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Public Citizen 2025 Special 301 Review Comment

Re: 2025 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing

January 27, 2025

Public Citizen submits the following comments in response to the request by the Office of the United States Trade Representative (USTR) for "written comments that identify acts, policies, or practices that may form the basis of a country's identification as a Priority Foreign Country or placement on the Priority Watch List or Watch List." Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the U.S. and around the world to make medicines available for all through tools in policy and law.

The submission draws on our experience providing technical assistance to public agencies, particularly in developing countries, including on intellectual property (IP) rules to protect access to medicines. First, we discuss how international commitments and U.S. policies related to health security and drug pricing should inform the Special 301 process. We review health-protective flexibilities in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), including several that are sometimes overlooked that the Special 301 Report should respect. Finally, we provide recommendations based on country listings in recent Special 301 Reports.

Health Security

Health security is national security. The United States benefits from a trade agenda that allows trading partners to address local health needs. For example, a country that is empowered to adopt laws and policies that facilitate its ability to recognize and respond to infectious disease threats may be more well equipped to stop an outbreak before it spreads to other countries—and thus, before it can cause disastrous impacts on health, economies, and global trade.

In practice, this requires implementing trade policies that do not put corporate interests over the public interest, including health and access to affordable medicine.

Each Special 301 Report since the adoption of the 2001 Declaration on the TRIPS agreement and public health (Doha Declaration), has referenced the declaration, which details WTO member state commitments to public health and access to medicines. Every Special 301 Report over the last 15 years has stated that the assessments in the report "are based on various critical factors, including, where relevant, the Doha Declaration." Nonetheless, Special 301 reports have criticized and otherwise cited country practices that support health. We therefore welcome the principle USTR recently articulated, that the United States declines to "call out countries for exercising TRIPS flexibilities, including with respect to compulsory licenses, in a manner consistent with TRIPS obligations."[1]

[1] USTR Releases 2024 Special 301 Report on Intellectual Property Protection and Enforcement, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/april/ustr-releases-2024-special-301-report-intellectual-property-protection-and-enforcement

Public Citizen invites USTR and all agencies engaged in the Special 301 process to continue to make meaningful U.S. commitments to protecting public health at home and abroad, by omitting expressed or implied references to countries' public interest practices that comply with treaty obligations.

Drug Pricing

High prescription drug prices are a grave U.S. and global concern.[2] Treatment rationing due to high prices is a daily reality here in the U.S. and throughout the world. It costs people their health and far too often their lives. The U.S. government and most governments recognize that expansive patent monopolies facilitate manufacturers' high prices. Congress, federal agencies and the states, like many U.S. trading partners, are reexamining how to protect public health under their intellectual property regimes.

In recent years, the Special 301 Report has included notable improvements respecting practices designed to make medicines affordable. These improvements bring the Special 301 Report into greater coherence with U.S. commitments.[3] However, recent Special 301 reports still have included criticisms[4] that may be harmful to access to medicines, applying standards required neither by TRIPS nor country commitments to the United States, and advancing interests of the patent-based pharmaceutical industry at the expense of countries' public interest policies.

Despite some areas where more progress is needed, recent shifts support a trade policy that allows governments to address high drug prices and anti-competitive practices while also building stronger relationships with U.S. trade partners.

Unfortunately, prescription drug corporations often see their interests elevated in U.S. trade policy without adequate justification, including via the listing of public interest policies that seek to support access to medicines in the Special 301 Report. This despite the fact that the U.S. also contends with problems posed by limited competitive constraints on the pharmaceutical industry, resulting in extraordinary prescription drug prices that force families to choose between treatment and groceries and force public programs to limit the health services they can provide. Accordingly, Americans are increasingly supportive of actions to rein in prices. American voters consistently rank lowering drug prices among their top priorities for Congress. The provision in the Inflation Reduction Act that allows

[2] KFF, Public Opinion on Prescription Drugs and Their Prices (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ (finding that 82% of adults in the U.S. consider the cost of prescription drugs is unreasonable and about three in ten report not taking their medicines as prescribed because of the cost).

[3] Recent Special 301 reports include a statement of U.S. respect for trading partners' rights to grant compulsory licensing consistent with the TRIPS Agreement. Recent reports also ceased to list countries for compulsory licensing—a practice that recognizes U.S. affirmation of the right to protect public health and promote access to medicines in the Doha Declaration. Similarly, recent reports have more broadly recognized the right of U.S. trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement.

[4] Comments related to patentability standards, test data protection, patent linkage, patent term adjustment, technology transfer, and local working requirements for pharmaceuticals persist in the Special 301 Report. Additionally, the Special 301 has recently given greater emphasis to areas such as trade secret protection, grant of injunction in IP adjudication, and use of competition laws, which may have negative implications for access to medicines.

Medicare to negotiate prices of patented drugs has widespread support among voters—with 85% of voters supporting authorizing the federal government to negotiate prices.[5]

What's more, foreign practices criticized in past Special 301 reports can address high drug prices in the United States. For example, hugely popular new diabetes and obesity drugs like Novo Nordisk's Ozempic and Wegovy threaten to bankrupt the American healthcare system at their current prices. Elon Musk, whom President Trump selected to co-lead the "Department of Government Efficiency", has voiced his support for making these drugs "super low cost to the public."[6] Noting the financial burden these drugs impose on patients and health budgets, Public Citizen petitioned the Department of Health and Human Services to address Novo Nordisk's price gouging by authorizing generic competition.[7] Public Citizen estimates that generic competition on these drugs could save tens of billions of dollars annually for Medicare alone.[8]

When the U.S. government criticizes developing countries' TRIPS-compliant policies, it seeks to deter health-protective practices from taking root. In our view, this practice is inappropriate, and increasingly out of line with U.S. national policy. Fortunately, there are several discrete areas for improvement that would make a difference.

Principles

Our comments address specific Special 301 practices that can and should be improved. The following principles can help guide the review process:

I. **The Special 301 Report should not list countries for TRIPS-compliant policies or for using TRIPS flexibilities to safeguard public health and access to medicines.**[9]

II. **The Special 301 Report should not list countries for policy preferences they have no bilateral or multilateral obligation to adopt.** Even if the Special 301 Report continues to cite countries for

[5] KFF Health Tracking Poll September 2024: Support for Reducing Prescription Drug Prices Remains High, Even As Awareness of IRA Provisions Lags (Sept. 13, 2024), https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-september-2024-support-for-reducing-prescription-drug-prices-remains-high/

[6] Elon Musk's 'Ozempic Santa' post turns heads, clashes with RFK Jr.'s stance, USA Today, https://www.usatoday.com/story/life/health-wellness/2024/12/26/elon-musk-ozempic-rfk-jr-clash/77232528007/

[7] Letter from Public Citizen to the U.S. Department of Health and Human Services requesting use of 28 U.S.C. § 1498 to increase affordability and access to semaglutide, https://www.citizen.org/article/public-citizen-petitions-hhs-to-license-generic-competition-on-ozempic-and-wegovy/

[8] Estimate of Savings from Generic Competitors to Ozempic and Wegovy, https://www.citizen.org/article/estimate-of-savings-from-generic-competitors-to-ozempic-and-wegovy/

[9] Last year, the Special 301 committee asked how our argument that the Special 301 Report should not identify country policies or practices that are compliant with the TRIPS Agreement aligns with the statement from Congress to USTR that a country, "may be determined to deny adequate and effective protection of intellectual properties, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the TRIPS Agreement." We explained that while the statute states that a country "may" be determined to deny adequate and effective protection of IP rights notwithstanding TRIPS compliance, it does not instruct the review committee to cite countries for TRIPS-compliant practices, or to apply any particular standard. The committee has the discretion not to cite countries for TRIPS-compliant practices, and we believe this is particularly important as regards practices that support health. For our full response, *see* https://www.citizen.org/article/public-citizen-post-hearing-comment-for-the-2024-special-301-review/

TRIPS-compliant policies, Special 301 should not list a country for the absence of a policy that the country is not bound to uphold. For example, a country should not be listed for declining to adopt a policy analogous to data exclusivity or patent linkage if that country does not have an agreement with the U.S. expressly and specifically requiring the same.

III. **The Special 301 Report should not criticize countries for a lack of transparency or due process, unless such criticism clearly articulates the alleged violation of a TRIPS standard.** The TRIPS Agreement provides not only substantive standards, but also standards for transparency and due process, which were carefully negotiated (*see e.g.* much of Article 31).[10] It is inappropriate to list (and thereby sanction) a country for an allegedly non-transparent practice, if the criteria for the listing is itself non-transparent and not articulated.

IV. **The Special 301 Report should not address ancillary policies such as pharmaceutical pricing unless those policies are specifically alleged to be discriminatory.**

V. **The Special 301 Report should treat public policy disagreements as a matter of lower priority than criminal activity.** If, in spite of the principles above, the Special 301 Report nevertheless cites countries for their TRIPS-compliant public policies, such country choices are clearly less objectionable than the prevalence of criminal activity, such as alleged trade secret theft. The 301 Report should clearly reflect this ordering of priorities. Pharmaceutical or other public policy disagreements should not be cause for inclusion on the Priority Watch List.

VI. **At a minimum, the Special 301 Report should not repudiate country practices that the U.S. is considering using to lower prescription drug prices or make available needed medical supplies.** Even if the Special 301 Report subjects wealthy countries to criticism for TRIPS-compliant public interest policies, developing countries should be given greater leeway.

VII. **Criticism in the Special 301 Report should be accompanied by express and clearly articulated criteria.** If a critique is too vague to be disproven, it is both manifestly unfair and also difficult to remedy.

VIII. **The Special 301 committee should require adequate justification before incorporating industry complaints into the report.** In cases where comments from industry are at odds with comments from other stakeholders, such as governments or civil society, further investigation should be undertaken before inclusion in the Special 301 Report.

Appropriate Scope for Special 301

In past years, in response to concerns articulated by public interest groups about the Special 301 process, the Special 301 committee has asked what issues, then, are appropriate for Special 301 attention. Our answer to this question is willful trademark counterfeiting and copyright piracy on a commercial scale.

The World Trade Organization's Agreement on TRIPS helpfully distinguishes between civil and criminal intellectual property infringements. We believe the latter to be more appropriate for Special 301 attention. While national courts are available to litigate civil disputes, criminal activity such as counterfeiting and piracy seeks to avoid the law. When Special 301 focuses on civil cases or national

[10] For Public Citizen's discussion of additional TRIPS standards, *see* https://www.citizen.org/article/public-citizen-post-hearing-comment-for-the-2024-special-301-review/

intellectual property policy, it is calling into question countries' judicial branches and sovereign decisions regarding how to balance the public interests at stake. By contrast, when Special 301 critiques criminal counterfeiting and piracy, it is simply drawing attention to inadequate enforcement of that country's laws and international obligations. This is in keeping with principles of sovereignty.

The primary question regarding challenging counterfeiting and piracy is one of resource allocation. What resources should the United States and its trading partners allocate to prevent and prosecute counterfeiting and piracy, given scarce law enforcement resources and other pressing national priorities? Even where parties disagree on resources or priorities, they can agree that the law must be enforced. The United States is in a much stronger position to insist that countries prosecute criminal activity than it is to insist countries change policy to U.S. preferences. Indeed, U.S. insistence on controversial policy changes that many people believe could harm access to medicines has undercut some support for cooperation against counterfeiting and piracy.

Piracy and counterfeiting sometimes constitute mass responses to market failures (for example, a lack of content available at a price people can afford). But neither is a policy response to these failures. It is appropriate and sensible that the U.S. government insist its trading partners enforce the laws to which all have agreed.

The TRIPS Agreement

The WTO's TRIPS agreement reserves to signatory nations certain sovereign rights and flexibilities. The TRIPS Agreement allows for diversity in the methods of implementing its provisions.[11] Members are not obliged to adopt standards that are more extensive or onerous than the ones articulated in the TRIPS Agreement. Even though the patent-based pharmaceutical industry played a key role originating TRIPS and had a massively outsize influence in its drafting, WTO member states ensured that TRIPS left countries room to adopt national policies that favor the public interest, competition, technology transfer, and local innovation.

The "objectives" introduced by TRIPS Article 7 as well as the "principles" within Article 8 provide the guiding rules necessary to interpret the agreement. These provisions are as effective as the other provisions of the TRIPS Agreement. Article 7 explicitly references "the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge" as an objective of the agreement. Article 8.1 notes that "Members may … adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."

Attempts by the U.S. to block TRIPS-compliant measures to increase access to AIDS medicines at the peak of the epidemic in South Africa brought shame upon our government.[12] WTO members including the U.S. subsequently unanimously agreed upon a Declaration on the TRIPS Agreement and Public Health. The Doha Declaration states:

[11] TRIPS, Article 1 ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.")

[12] SECTION27 and TAC, Standing Up For Our Lives: A History of the South African Access To Medicines Movement (2018), https://standingupforourlives.section27.org.za/ (documenting how the U.S. and pharmaceutical industry sought to block efforts to increase access to medicines by claiming they were inconsistent with TRIPS).

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[13]

The flexibilities in the TRIPS Agreement enable governments to mitigate—through the enactment of appropriate legislation and regulations—the negative impact that intellectual property rules may have on public health.

Patent-Eligible Subject Matter and Patentability Criteria

Article 27.1 of the TRIPS Agreement employs a substantive notion of "invention." It notes that "subject to the provisions of paragraphs 2 and 3 [exclusions from patentability], patents shall be available for any inventions." TRIPS does not define the term "invention." One crucial TRIPS flexibility thus is the ability of a WTO member to determine for itself what constitutes an "invention." The United States itself uses this flexibility to exclude certain subject matter from its definition of invention. For example, the U.S. Supreme Court has ruled that isolated DNA is not patent-eligible subject matter.[14]

If the subject matter of a patent claim does not constitute an invention, i.e., not patent-eligible, then, by definition, it may not be patented, even if the subject matter claimed otherwise satisfies the criteria of novelty, inventive step, and capacity for industrial application. The subject matter eligibility analysis precedes the analysis of whether a claimed invention satisfies other patentability criteria.

According to Article 1.1, WTO members may determine substantive requirements in accordance with their own local systems and practices. Article 27.1 does not provide definitions for "novelty," "inventive step," or "capable of industrial application." WTO members are free to define these three patentability criteria. The article clarifies in a footnote that the term "industrial application" is meant to be synonymous with "useful." However, countries are still free to determine what the term means. Nothing prevents WTO members from applying rigorous patentability criteria to ensure high-quality patents.

Compulsory Licenses

Compulsory licenses authorize generic competition with patented drugs, typically to support affordability or timely and diverse supply or to address anticompetitive practices. Under the TRIPS Agreement, members have the right to issue compulsory licenses on grounds they determine appropriate, including to address diseases they believe important.

The TRIPS Agreement allows countries to grant compulsory licenses on grounds of their choosing. The WTO's Doha Declaration clarified the ability of countries to define grounds for compulsory licenses and to use compulsory licenses to advance public health and to ensure access to medicines for all. Procedurally, countries are not obligated to engage in prior negotiation with patent holders if licenses are designated for public noncommercial use (also known as government use).

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[13] Paragraph 4, Doha Declaration, Adopted November 14, 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[14] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (U.S. 2013)

Data Protection

TRIPS Article 39 covers the "protection of undisclosed information," which relates broadly to what are sometimes called trade secrets. It does not require "data exclusivity," which prevents regulators from relying on a pharmaceutical company's data to evaluate competing products. Instead, Article 39.3 requires only "protection of undisclosed test data on new chemical entities, (the collection of which involved considerable effort) against disclosure unless steps are taken to ensure that the data is protected against 'unfair commercial use.'" In other words, it provides protection against data disclosure, not against data use, and is not designed to confer government-protected monopoly marketing periods.

The North American Free Trade Agreement (NAFTA) included a similar passage, but also a paragraph specifically preventing regulators from relying on an originator's data for a reasonable period. The U.S. sought the inclusion of a provision in TRIPS based on this NAFTA paragraph. This proposed provision was excised from the TRIPS Dunkel Draft in 1991 and never restored to the Final TRIPS Act of 1994. The refusal of TRIPS drafters to adopt the NAFTA provision is one of several factors demonstrating their intention to provide for data protection, not data exclusivity, in TRIPS.

Local Working Requirements

The drafting history of the TRIPS Agreement demonstrates that country delegations explicitly excluded limitations on the ability of member states to address local working requirements in their patent laws from the final agreement.

During the TRIPS negotiations, U.S.-proposed language to prohibit local working requirements was soundly rejected by the other negotiating countries. Article 31 provides no limits on grounds for compulsory licensing—except with particular regard to semiconductors. If the drafters listed a specific limit on grounds for semiconductors, they also could have prohibited working failure grounds. They did not. *Expresio unius est exclusion alterius*: express inclusion of one thing (the semiconductor limit) implies exclusion of others (no prohibition of local working grounds). This is a standard canon of statutory interpretation.

The TRIPS Agreement explicitly incorporates by reference Article 5, Section A (2) of the Paris Convention of 1967, which specifically gives member states the right to legislate against "abuses which ... result from the exercise of the exclusive rights conferred by the patent" subject to the conditions found in Sections A (3) and A (4). The clause specifically cites 'failure to work' the patent as an example abuse.

Traditionally, "failure to work" is defined as the failure to industrially produce the product; sales or importation of the patented product do not rise to the level of "working" the patent. But the convention also says that member states may freely define "failure to work" to include the refusal to grant licenses on reasonable terms, insufficient supply of the national market, or excessive prices.

Independent of the convention and consistent with Article 8 and Article 2.1(2) of TRIPS, members may still legislate in the public interest, especially in matters of military security or public health. Further, the Doha Declaration on the TRIPS Agreement and Public Health has reaffirmed that the Agreement should be interpreted in a manner supportive of public health, and member states are free to determine both the grounds on which compulsory licenses are granted and what constitutes a "national emergency or other circumstances of extreme urgency."

Working failure integrates human rights considerations into the patent law discourse. It prioritizes availability of patented technologies as a sensible requisite of exclusivity. Access to medicines in many middle- and low-income communities can be assisted by this consideration.

Competition Law

TRIPS includes the promotion of competition as an overarching objective and provides flexibility to take additional measures to address anti-competitive practices beyond the minimum standards (see articles 8, 31, and 40).[15] Competition law can help address excessive pricing of pharmaceuticals, as the U.S. Federal Trade Commission is exploring today.

In the absence of multilateral standards on competition law, WTO member states are free to set normative standards and to remedy anticompetitive practices within the competition law framework. This allows WTO member states, especially developing countries, to address the issue of excessive prices of patented medicines without necessarily following the approaches of developed country competition law authorities.[16]

For example, the U.S.-based pharmaceutical company Johnson & Johnson recently came under investigation by South Africa's antitrust regulator for allegedly charging excessive prices for bedaquiline, a vital drug used to treat drug-resistant tuberculosis (TB).[17] Global TB cases increased in 2021 for the first time in years, heightening the urgency for affordable treatments. Johnson & Johnson had faced calls to reduce the price for bedaquiline. Subsequently, the company announced a six-month course of the drug would be provided at a cost of $130 through the Stop TB Partnership's Global Drug Facility. However, the South African government, which procures bedaquiline directly from Johnson & Johnson and Janssen, was paying approximately $280 per six-month course per patient. The South African investigation sheds light on the critical issue of excessive pricing, especially for life-saving medications in countries with a high burden of disease.

[15] Vitor Henrique Pinto Ido, Designing Pro-Health Competition Policies in Developing Countries, South Centre (2020), https://www.southcentre.int/research-paper-125-december-2020/

[16] Shirin Syed, Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals, Routledge Taylor & Francis, at 362–378.

[17] Gerald Imray, Big Pharma's Johnson & Johnson under investigation in South Africa over 'excessive' drug prices, AP News (Sept. 15, 2023), https://apnews.com/article/johnson-investigation-south-africa-pharmaceutical-eb8525424c07f6c8e6645fa036cdf284

Injunctions

Articles 44 and 50 of the TRIPS Agreement require national judicial systems to have the authority to grant injunctions, however, the Agreement does not require that injunctions be issued.[18] In cases of suspected infringement, patent holders may file a lawsuit in which an injunction may be granted at the discretion of the judiciary authorities. Generally, injunctions can be preliminary, which aim to grant immediate cessation of infringement, or permanent, which commence after the full determination of the merits of the infringement case by the courts.[19]

Availability of preliminary injunctive relief can sometimes lead to abuse. For example, in the U.S., patent holders can claim infringement against a generic entrant and be granted an automatic 30-month stay. This maintains high drug prices, even when the claimed patent is later found to have been improperly granted and invalidated.

The Federal Trade Commission characterized the harmful impact of this abuse as follows:

> When this stay is triggered by a patent that is improperly filed and does not meet the statutory listing criteria, the stay may improperly delay consumer access to a competing product that might reduce prices, improve quality and access, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for consumers in accessing cost-effective medications[20]

In cases where infringement is claimed, it may remove the only source of affordable supply for developing countries. Additionally, it is sometimes in the public interest to allow infringement to continue.

The United States Court of Appeals for the Federal Circuit, prior to the late 1980s, consistently awarded permanent injunctions to patent holders in line with existing legal precedents. However, this practice

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[18] Joshua D Sarnoff, *TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection* (Oct. 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3905488;
There are three important flexibilities under Article 44 of the TRIPS Agreement:
Article 44.1: If the subject matter is acquired or ordered by a person prior to knowing or having reasonable grounds to know it would entail IP infringement. This means that where an infringing matter is innocently acquired, Members are free to refuse an injunction and allow the bona fide acquirer to use or further dispose of the infringing subject matter.
Article 44.2 contains the other two flexibilities. The first part of the article 44.2 recognizes that in some countries injunctions are not allowed as a remedy in cases of government use. In the United States, for example, section 28 USC 1498 limits remedies to compensation in cases of government use of patents and copyrights. The section part of Article 44.2 goes even further and allows Member States to limit remedies in cases of infringement not more than declaratory judgments and adequate compensation. Moreover, differentiating from the first part of article 44.2 (for compulsory license and government use), this flexibility is not limited only to patents and integrated circuits, but can potentially apply to infringements of all types of intellectual property rights.

[19] Shirin Syed, *Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India*, South Centre (Feb. 15, 2024),
https://www.southcentre.int/wp-content/uploads/2024/02/RP194_Implementation-of-TRIPS-Flexibilities-and-Injunctions-A-Case-Study-of-India_EN.pdf

[20] Federal Trade Commission, FTC Files Amicus Brief Outlining Anticompetitive Harm Caused by Improper Orange Book Listings, (Nov. 20, 2023),
https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-files-amicus-brief-outlining-anticompetitive-harm-caused-improper-orange-book-listings

was significantly altered in 2006 following the U.S. Supreme Court's ruling in eBay v. MercExchange. Contrary to the Federal Circuit's stance, the Supreme Court determined that a patent holder is not automatically entitled to injunctive relief simply because they have successfully proven infringement and defended the patent's validity. The Supreme Court stipulated a four-pronged test that a patent holder must satisfy to qualify for such relief: (1) proof of irreparable harm; (2) demonstration that legal remedies, like financial compensation, are insufficient; (3) evidence that the balance of hardships between the plaintiff and defendant justifies an equitable solution; and (4) assurance that a permanent injunction would not be detrimental to the public interest. In cases where infringement is allowed to continue in the public interest, royalties may be offered for ongoing use of the patent, effectively acting as a compulsory license.

U.S. courts have considered the broader social implications when determining whether or not to grant injunctions. If an injunction negatively impacts the public interest, the court will explore alternative means of compensating the patent holder. In making discretionary decisions concerning injunctions, judicial bodies may refer to the overarching objectives and principles of the TRIPS Agreement for direction.[21] USTR should take care that its work on injunctions does not compromise access to medicine.

Country Recommendations

ARGENTINA

Argentina remained on the Priority Watch List in 2024.

The Special 301 Report includes “inadequate protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval” for products in the agricultural chemical and pharmaceutical sectors as an ongoing challenge to the innovative agricultural chemical and pharmaceutical sectors.

The 2024 Special 301 Report, appropriately, removed prior year comments regarding Argentina's TRIPS-compliant patenting standards.

Data Protection

Argentina is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement. Protection of clinical test data is available under Argentina’s “Confidentiality Law” (Decree 24,766).

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[21] Shirin Syed, *Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India*, South Centre (Feb. 15, 2024), https://www.southcentre.int/wp-content/uploads/2024/02/RP194_Implementation-of-TRIPS-Flexibilities-and-Injunctions-A-Case-Study-of-India_EN.pdf
(Article 44.1 of the TRIPS Agreement establishes an important exception to the rule that Members are not obliged to accord judges the authority to grant injunctions in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right. This means that where an infringing matter is innocently acquired, Members are free to refuse an injunction and allow the bona fide acquirer to use or further dispose of the infringing subject matter.
Article 44.2 provides the freedom to Member States to deny the injunction remedy to the disputes related to government use and limit the scope of remedy only to the quantum of compensation).

According to Art. 4 of the Confidentiality Law, information proving the efficacy and safety of the product submitted to the local regulatory authority is protected against any dishonest commercial use, provided that the requirements of Section 1 and Article 39.2 of the TRIPS Agreement are met (i.e., secrecy, commercial value because of the secrecy, and the adoption of reasonable steps to keep the information secret). Generic competitors do not have access to the confidential information submitted by the applicant.

In the event that third parties gain access to the information in a manner that is contrary to honest commercial practices, the information holder has the right to request preliminary proceedings to prevent the disclosure of such information or to prevent it from being acquired or used by any third party, and to claim compensation for the damages caused (Art. 11 and 12).

In 2000, the U.S. requested WTO consultations with Argentina concerning Argentina's legal rules on data protection in Law 24,766 and Regulation 440/98. The dispute was settled by mutual consent without any change in Argentinian legislation.[22]

The Special 301 Report should not cite Argentina for its TRIPS-compliant protection of undisclosed test data.

Patenting Standards

Argentinian guidelines for examining patent applications advise patent examiners how to assess the patentability requirements of applications relating to pharmaceutical products and processes, as well as the use of pharmaceutical products. Pharmaceutical patent applications for polymorphs, salts, and formulations—secondary patents—do not contribute to innovation, and they restrict access to affordable medicines. It is a justified and TRIPS-compliant application of patentability standards to prevent the grant of "poor quality" secondary patents. Such an application would also promote the objectives introduced by Article 7, as well as the principles within Article 8, of the TRIPS Agreement.

Argentinian guidelines do not intend to modify the standards of patentability established by the Argentinian patent law (Law No. 24,481 modified by Law No. 24,572, Decree 260/96), or to introduce additional standards. Instead, they aim to ensure the correct application of those standards in view of the specific nature of the claimed subject matter and the public health relevance of the decisions: "Patents are granted or denied on the basis of the consideration for each application of the conditions for patentability contained in patent legislation: novelty, inventive step and industrial applicability, as well as the rules pertaining to what are considered to be inventions and which inventions are excluded from patentability in accordance with that legislation.[23]

The Special 301 Report should continue to not cite Argentina for its patenting standards and patent examination guidelines that comply with the TRIPS Agreement and provide clarity on the application of Argentinian patent law.

BRAZIL

Brazil remained on the Watch List in 2024.

[22] *See* DS196: Argentina — Certain Measures on the Protection of Patents and Test Data, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm

[23] Eduardo Arias, PPT on "Guidelines for the examination of patentability of chemical-pharmaceutical inventions," INPI, Argentina, 2014.

The Special 301 Report urges Brazil to "provide protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products like it does for veterinary and agricultural chemical products." The Special 301 Report also raises concerns about the overall average pendency of patent applications, particularly biopharmaceutical patent applications, and the impact of that pendency on the effective patent term.

Data Protection

Brazil is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement. Such protection of clinical test data is available under Brazilian law.

The protection of undisclosed pharmaceutical test data in Brazil prevents unfair commercial use and unauthorized disclosure, but permits "disclosure by a government body competent to authorize the marketing of products, when necessary to protect the public," as allowed by Article 39.3 of the TRIPS Agreement (Article 195, XIV § 2°, Law 9.279/96). The use of undisclosed data by ANVISA is in accordance with the social functions of property (art. 5°, XXIII, CF/88) which impose limits on the procedures through which the owner can exercise his right of property. Accordingly, ANVISA can analyze the undisclosed data to ensure the sanitary security, efficacy, and quality of products. Unless it is necessary to protect the public, ANVISA keeps the data submitted by the originator company confidential and protects it against unfair competition (Article 195, XIV § 2°, Law 9.279/96). The Special 301 Report should not cite Brazil for its TRIPS-compliant protection of undisclosed test data.

Patent Term Extension

The 2024 Special 301 Report raises concerns about the effect of patent pendency in Brazil on the effective patent term.

The TRIPS Agreement does not require patent term adjustments for patent office or other administrative delays. Patent term adjustments significantly delay market entry of generic medicines and restrict access to affordable medicines. While they are allocated ostensibly for "delays" in regulatory review or patent prosecution, variance in review periods is a normal part of each system, and patent terms are not shortened when review proceeds more quickly than usual.

Further, in 2021, the Brazilian Supreme Court ruled a provision of Brazil's Industrial Property Law granting a minimum patent term unconstitutional. Despite this ruling, one pharmaceutical company, Novo Nordisk, reportedly proposed changes to Brazil's Industrial Property Law to provide for patent term adjustment.[24]

USTR should ensure that it does not seek the adoption of measures beyond the minimum requirements of the TRIPS Agreement.

CHILE

Chile remained on the Priority Watch List in 2024.

[24] CNN Brasil, Fabricante do Ozempic se reuniu com Alckmin para pedir sobrevida de patentes (Jan. 3, 2025), https://www.cnnbrasil.com.br/blogs/basilia-rodrigues/economia/macroeconomia/fabricante-do-ozempic-se-reuniu-com-alckmin-para-pedir-sobrevida-de-patentes/

The Special 301 Report states that "pharmaceutical stakeholders continue to raise concerns over the efficacy of Chile's system for resolving patent issues expeditiously in connection with applications to market pharmaceutical products," and raised concerns "over the provision of adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products."

Data Protection

The U.S.-Chile Free Trade Agreement (Chile FTA) provides at least five years of exclusive protection to undisclosed data concerning the safety and efficacy of a pharmaceutical product that utilizes a new chemical entity (Article 17.10.01). Chile enacted Law No. 19.996, which modified Chile's Industrial Property Law and Decree No. 107 from the Ministry of Health in order to implement the obligations established in the U.S.-Chile FTA. Article 89 of the Industrial Property Law goes beyond the obligations of the U.S-Chile FTA. It protects not only data related to the efficacy or safety of the pharmaceutical product from clinical and preclinical trials, but also any other data that is "required" by the authority. The FTA requires exclusivity only for "undisclosed" data. The Chilean law goes beyond the FTA obligations by extending protection to the disclosed data if it "has been the object of reasonable measures to keep it" undisclosed. Article 90 of Law 19.039 defines "a new chemical entity" broadly to cover any active ingredient that has not been previously included in health registrations or authorizations, or that has not been marketed in the national territory prior to the health registration or authorization application. Once again, going beyond its FTA obligations, Chilean law provides data exclusivity for biologics as well, even though biologics are recognized to be distinct from new chemical entities and thus not subject to the same FTA obligations. Footnote 25 of the U.S.-Chile FTA allows parties to maintain their respective systems for protection of test data in cases of new uses or indications. Chile does not provide data exclusivity in such cases. Chile is in compliance with the terms of its U.S. FTA. It is unclear from the language of the 2024 Special 301 Report what further protection the U.S. government perceives Chile is obligated to apply.

INDIA

India remained on the Priority Watch List in 2024.

The Special 301 Report notes concerns regarding the impact of "the procedural and discretionary invocation of patentability criteria under the Indian Patents Act," across different sectors. The report also notes that, with respect to the pharmaceutical sector, the U.S. "continues to monitor the restriction on patent-eligible subject matter in Section 3(d) of the Indian Patents Act and its impacts."

The report also communicates pharmaceutical stakeholder concerns regarding whether India has an "effective system" for test data protection or for the "early resolution of potential pharmaceutical patent disputes."

Patent-Eligible Subject Matter

While past Special 301 reports complained of "narrow patentability criteria" under the India Patents Act, the 2024 Special 301 Report excluded such citations for India, instead focusing on the "procedural and discretionary invocation of patentability criteria." The 2024 report also states that the U.S. "continues to monitor the restriction on patent-eligible subject matter in Section 3(d) of the Indian Patents Act and its impacts."

Article 1.1 of TRIPS provides that "[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." The WTO members can adopt practical solutions to implement TRIPS requirements. Under the India Patents Act, before patentability criteria are applied, India asks whether the subject matter of a patent qualifies as an invention, per its right to define the term under Article 27 of the TRIPS Agreement. Section 3(d) of the Act, which has been criticized in past Special 301 Reports, does not have a "universal application" but rather it could permissibly prohibit any new form of a known substance to be patent eligible when it does not "result in the enhancement of the known efficacy of that [known] substance." Patent applicants have an opportunity to overcome this presumption.

The Supreme Court of India utilized the patent eligibility test under Section 3(d) in its 2013 decision about the anti-cancer drug Glivec. Novartis' claim was required to demonstrate improvement over the known efficacy of imatinib mesylate in order to pass the subject matter eligibility threshold. Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.[25] A thorough examination of Section 3(d) should consider all of the principles clarified in the Supreme Court of India's ruling in this case. The Court upheld the refusal of a patent claim filed by Novartis on a crystalline form of imatinib mesylate on the grounds that imatinib mesylate was anticipated by U.S. Patent No. 5,521,184 and led to a non-inventive finding. The argument of pharmaceutical corporations that Indian patent offices are rejecting patent claims merely on the basis of Section 3(d) is misleading and deliberately intended to ignore the fact that the amendment was introduced to prevent the grant of poor-quality evergreening patents. The definition of invention under Section 3 complies with the TRIPS Agreement. The Special 301 Report should not list India for its TRIPS-compliant interpretation of patent-eligible subject matter.

Data Protection

India is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement. Further exclusivity is a TRIPS-plus provision. Nevertheless, India provides four years of data exclusivity for new drugs under the Drugs and Cosmetics Act of 1940, section 122E.

The TRIPS Agreement allows India to exercise flexibility in providing data protection. The Special 301 Report should not cite India for its TRIPS-compliant protection of undisclosed test data.

Patent Linkage

USTR claims that India still lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. Patent linkage, which is not part of Indian law, is a TRIPS-plus provision. USTR is asking India to provide greater protection than is required by TRIPS. India has sovereign rights to adopt its own standards on patents and pharmaceuticals while maintaining baseline compliance with the minimum standards set forth in TRIPS.

INDONESIA

Indonesia remained on the Priority Watch List in 2024.

[25] Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013, Supreme Court of India.

The Special 301 Report expresses concerns that Indonesia "lack[s] an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products."

Data Protection

Indonesia is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement. Such protection of clinical test data is available under Indonesia's "Law Concerning Prohibition of Monopolistic Practices and Unfair Business Competition," Law n° 5 of 1999.

The TRIPS Agreement allows Indonesia to exercise flexibility in providing data protection. The Special 301 Report should not cite Indonesia for its TRIPS-compliant protection of undisclosed test data.

THAILAND

Thailand remained on the Watch List in 2024.

The Special 301 Report encourages Thailand to "provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products."

Data Protection

Thailand's Trade Secrets Act BE 2545,68[26] creates a legal framework for the protection of trade secrets and other confidential information. It renders the unauthorized use and disclosure of such information to be an actionable offense, punishable by civil and criminal remedies. The Act recognizes that data required to obtain medicine market approval, in whole or in part, may amount to a trade secret in the form of a testing result, or other information regarding its preparation, discovery, or creation. The owner of data can request marketing approval authority to maintain the confidentiality of the data submitted.

On such request, the Food and Drug Administration (FDA) has "the duties to maintain the trade secrets from being disclosed, deprived of or used in unfair trading activities, in accordance with the regulations prescribed by the Minister." (Section 15, Trade Secrets Act B.E. 2545 (2002)). According to the Public Health Ministerial Regulation regarding Trade Secrets (2007), upon such request, the FDA will keep such data confidential for five years from the date of notification. The protection of undisclosed pharmaceutical test data in Thailand prevents unfair commercial use and unauthorized disclosure but permits FDA to rely on such data to assess and approve a subsequent generic application, as allowed by TRIPS Article 39.3. The USTR is asking Thailand to provide greater protection to data than is required by TRIPS. Thailand is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement. The Special 301 Report should not cite Thailand for its TRIPS-compliant protection of undisclosed test data.

TURKEY

Turkey remained on the Watch List in 2024.

[26] Trade Secrets Act B.E. 2545 (2002) (as amended by Trade Secrets Act (No. 2) B.E. 2558 (2015)).

The Special 301 Report states that stakeholders "continue to raise concerns that Turkey does not adequately protect against the unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products and has not done enough to reduce regulatory and administrative delays in granting marketing approvals for products." The USTR also states that U.S. companies "report that Turkey's national pricing and reimbursement policies for pharmaceutical products continue to suffer from a lack of transparency and due process."

The report also urges Turkey "to establish an effective mechanism for the early resolution of potential pharmaceutical patent disputes."

Pharmaceutical Pricing

Some recent comments have focused on Turkish pharmaceutical pricing policies. We note that these are not intellectual property complaints, and unless they allege discrimination or violation of international agreements, they should be outside the scope of the Special 301 Report.

Data Protection

Turkey fulfills its obligations under Article 39.3 of the TRIPS Agreement to provide protection against unfair commercial use of clinical trial data and takes necessary steps not to disclose the contents of these submissions to unauthorized third parties. In addition to protection against unfair commercial use, the Turkish system provides data exclusivity over clinical trial data for six years. The USTR is asking Turkey to provide greater protection to data than is required by the TRIPS Agreement.

Patent Term Extension

The 2024 Special 301 Report raises concerns about regulatory and administrative delays in granting marketing approvals for products in Turkey. The TRIPS Agreement does not require patent term extensions for regulatory or administrative delays. The USTR should not cite Turkey for TRIPS-compliant law and practices.

VIETNAM

Vietnam remained on the Watch List in 2024.

The Special 301 Report calls on Vietnam to clarify its "system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products."

Data Protection

Consistent with the TRIPS Agreement, Vietnamese law allows health authorities to rely on disclosed data to register generic medicines. The TRIPS Agreement provides protection for undisclosed test data submitted to drug regulatory authorities for the purposes of obtaining marketing approval against unfair commercial use.

Vietnamese law protects the undisclosed data and trade secrets that are products of "investment of considerable effort." Intellectual Property Law of Vietnam 2005, Article 128(1). The regulatory agency is obligated to take necessary measures to ensure that submitted data is neither used for unfair commercial purposes nor disclosed, except where the disclosure is necessary to protect the public.

Within five years from the date that marketing approval is granted, a regulatory agency cannot approve subsequent applications in which the same secret data are used without consent of the original data submitter, unless the data are proved to be independently created. Article 128(2). Neither Vietnamese law nor the U.S.-Vietnam Bilateral Trade Agreement (U.S.-Vietnam BTA) provides exclusive control over disclosed data.

The Special 301 Report should not cite Vietnam for its interpretation of protection of undisclosed test data.

We appreciate the opportunity to comment. Thank you.