countries that use TRIPS flexibilities to increase access to medicines, how USTR’s actions threaten countries that refuse to implement TRIPS-plus IP protections, and how USTR uses Special 301 to promote trade interests outside the realm of IP.

6 JAGDISH BHAGWATI. IN DEFENSE OF GLOBALIZATION 183 (2004).

7 See Pub. L. 103–465, § 313(2)(B).

8 After the creation of the WTO, few countries have received a Priority Foreign Country designation, where the investigations can lead to unilateral sanctions, despite industry requests.

I reviewed the Special 301 Reports and PhRMA Special 301 Comments (as opposed to testimonies) from 2009 through 2020 and recorded the specific complaints against each country in each year that were *related to access to health care*. I did not record complaints against countries in Special 301 Reports that were unrelated to patents, data exclusivity, or medicines. This focus on IP and healthcare is not meant to downplay the significance of USTR blacklisting countries that use TRIPS flexibilities to expand access to information (which is clearly important for development).⁹

The review produced a dataset demonstrating how the prevalence of different country listings and particular policy complaints have changed over time. The dataset records USTR's specific allegations for each country and PhRMA's listing recommendations for each year, and allows one to see the changing landscape of the USTR Special 301 Report and its responsiveness to PhRMA's input. Reasons cited for including a country on a Special 301 List typically fit into one of three categories: (a) use of TRIPS flexibilities (b) poor enforcement of IP rights; and (c) inadequate market access for firms that rely on IP. The following section will explain the reasons for listing in these categories.

Typology of Complaints Against Countries in the Special 301 Report

Use of TRIPS Flexibilities

The TRIPS Agreement sets minimum global standards for IP protection, but it leaves policy space (referred to as “flexibilities”) for countries to implement these standards as they see fit. USTR routinely lists countries for exercising TRIPS flexibilities to allow generic medicines. This section identifies specific health-related TRIPS flexibilities that USTR has criticized countries for using in its Special 301 Reports.

Test Data Protection

Pharmaceutical manufacturers need to obtain marketing approval from health regulators in order to sell their products in most markets. Brand name manufacturers submit clinical test data to regulators to prove the safety and effectiveness of the drug. Much of the cost of drug development is the cost of conducting clinical trials to generate this data. Generic firms typically obtain marketing approval based on the originator's clinical trial data (and their own bioequivalence data), allowing them to bring their products to the market at a lower price.

Article 39.3 of the TRIPS Agreement requires companies to protect test data against “unfair commercial use.” In the U.S. and most other developed

9 Ruth Okediji, *The Limits of International Copyright Exceptions for Developing Countries*, 21 VAN. J. ENVIRON. TECHNOL. L. 3, 689, 725 (2019).

countries, this protection takes the form of data exclusivity – a period of time during which generic firms may not apply for marketing approval based on the originator’s test data. Data exclusivity is a second IP barrier to the entry of generic products to the market. It has the potential to block generic entry in situations where a patent has expired or was never in force.

The United States promotes data exclusivity as the proper way for countries to implement TRIPS Article 39.3. Hence, data exclusivity requirements are included in all the bilateral and regional trade agreements the United States has negotiated since the creation of the WTO. Countries that do not provide data exclusivity for a wide range of pharmaceutical products are often cited in the Special 301 Report for failing to adequately protect test data.

However, there is no WTO rule mandating data exclusivity. Under the TRIPS Agreement, countries are free to implement Article 39.3 in other ways, including through restrictive definitions of “unfair commercial use” and through limiting the scope of new products eligible for data protection.¹⁰

Patent Linkage

Patent linkage refers to a mechanism for ensuring that health regulatory authorities do not approve a generic product for sale while an unexpired patent protects the drug, or a mechanism to ensure that patent owners are notified when a generic manufacture applies for regulatory approval to sell a follow-on product. In practice, patent linkage has led to problems with follow-on patents (and with patents of poor quality) delaying the entry of generics, sometimes even after the expiration of the relevant patent. Patent linkage is not required under the TRIPS Agreement but has been included in most bilateral and regional free trade agreements (FTAs) with the United States after the TRIPS Agreement took effect.

Scope of Patentability

The TRIPS Agreement requires patents to be made available for inventions that are “new, involve an inventive step and are capable of industrial application.”¹¹ However, countries are free to define what is new and what is useful according to their own laws. This ability to define patentable subject matter is one of the most important flexibilities in the TRIPS Agreement.¹²

10 PEDRO ROFFE & CHRISTOPH SPENNEMANN, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 530–531 (1995).

11 TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1995), https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5 [hereinafter TRIPS Agreement], art. 27.

12 Carlos Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, UNDP (2016), https://www.researchgate.net/publication/304396604_.

The scope of patentability varies between countries. Many have implemented strict standards of patentability to avoid granting patents on innovations that are not completely new, like second uses of existing medical products or common derivatives of known substances (such as polymorphs and isomers).¹³ Some countries have different rules for biologic inventions, which may be simulations of substances created in nature. Other countries have relatively loose standards of patentability, making it easier for firms to patent variations of existing products. The United States advocates broad standards of patentability to allow protection for a wide range of products. USTR lists countries in the Special 301 Report for alleged inadequacies regarding what a firm can patent.

Compulsory Licensing

A compulsory license (CL) authorizes a third party to produce and/or sell a patented invention without the permission of the patent holder, subject to conditions listed under Article 31 of the TRIPS Agreement. CLs have been part of the international patent law landscape since at least the Paris Convention of 1883. Most countries' domestic laws have provisions for CLs, including the United States. Domestic laws typically allow CLs for a variety of public interest purposes, including (but not limited to) meeting public health needs. They often establish conditions that must be met for the issuance of a license, such as payment of royalties to the patent holder. The specific details of compulsory licensing policies vary from one country to the next.

Countries at all levels of development have issued CLs to meet health needs. Since the 1990s, many CLs have been issued for medicines needed to treat HIV/AIDS.¹⁴ The US government has a history of opposing the issuance of CLs for medicines, through listing in the Special 301 Report as well as other means.

Other IP Policies Drawing Criticism in Special 301 Reports

Special 301 Reports also include IP complaints unrelated to the use of TRIPS flexibilities. For instance, many patent offices have large backlogs; there may be few examiners, or a patent office may face other resource constraints that delay patent prosecution. Other alleged problems with patent application processes

13 A polymorph has minor modifications of the structure or chemical makeup of a molecule and is different from crystalline form. An isomer has the same molecular formula but with a different atomic arrangement. See Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLoS ONE 12, e49470 (2012), <https://doi.org/10.1371/journal.pone.0049470>.

14 See TRIPS Flexibilities Database, HEALTH LAW & POLICY, <http://tripsflexibilities.medicineslawandpolicy.org>. See also Ellen t' Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORGAN. 185–193 (2018), <http://dx.doi.org/10.2471/BLT.17.199364>.

include a lack of transparency, overly meticulous patent examination, and prosecution processes allegedly discriminating against foreign patent applicants.

Special 301 Reports also include complaints about trade secret protection and trademark squatting, which are outside the scope of this chapter.

Intellectual Property Enforcement

Many complaints against countries in the Special 301 Report focus on the enforcement of IP, rather than IP provisions themselves. Under the WTO Dispute Settlement Understanding, countries should settle disputes related to TRIPS enforcement through the WTO's system, yet USTR alleges TRIPS non-compliance regarding enforcement for most of the countries listed. The following enforcement-related complaints are often found in Special 301 Reports and in PhRMA's comments:

- The presence of excessive counterfeit goods in the market
- Underfunded or under-resourced enforcement agencies (including police, courts, and border authorities)
- Enforcement officials (including police and border authorities) lacking *ex officio* authority to take action on their own, without the request of a right holder, for suspected IP infringement
- Penalties for IP infringement deemed insufficiently severe to have a deterrent effect
- Problems with judicial systems, including administrative delays and non-transparent proceedings
- Border enforcement deficiencies resulting in inflow of infringing goods or export of counterfeit goods

Market Access Issues Other Than Intellectual Property Protection

Other complaints allege that countries “deny fair and equitable market access to U.S. persons who rely on IP protection.” These types of complaints include:

- Import substitution, used to block imports of drugs if a local (generic) manufacturer is producing it. This is rare, and when described in PhRMA complaints it has been used for high-value medications.
- Tariffs and high taxes on medicines. In some cases, PhRMA has alleged discriminatory taxes if they are applied differently to multinational companies than domestic ones.
- Licensing or permitting policies that discriminate against foreign firms, including local ownership requirements.
- Allegations of forced technology transfer if firms are required to transfer technologies to local partners in order to do business in a third country. USTR regularly cites China for this.
- Health regulations that may be interpreted in a manner discriminating against foreign firms.

Findings

Figure 14.1(a) shows the overall change in the number of countries that PhRMA requested to have listed in the Special 301 Report each year, and the number of *these* countries that were included in the same year's Special 301 Report. The number of countries PhRMA requested to have placed in the Special 301 Report fell by about half between 2009 and 2020, with a big drop in 2016. Figure 14.1(b) shows that USTR has remained responsive to

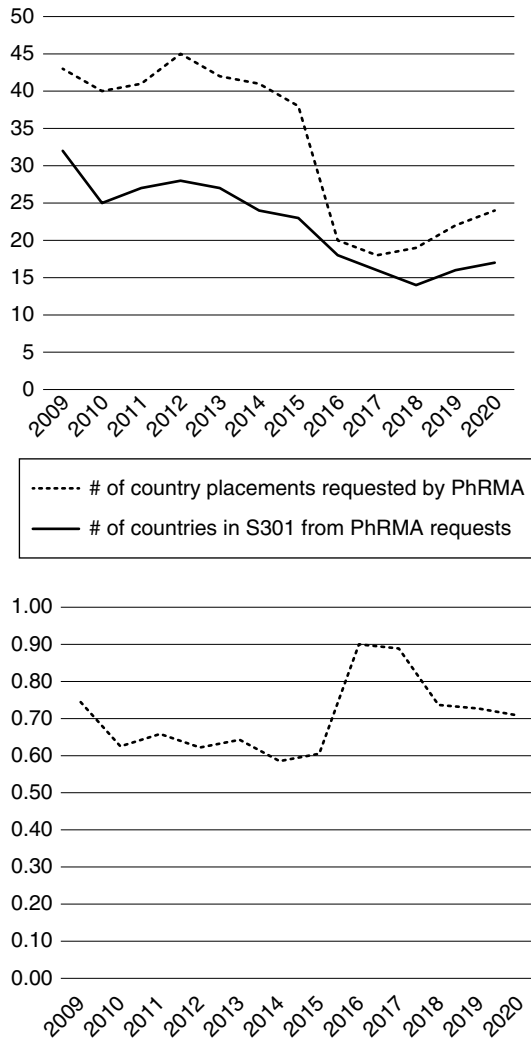


Figure 14.1 *PhRMA and USTR Identify Fewer Countries; USTR's Responsiveness to PhRMA is Consistent* (a) PhRMA country requests & USTR inclusions and (b) PhRMA's inclusion requests in report (%)

PhRMA's requests, becoming more responsive as the number of listing requests by PhRMA has fallen.

- a Between 2009 and 2015, USTR listed 64 percent of the countries requested by PhRMA.
- b Between 2016 and 2020, USTR listed 79 percent. (Notably, as PhRMA requests the listing of fewer countries in the report, changes in USTR's response yield larger percentage changes in its responsiveness to PhRMA requests.)

Figure 14.2(a) demonstrates a decrease in country requests and country listings that PhRMA prioritized by asking USTR to include the country as a PFC, on the PWL, or to list as a subject of Section 306 monitoring. This represents a subset of the countries from Figure 14.1(a). The countries in Figure 14.2(a) are those that seem to be highly prioritized by PhRMA. In 2009, PhRMA asked USTR to include 24 countries in the report at these levels. In 2020, PhRMA asked USTR to include 17 countries at these levels – a decline of 29 percent.

Figure 14.2(b) shows that USTR has consistently been very responsive to these requests over the 12-year period. On average, 82 percent of the countries prioritized by PhRMA through its listing recommendations were included in the Special 301 Report. The number of countries that USTR added as a PFC, PWL, or Section 306 country varied from a low of 46 percent in 2009 to a high of 65 percent in 2011, and has averaged 54 percent over the 12 years. The figures above show a temporary increase in USTR's responsiveness in 2016 to 2017. All of the countries PhRMA requested to have listed as PFC/PWL/306 were included USTR's report in these years. In 2018, PhRMA unsuccessfully requested the inclusions of South Korea and Japan, causing the bump to recede.

PhRMA-identified Special 301 Listings Focus on Middle-income Countries

Countries identified by PhRMA and then listed in the Special 301 Reports tend to be middle-income countries (based on the World Bank classification). Since 2012, over 75 percent of such countries have been middle-income countries each year, and the remainder were high-income countries (see Figure 14.3(a)). With the exception of Tajikistan, PhRMA did not ask USTR to list any low-income countries during this period.

The average income per capita in the listed countries has fallen as USTR has listed relatively less wealthy countries. As demonstrated in Figure 14.3(b), the average Gross National Income per capita of countries identified by PhRMA and listed by USTR was above the World Bank's threshold for classification as a high-income country until 2014, after which the average has been below

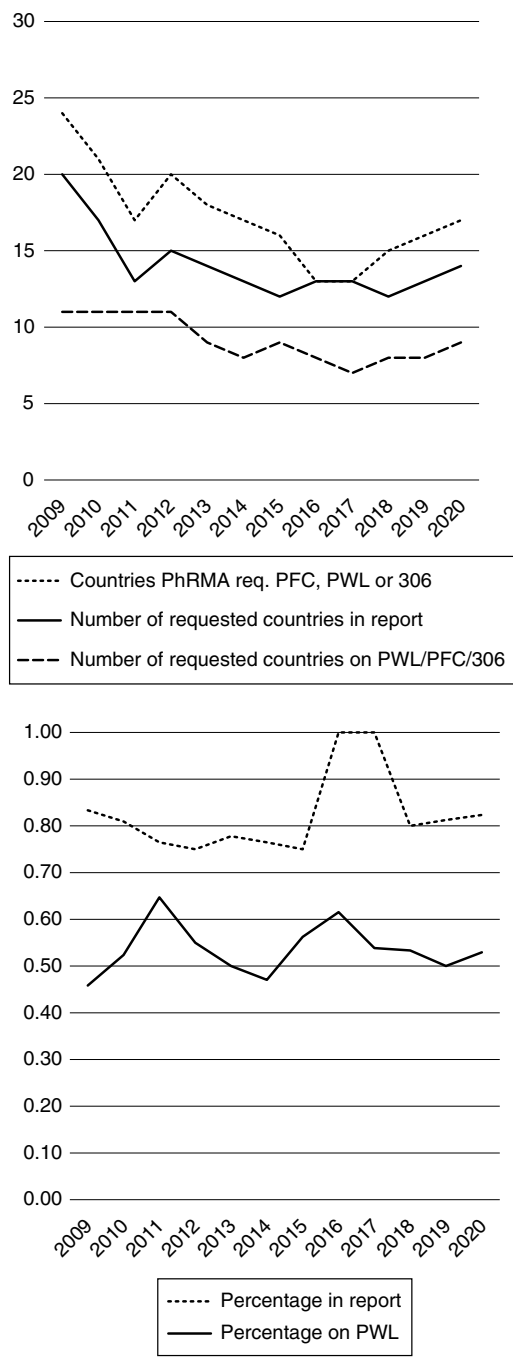


Figure 14.2 (a) PhRMA requests for PFC/PWL/306 & USTR inclusions and (b) USTR responsiveness to PhRMA req. For PFC/PWL/306 (%)

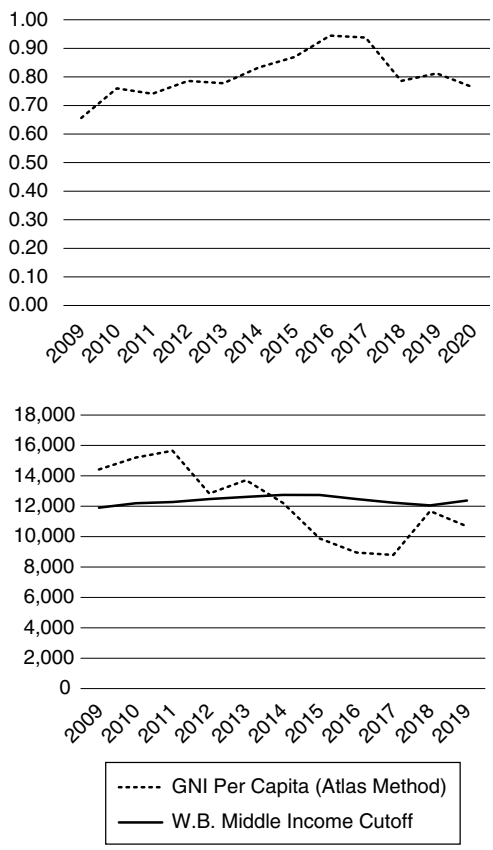


Figure 14.3 (a) Percentage of countries identified by PhRMA and subsequently listed by USTR that are designated “Middle Income” by World Bank and (b) average income of countries identified by PhRMA and subsequently listed by USTR v. Middle Income Classification (US\$)

the threshold.¹⁵ The cutoff changed slightly from year to year, but it remained approximately \$12,000 over the period.

PhRMA-identified Special 301 Listings Increasingly Focus on More Populous Countries

The countries included in the Special 301 Report for health reasons tend to be large in terms of population. This is apparent from the annual inclusions

15 See World Bank Development Indicators, WORLD BANK, <https://datacatalog.worldbank.org/dataset/world-development-indicators> (for data on Gross National Income per capita through 2019).

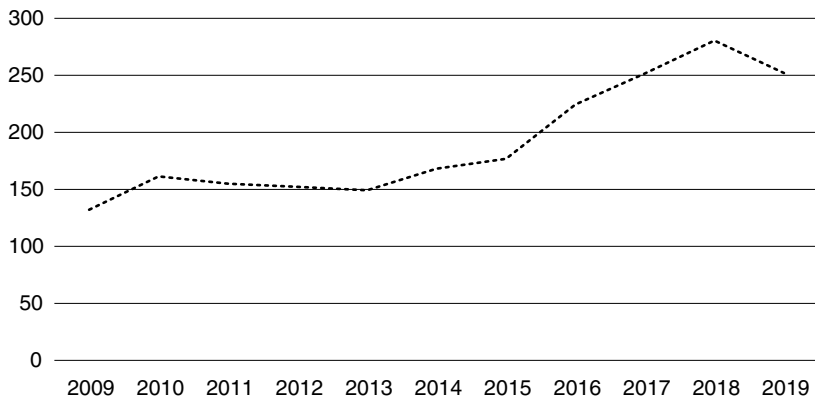


Figure 14.4 Average population identified by PhRMA and subsequently listed by USTR

of China and India alone, but it bears mentioning that more than half of the world's population resides in countries identified by PhRMA and subsequently listed by USTR in the Special 301 Report.

As shown by [Figure 14.4](#), the average population in countries identified by PhRMA and listed by USTR has increased as the overall number of countries in the report has fallen,¹⁶ indicating a sustained focus on relatively populous countries.

Trends in the Reasons Cited for Listing Countries in the Special 301 Report

This section examines trends in the reasons given by USTR for its listing of the countries that PhRMA had requested to have included in the Special 301 Reports. It shows where the *relative* focus of USTR is as the overall number of countries listed has declined.

[Figure 14.5](#) shows three categories of alleged policy shortcomings cited by USTR in its listings of countries: (a) IP enforcement shortcomings; (b) use of TRIPS flexibilities; and (c) market access barriers for US firms that rely on IP protection. The percentage of complaints about inadequate enforcement of IP and the use of TRIPS flexibilities have been relatively stable as the overall number of countries listed has fallen. However, the percentage of countries cited for market access violations outside of the realm of IP has increased.

There are also many instances where USTR makes vague complaints about unnamed inadequacies of a country's IP landscape. For instance, USTR

16 *Id.*

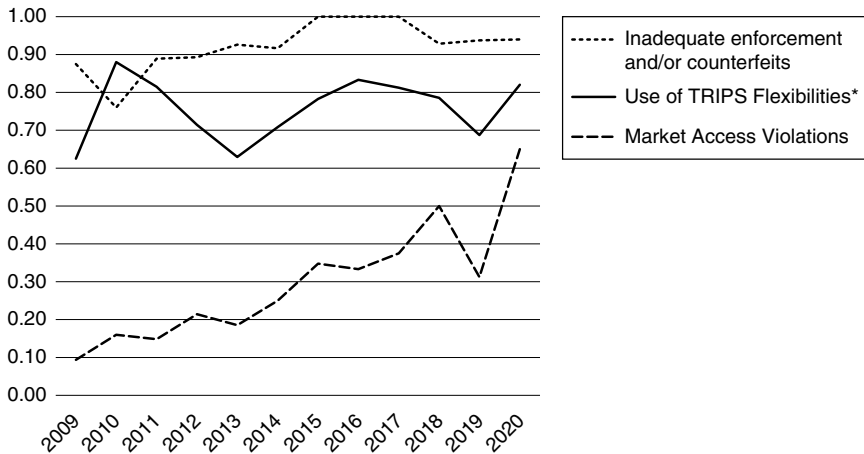


Figure 14.5 Among countries PhRMA requested to have placed in the Special 301 Report that were included, % of countries cited by USTR

regularly refers to pending patent legislation in Jamaica without indicating what is in the bill. The 2009 Special 301 Report claimed the legislation was “intended to implement Jamaica’s obligations under the TRIPS Agreement,”¹⁷ without describing how Jamaica was out of compliance with the TRIPS Agreement or how the legislation would change the standing law. USTR continued to push for passage of the legislation without addressing the specific shortcomings of patent protection in the country: “Jamaica remains on the Watch List in 2019 due to its outdated patent and industrial designs regime.”¹⁸ Jamaica was dropped from the WL in the 2020 Special 301 Report, which notes that the legislation passed, but does not indicate how the law changed.¹⁹

Many individual country listings include a set of specific grievances and close with a statement that USTR is also concerned with other unspecified policies or shortcomings. For instance, after listing a number of problems with IP enforcement in Bolivia, USTR wrote in 2011 that it would monitor Bolivia’s progress on these “and other” issues.²⁰ USTR promised to monitor “other matters” in the Dominican Republic the same year.²¹

17 OFFICE OF THE U.S. TRADE REP., 2009 SPECIAL 301 REPORT, 27 (2009), <https://ustr.gov/> [hereinafter 2009 SPECIAL 301 REPORT].

18 OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2019 SPECIAL 301 REPORT, 82 (2019), <https://ustr.gov/>.

19 2020 SPECIAL 301 REPORT, *supra* note 3, at 31.

20 OFFICE OF THE U.S. TRADE REP., 2011 SPECIAL 301 REPORT, 32 (2011), <https://ustr.gov/>.

21 *Id.* at 34.

Countries Listed on PhRMA's Request were Criticized for Using TRIPS Flexibilities in 75 Percent of the Listings

Approximately 75 percent of countries identified by PhRMA and listed by USTR were criticized each year for using TRIPS flexibilities (see Figure 14.5). Variation by year ranged from a low of 63 percent in 2009 and 2013, to a high of 88 percent in 2010. In 2020, USTR cited 82 percent of these countries for using TRIPS flexibilities. This finding is based on tallying the instances of four types of TRIPS flexibilities in the country listings – test data protection policies short of data exclusivity; lack of patent linkage; setting the scope of patentability such that certain drugs patentable in the United States were denied patents in the listed country; and compulsory licensing.

Figure 14.6 shows how often each of these alleged violations were cited in the Special 301 Report in countries identified by PhRMA. Inadequacy in test data protection is the alleged shortcoming that USTR cites most frequently. Each year, between 47 percent and 79 percent of the countries listed by PhRMA were cited for having weaknesses in test data protection. This tally includes countries with laws that protect test data with mechanisms other than data exclusivity, such as Argentina, which meets its TRIPS obligation with a law that prohibits dishonest use of test data submitted to health authorities and permits generic pharmaceutical firms to win marketing approval based on foreign regulatory filings.²²

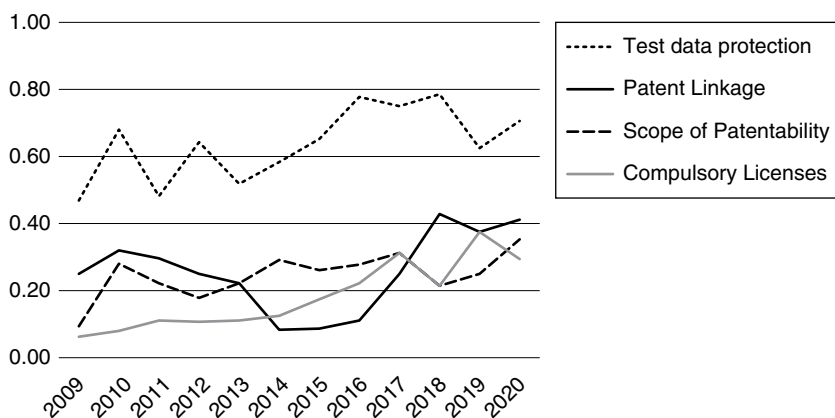


Figure 14.6 Frequency of TRIPS flexibilities cited in countries identified by PhRMA and listed by USTR (%)

22 The United States challenged this law through the WTO dispute settlement process in 1999, but the countries reached a Mutually Agreed Solution in 2002, which left specifics on data exclusivity open to further negotiation. The Dispute Settlement Panel never issued a Report on the matter. See *Argentina - Certain Measures on the Protection of Patents and test Data* (WT/DS196), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm.

It also includes countries that have data exclusivity rules that are implemented in ways that do not provide exclusivity for all types of medicine products, such as China, which grants six years of data exclusivity to new pharmaceutical products. In 2016, USTR cited China for inadequate protection of test data, noting a regulation that limited the definition of “new drugs” to “those for which marketing approval is first sought in China.”²³

Listings for lacking patent linkage fell from 32 percent in 2010 to a low of 13 percent in 2014 and have generally risen since then, hitting an all-time high of 43 percent in 2018 (and 42 percent in 2020). Usually, USTR does not use the term “linkage” in the Special 301 Reports but describes the countries as lacking a mechanism to help patent holders block infringing products before they reach the market. For instance, in the 2018 Special 301 Report, USTR cited Egypt for lacking an “effective system for notifying interested parties of applications for marketing approval of follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes.”²⁴

Listings for limiting the scope of patentability have averaged 25 percent over the 12-year period, with a gradually increasing trend. In 2020, USTR cited 35 percent of PhRMA-identified countries for issues related to the scope of patentability. These include (a) countries that did not allow patents on new uses of known medical products, such as Colombia;²⁵ (b) countries that did not allow new versions of existing products, such as Brazil;²⁶ and (c) countries that provided process patents protection for pharmaceuticals during the pre-TRIPS years, specifically Finland and Norway.²⁷

India was regularly included by USTR in the Special 301 Report for allegations that Section 3(d) of India’s Patents Act violates the TRIPS Agreement’s requirements of patentability. Section 3(d) denies patents for the “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance...” However, as stated above, many countries deny patents for new uses and new forms of medicines.²⁸

Citations of countries for compulsory licensing have increased over the 12-year period. In 2009 and 2010, countries were rarely cited for compulsory licensing, but 37.5 percent of the countries singled out by PhRMA and included in the 2019 Special 301 Report were criticized for policies related to this flexibility.

23 OFFICE OF THE U.S. TRADE REP., 2016 SPECIAL 301 REPORT, 36 (2016), <https://ustr.gov/>.

24 OFFICE OF THE U.S. TRADE REP., 2018 SPECIAL 301 REPORT, 69 (2018), <https://ustr.gov/>.

25 OFFICE OF THE U.S. TRADE REP., 2014 SPECIAL 301 REPORT, 50 (2014), <https://ustr.gov/> [hereinafter 2014 SPECIAL 301 REPORT] (vaguely alleging problems with scope of patentability); see also PhRMA Special 301 comments in 2014 SPECIAL 301 REPORT, at 186 (asserting that Colombia does not issue “second use” patents).

26 2009 SPECIAL 301 REPORT, *supra* note 17, at 23 (Brazil was cited for not allowing patents on polymorphs).

27 *Id.* at 26 and 29.

28 Clara Ducimetière, *Second Medical Use Patents: Legal Treatment and Public Health Issues*, South Centre Research Paper No. 101 (2019), <https://www.southcentre.int/research-paper-101-december-2019/>.

This figure dropped to 29 percent in 2020. The countries cited for compulsory licensing include some that have taken a well-known stand on the issue to expand access to medicines for thousands of patients. For instance, Thailand issued CLs on *Efavirenz* and *Lopinavir+Ritonavir*, expanding treatment to 20,000 and 8000 patients, respectively.²⁹ Other countries have not actually used CLs, but have taken steps needed to issue a license under their domestic laws. The 2019 Special 301 Report complained that Chile passed a health resolution “which declared that there are public health reasons that justify issuing CLs on certain patent-protected drugs used to treat hepatitis C. While Chile has not issued a CL, the resolution satisfies an initial legal requirement after which a third party may then make the request.”³⁰

From 2009 through 2018, only middle-income countries were cited for compulsory licensing (China, Ecuador, India, Indonesia, and Thailand). USTR cited Chile for its new CL policy in the 2019 and 2020 reports. It did not cite other high-income countries that issued licenses or changed their compulsory licensing laws in March 2020 in response to the coronavirus. These include Israel (which issued a CL for a potential COVID-19 treatment in March);³¹ Canada (which amended its law to accelerate the process of compulsory licensing for health reasons);³² and Germany (which passed a law granting the government more authority to issue CLs in epidemics).³³

Other alleged IP violations are routinely included in Special 301 Reports, often at the request of PhRMA. These include backlogs of patent applications and problems with patent prosecution. Sometimes, these allegations are paired with calls to extend patent terms (which countries are not required to do under the TRIPS Agreement). Other times, USTR simply criticizes the country for delays. These are not included in Figure 14.4 because the delays are not a TRIPS flexibility – though the right to refuse to extend patent terms beyond 20 years is a flexibility.

Special 301 Reports have Focused More on Enforcement of IP Protection Than on Specific Policies

Allegations of inadequate enforcement of IP were more frequent than allegations of inadequate policies. Almost all countries listed by USTR in the Special

29 Thai Ministry of Public Health and National Health Security Office of Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* (2007), <http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf>.

30 2019 SPECIAL 301 REPORT, *supra* note 17, at 65.

31 Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/>.

32 *Id.*

33 Christian Dekoninck et al., *COVID-19 and Public Compulsory Licensing of Drugs in Europe*, SYNAPSE: TAYLOR WESSING (Apr. 17, 2020), <https://www.taylorwessing.com/fr/insights-and-events/insights/2020/04/covid-19-and-public-compulsory-licensing-of-drugs-in-europe>.

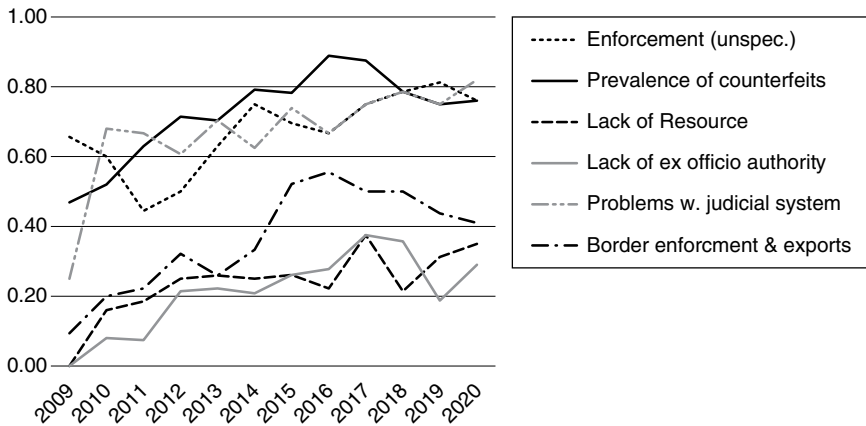


Figure 14.7 IP enforcement citations in countries identified by PhRMA and listed by USTR (%)

301 Report for IP and healthcare reasons contain some form of allegation that enforcement is lacking.

Figure 14.5 shows that 92% of the countries identified by PhRMA and listed by USTR were cited for IP enforcement concerns between 2009 and 2020. The percentage of such countries being cited for alleged problems with IP enforcement was consistently high, reaching 100% from 2015 through 2017.

Figure 14.7 shows the types of enforcement complaints commonly found in the Special 301 Report. The most common complaint was the prevalence of counterfeits on the market in a given country. Seventy-two percent of the countries recommended by PhRMA and listed by USTR were criticized for this. Other common enforcement shortcomings cited in the Special 301 Report included concerns with the judicial process, including sentences not strong enough to deter future infringement (67 percent); under-resourced enforcement authorities (24 percent); a lack of *ex officio* authority for enforcement authorities (21 percent); and weak border enforcement and/or the export of infringing products (36 percent).

USTR frequently highlights the need to strengthen enforcement generally, usually in addition to other specific allegations. For instance, the 2017 Special 301 Report urges Guatemala to “take clear and effective actions in 2017 to improve the protection and enforcement of IP in Guatemala.”³⁴ Such unspecific criticisms of IP enforcement occurred in 66 percent of the listings of countries identified by PhRMA and included by USTR.

34 OFFICE OF THE U.S. TRADE REP., 2017 SPECIAL 301 REPORT, 64 (2017), <https://ustr.gov/>.

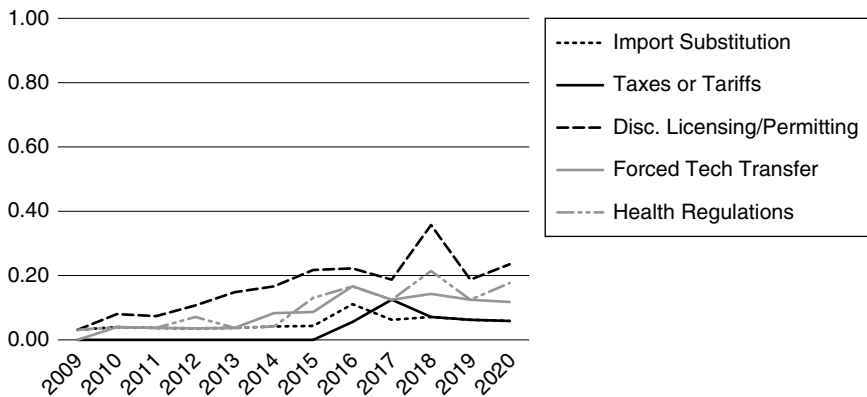


Figure 14.8 Market access policies (non-IP) cited in countries identified by PhRMA and listed by USTR (%)

Countries are Increasingly Listed for Market Access Violations Outside the Intellectual Property Realm

USTR increasingly uses the Special 301 Report to criticize countries for policies that have nothing to do with IP. These fall under the scope of the Trade Act’s instructions to identify countries that deny “fair and equitable market access to United States persons that rely upon intellectual property rights.” PhRMA’s comments to USTR regularly complain of such market access barriers. Initially, USTR focused more directly on alleged IP shortcomings, but it has increased these types of allegations over time. Figure 14.5 shows that these complaints were in 9 percent of the Special 301 Report listings of countries identified by PhRMA in 2009 and 65 percent in 2020. This finding is based on a tally of allegations of various licensing and permitting policies that discriminate against foreign firms (including local ownership requirements); forced technology transfer; import substitution; tariffs and other taxes on medicines; and allegedly discriminatory health regulations. Figure 14.8 shows how each of these have grown in percentage since 2009.

The percentage of countries identified by PhRMA and listed by USTR that were singled out for discriminatory licensing and permitting policies has grown the most – starting at 3 percent in 2009 and remaining at or above 19 percent since 2015. Allegations of discriminatory use of health regulations applied to 3 percent of the listed countries in 2009, but to 13 percent or higher each year since 2015. There have been smaller increases in citations for policies requiring technology transfer for US firms to operate in listed countries, as well as citations about taxes and tariffs.

Conclusion

Since its inception, the Special 301 Report has been an instrument used by USTR to pressure foreign nations to change their laws at the behest of American

business interests. Policies that allow countries to access lower priced generic medicines feature prominently in USTR's allegations of inadequate and ineffective protection of IP.

This report has reviewed trends over the past 12 years. USTR has reduced the number of countries listed in the Special 301 Report, but it has been consistent in its responsiveness to country listing requests by PhRMA. This is especially true for the countries prioritized by PhRMA. USTR included between 75 percent and 100 percent of these PhRMA-prioritized countries in each year's Special 301 Report over the period studied. It also consistently focused its attention on middle-income countries and populous countries.

USTR has regularly used the report to criticize countries for employing TRIPS flexibilities. There has been an increased number of complaints about (mostly middle-income) countries issuing CLs or adopting pro-compulsory licensing policies. Alleged inadequacies in countries' test data protection, patent linkage, and the scope of patentability have all been criticized in the Special 301 Reports as well. There have been increased complaints against countries for inadequate enforcement of intellectual property, and increased complaints that pharmaceutical firms have been denied fair market access.

The 2020 Special 301 Report did not criticize countries for exploring and expanding TRIPS flexibilities in the face of the COVID-19 pandemic. Indeed, neither the word "coronavirus" nor "COVID-19" appears in the report. The absence of citations for countries seeking to use TRIPS flexibilities to fight the COVID-19 pandemic is notable, especially given press reports that countries were preparing to issue CLs, and in Israel's case, had already issued one. Perhaps the obvious need for access to COVID-19 treatments took precedence over the need to protect pharmaceutical firms' IP. If this is the case, it is fair to ask why the use of TRIPS flexibilities for other urgent health needs (such as HIV/AIDS, hepatitis C, or cancer) does not get the same deference. It may also be that policy inertia and the report's regular focus on health actions by middle-income countries caused the report's authors to overlook the actions of high-income trading partners in this area.

There are many avenues for further research into the Special 301 Report. One could examine the impact that Special 301 listings have on the ground in countries included in the reports. Does inclusion in a report lead policy makers in these countries to change laws and policies in ways favorable to US interests? How directly are Special 301 listings connected to other trade and diplomatic pressures?

Finally, PhRMA is only one of the groups that submit comments and testify in support of pharmaceutical industry interests. Further research could examine how USTR has responded to listing suggestions by other groups such as the Biotechnology Innovation Organization and the Chamber of Commerce's Global Innovation Policy Center. One could also compare USTR's responsiveness to the pharmaceutical industry to its responsiveness to other IP-intensive industries, such as publishing and media.



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Part III

Global Patterns and Emerging Issues

Third Generation