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Public Citizen Comments for the 2024 Special 301 Review

*Re: 2024 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 30, 2024

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 recent U.S. government policy changes favoring access to medicines, at home and abroad, which we believe should inform the Special 301 process. We review flexibilities protecting public health in the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), including several which are sometimes overlooked and Special 301 should respect. Finally, we provide recommendations based on country listings in recent Special 301 Reports.

The COVID-19 Pandemic and Biden Administration Policy Shift

In May 2021, U.S. Trade Representative Katherine Tai announced the Biden administration’s support for a temporary waiver of certain intellectual property (IP) protections for COVID-19 vaccines. This facilitated text-based negotiations on the proposed waiver and represented a marked change from the Trump administration’s opposition.¹ Special 301 Reports released under the Biden administration have further expressed this change. The 2023 Report restates the administration’s support for the TRIPS waiver, for exceptions to patent rights and compulsory licensing, as well as more explicitly recognizing use of TRIPS flexibilities in accordance with the Doha Declaration to protect public health and access to medicines. The 2023 Report states:

*The United States respects the right of its trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement, including Article 30, Article 31, and Article 31bis, and the Doha Declaration.*²

This is welcome progress.

¹ *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-i-covid-19-trips-waiver>

² 2023 Special 301 Report, at 36, <https://ustr.gov/sites/default/files/2023-04/2023%20Special%20301%20Report.pdf>

Yet recent Special 301 reports still have included a swath of criticisms³ 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. Improvements are needed, and quite possible.

Domestically, the Biden administration has taken increasingly assertive steps to rein in high drug prices. U.S. policy limits the prices Medicare will pay for patented drugs through the Inflation Reduction Act's provisions on price spikes and price negotiation. The Federal Trade Commission is challenging⁴ pharmaceutical patent abuse. In December, the White House announced that reasonable pricing conditions would attach to all new medicines funded by Health & Human Services' Administration for Strategic Preparedness and Response.⁵ President Biden also announced a framework for the federal use of "march-in rights,"⁶ or compulsory licensing for publicly funded medicines. The White House says its policy will:

"... put drug companies on notice if products developed using federal funds are not made available to the public on reasonable terms, including based on price. The proposal would promote the federal government's ability to license a patent — such as those used to create life-saving drugs — to a competitor with the goal of increasing competition and bringing costs down for families."⁷

U.S. policy has changed. The Special 301 Report should continue to change with it. When the U.S. government criticizes developing country TRIPS-compliant policies, it seeks to deter practices that can protect health from taking root. In our view, this practice is inappropriate, and increasingly out of line with U.S. domestic medicines policy and global development goals. 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, to mitigate its negative impact. The following principles can help guide the review process:

I. Countries should not be listed in the Special 301 Report for TRIPS-compliant policies or for using TRIPS flexibilities to safeguard public health and access to medicines.

³ Longstanding complaints 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.

⁴ Stat News, "[FTC says it's on 'an incredible winning streak' against pharma \(statnews.com\)](https://www.statnews.com/2024/01/24/ftc-says-it-s-on-an-incredible-winning-streak-against-pharma/)," Ed Silverman, Jan. 24, 2024.

⁵ *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, The White House Briefing Room: Statements & Releases (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administrati-on-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/>

⁶ *FACT SHEET: Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition*, The White House Briefing Room: Statements & Releases (Dec. 7, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administrati-on-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/>

⁷ *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, The White House Briefing Room: Statements & Releases (Dec. 14, 2023)

- II. **The Special 301 Report should not list countries for declining to adopt U.S. policy preferences, if those countries have no bilateral or international treaty obligation to do so.** Even if the Special 301 Report continues to cite countries for 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 criticized 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. It is inappropriate to list (and thereby sanction) a country for an allegedly non-transparent practice, if the criteria for the listing is itself nontransparent 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 disagreement as a matter of clearly 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 never land a country on the Priority Watch List.
- VI. **At a bare 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, as we would argue has been the case in past Special 301 Reports, then it is manifestly unfair.
- VIII. **The Special 301 Report should refrain from stating stakeholder input as fact.** If including industry complaints related to medicines as part of its process for composing the Report, it should refrain from putting forth these complaints as fact. In cases where comments from industry are at odds with comments from governments and access to medicines advocates, further investigation into industry complaints 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 much 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 legal process. When Special 301 focuses on civil cases or national intellectual property policy, it is calling into question countries' judicial branches and sovereign decisions regarding how best to balance the various public interests at stake. By contrast, when Special 301 critiques criminal counterfeiting and piracy, it is merely drawing attention to inadequate enforcement of that country's laws. This should prove less controversial, and more in keeping with principles of public interest.

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? This is an important and fair question. Yet even where parties or observers disagree, at least they can agree on the underlying laws and the belief that laws should be enforced. The United States is in a 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 taints parallel efforts to challenge 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 constitutes a policy response to these failures. It is sensible that the U.S. government insist its trading partners enforce the laws to which all have agreed.

Below, we describe select flexibilities available under TRIPS to protect public interests.

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.⁸ 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.⁹ WTO members including the

⁸ 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.")

⁹ 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 US and pharmaceutical industry sought to block efforts to increase access to medicines by claiming they were inconsistent with TRIPS).

U.S. subsequently unanimously agreed upon a Declaration on the TRIPS Agreement and Public Health. The Doha Declaration states:

“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.”¹⁰

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.¹¹

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.

The WHO Commission on Intellectual Property Rights, Innovation and Public Health has stated that:

“[t]he TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws, subject to meeting its minimum standards, including the criteria for patentability laid down in TRIPS. Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs. Thus, developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights

¹⁰ Paragraph 4, Doha Declaration, Adopted November 14, 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

¹¹ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (U.S. 2013).

conferred on patent owners and what exceptions to patentability are permitted, provided these are consistent with the relevant articles of TRIPS (for WTO members)."¹²

Compulsory Licenses

Compulsory licenses authorize generic competition with patented drugs, typically to support affordability or timely and diverse supply or to address anticompetitive practices. The “march-in rights” recently embraced by the White House to address pharmaceutical price abuse are a type of compulsory licensing for publicly-funded inventions. 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).

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) includes 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.

Technology Transfer

The Covid-19 emergency demonstrated the importance of technology transfer to improve global pandemic readiness. WHO has embarked on an ambitious mRNA Technology Transfer Program, with technical support provided by the U.S. National Institutes of Health Vaccine Research Center and the Biomedical Advanced Research and Development Authority. The State Department and HHS have stated their support for the project.

Various provisions in WTO agreements, and now many pandemic preparedness consensus statements, cite the need for technology transfer.

¹² WHO Commission on Intellectual Property Rights, Innovation and Public Health (2006), at 21, <https://www.who.int/publications/i/item/9241563230>

During the TRIPS negotiations, technology transfer was considered part of the “grand bargain” between developed and developing countries. Article 7 of TRIPS explicitly states that the protection and enforcement of intellectual property “should contribute to the promotion of technological innovation and to the transfer of and dissemination of technology.”

Article 66.2 of TRIPS requires developed country members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfers to least-developed country (LDCs) members, to enable them to create a sound and viable technological base in their respective economies. However, there is no clarity around how such a transfer can be carried out and if specific WTO measures need to be undertaken to encourage such flows of technology. The lack of implementation of this provision continues to be an outstanding issue in the TRIPS Council. Developed country members should take steps to improve the implementation of Article 66.2.

In the meantime, developing countries have been experimenting with policy incentives and initiatives for technology transfer and knowledge accumulation. Technology transfer remains important for innovation that drives economic development and the advancement of new technologies in developing countries. An element of Special 301 comments on technology transfer appears to be complaints of U.S. multinational companies that they should not be deprived of access to the large and growing emerging markets based on those countries’ regulatory policies and practices. We believe that invoking the power of the United States to monitor another country’s legitimate policies and regulatory practices at the suggestion of private interests damages our global standing. In some cases, it may harm people.

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. *Expressio unius est exclusio 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).¹³ 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.¹⁴

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).¹⁵ The WHO reported that 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 pricing 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.

Injunctions

¹³ Pinto Ido, VH, Designing Pro-Health Competition Policies in Developing Countries, South Centre, (2020), <https://www.southcentre.int/research-paper-125-december-2020/>

¹⁴ Shirin Syed, Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals, Routledge Taylor & Francis, pp.362–378.

¹⁵ 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>

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.¹⁶ 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.¹⁷

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.¹⁸

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”¹⁹

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 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

¹⁶ 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.

¹⁷ Shirin Syed, *Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India*. South Centre, Geneva upcoming 2023.

¹⁸ See, e.g. *Jazz Pharms., Inc., v. Avadel CNS Pharms., LLC*, <https://www.jdsupra.com/legalnews/patent-on-controlling-access-to-drug-3894602/>

¹⁹ 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>

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.²⁰ USTR should take care that its work on injunctions not compromise access to medicine.

The following section will address objections in the 2023 Special 301 Report with implications for access to medicines in developing countries.

2023 Special 301 Report and Implications for Access to Medicines

Compulsory Licensing

Past Special 301 Reports have criticized countries for considering or issuing compulsory licenses for pharmaceuticals. In some cases the criticism was direct. In others, the references were oblique or came in the form of pledges to monitor the situation.

The standard applied to compulsory licensing objections in Special 301 Reports during the Biden administration has undergone a clear and intentional shift. The first three reports under the Biden administration have not cited any countries for issues related to compulsory licensing of pharmaceuticals. Nor have recent reports been used to communicate “pharmaceutical stakeholder concerns” regarding compulsory licensing.

This is an admirable step. Patent licensing saves lives by authorizing affordable generic competition with expensive medications. Licensing is a standard and essential part of any patent system, intended to protect the public interest and defend against abuse. In 2001, all members of the WTO, including the United States, unanimously reaffirmed that IP rules included in the TRIPS agreement “does not and should not prevent members from taking measures to protect public health.” The declaration clarifies

²⁰ Shirin Syed, Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India. South Centre, Geneva (upcoming 2023)

(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).

the scope of several public health flexibilities laid out in the TRIPS Agreement²¹ that Members are entitled to use flexibility measures such as compulsory licenses to prevent or solve their public health crises.

USTR should clarify that U.S. respect for the use of TRIPS flexibilities including compulsory licensing is not limited to pandemics or urgent circumstances, but rather recognizes that flexibilities are available to countries at all times to meet public interest and development needs. Notably, the Biden administration's march-in guidance to federal agencies, for the compulsory licensing of publicly-funded medicines is not limited to urgent circumstances or particular disease areas.

Test Data Protection

In 2023, USTR listed 11 countries for objections related to inadequate protection “against the unfair commercial use, and unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products”. The Special 301 Report appears to list countries for failing to adopt U.S.-style data exclusivity regimes, which grant a term of market exclusivity by preventing generic firms from relying on an originator's test data to gain regulatory approval.

Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals. Pharmaceutical companies may obtain a term of data protection whether or not the product is available in a country. This can include circumstances where a company has not pursued patent approval in that country or where a patent has already expired, if the exclusivity lasts until a later date.

Article 39.3 of the TRIPS Agreement obliges member countries to safeguard "undisclosed test or other data" against "unfair commercial use." In this context, "unfair commercial use" pertains to laws aimed at correcting unfair business practices rather than granting exclusive rights to the data originator. Provisions under Article 39 are designed to regulate the marketplace behavior, not to protect competitive advantages. USTR's interpretation of Article 39.3 of TRIPS as requiring data exclusivity conflicts with the provisions of the Agreement, which amended out the requirement of exclusivity during its drafting process.²² USTR's continued pressure to adopt data protection measures beyond the requirements of TRIPS disregards the policy space included in the Agreement.

USTR should not ask for greater protection of data than what is required by the TRIPS Agreement. When assessing countries for inclusion in the Special 301 Report, USTR should apply the minimum standards provided by Article 39.3 of the TRIPS Agreement, namely protection against “unfair commercial use”. USTR should apply the exceptions in Article 39.3, permitting disclosure so long as steps are taken to ensure data are protected from unfair use and where necessary to protect the public. If USTR is to continue including listings objecting to pharmaceutical data protection, it should specify the specific policies being objected to instead of making vague reference to inadequate “protection against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval.”

²¹ The Doha Declaration on the TRIPS Agreement and Public Health.” World Health Organization. 2011.

http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html

²² UNCTAD, *Resource Book on TRIPs and Development*, (Nov. 30, 2004), p. 523,

https://unctad.org/system/files/official-document/ictsd2005d1_en.pdf

Select examples from the 2023 Special 301 Report

Argentina

“Another ongoing challenge to the innovative agricultural chemical and pharmaceutical sectors is 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 those sectors.”²³

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). Generic competitors do not have access to the confidential information submitted by the applicant.

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 Argentine legislation.²⁴

Brazil

“...pharmaceutical stakeholders remain concerned that Brazilian law and regulations do not 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 although such protection is provided for veterinary and agricultural chemical products.”²⁵

Brazil 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 Brazilian law.

The protection of undisclosed pharmaceutical test data in Brazil prevents unfair commercial use and unauthorized disclosure, but permits “use, by government bodies of test results or other undisclosed data, for market approval of products equivalent to the product for which they were initially presented,” as allowed by Article 39.3 of the TRIPS Agreement. Unless it is necessary to protect the public, the data submitted by the originator company is kept confidential and protected against unfair competition.

Patenting Standards

In 2023, USTR listed four countries for issues related to patentability standards. Listings in the Special 301 Report related to patentability cite countries for “narrow” patentability criteria or “unduly broad” limitations on patent-eligible subject matter. USTR also includes complaints regarding patent examination procedures. USTR continues to urge adoption of broad standards for patentability, applied

²³ 2023 Special 301 Report, at 41.

²⁴ 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

²⁵ 2023 Special 301 Report, at 70.

to a broad range of products, and indicates that categories of pharmaceutical products that are patentable in some jurisdictions should be so in all.²⁶

Patentability criteria and patentable subject matter determine what will be patented and, correspondingly, are important to preserving space for generic competition. Overly permissive standards facilitate patent evergreening, the extension of patent-based monopolies through minor changes with little benefit to innovation. A pharmaceutical patent usually provides exclusive control over not only the product itself, but also over all foreseen subsequent uses. But where there are unforeseen uses, countries can apply their own criteria. European patent law, for example, distinguishes between first and second uses. In order to identify evergreening practices, it is important to distinguish between first and second medical uses.

Article 27 of the TRIPS Agreement provides that countries are free to determine the scope of patentability so long as the invention is new, involves an inventive step, and is capable of industrial application. This is an important flexibility that provides necessary space for countries to implement their own rules surrounding patentability standards. Many countries choose to adopt strict patentability requirements to prevent issuance of poor quality patents and attempts to evergreen patents.

Patents are territorial rights, so protection in one country does not extend to other countries. Patent applicants need to obtain patents from each country or territory to protect their inventions. Whether or not a particular invention can be granted a patent depends on jurisprudences and practices under national patent laws. Countries have sovereign rights to adopt various standards on patentability while nonetheless maintaining baseline compliance with the minimum standards set forth in the TRIPS Agreement. The application of rigorous patenting standards prevents gaming of the patent system and is not a valid reason to list countries in the Special 301 Report.

Select examples from the 2023 Special 301 Report

Argentina

“In addition, a key deficiency in the legal framework for patents remains the unduly broad limitations on patent-eligible subject matter, including patent examination guidelines that automatically reject patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions and requirements that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale. Stakeholders remain concerned about the limits on patentability for biotechnological innovations based on living matter and natural substances in Resolution 283/2015, which differ from the standard in many other countries.”²⁷

Argentinian guidelines do not intend to modify the standards of patentability established by the Argentinian patent law 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

²⁶ 2023 Special Report, Argentina: “In addition, a key deficiency in the legal framework for patents remains the unduly broad limitations on patent-eligible subject matter, including patent examination guidelines that automatically reject patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions and requirements that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale.”

²⁷ 2023 Special 301 Report, at 40.

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.²⁸

Resolution 283/2015 provides guidance for the implementation of Argentina's patent law in assessing patentability with regard to living matter and natural substances. The Resolution clarifies the sufficiency of disclosure in these cases, an effort that can properly assess patent applications with vague or broad claims used to extend monopolies.²⁹

Patent examination guidelines are key to ensuring thorough implementation of patentability criteria. The International Centre for Trade and Sustainable Development (ICTSD), World Health Organization (WHO) and United Nations Conference on Trade and Development (UNCTAD) published draft guidelines to contribute to the improvement of examination of pharmaceutical inventions, particularly in developing countries.

India

"The potential threat of patent revocations, lack of presumption of patent validity, and the narrow patentability criteria under the Indian Patents Act impact companies across different sectors. ... In the pharmaceutical sector, the United States continues to monitor the restriction on patent-eligible subject matter in Section 3(d) of the Indian Patents Act and its impacts."³⁰

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." TRIPS established several rules that were new to many WTO members. The WTO members can adopt practical options or solutions in view of the lack of explicit rules in TRIPS. The definition of "invention" under national law is recognized as a practice.³¹

Section 3(d) falls under Chapter II of the Act, "Inventions Not Patentable," and Section 3, "What Are Not Inventions." 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.³² Section 3(d) does not have a "universal application"³³ 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

²⁸ Arias Eduardo, PPT on "Guidelines for the examination of patentability of chemical-pharmaceutical inventions," INPI, Argentina, 2014.

²⁹ Correa, CM, Special Section 301:US Interference with the Design and Implementation of National Patent Laws, (July 2020), <https://www.southcentre.int/research-paper-115-july-2020/#more-14632>

³⁰ 2023 Special 301 Report, at 56.

³¹ De Carvalho, N.P. (2002) The TRIPS Regime of Patent Rights. Kluwer Law International, London, p.80

³² See, Burcu Kilic & Luigi Palombi, The Question of Patent Eligible Subject Matter and Evergreening Practices, <http://infojustice.org/archives/30314#more-30314>

³³ Srividhya Ragavan, Sean Flynn, Brook Baker, Justifying India's Patent Position to the United States International Trade Commission and Office of the United States Trade Representative, Indian Journal of Intellectual Property Law (2015), <https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1808&context=facscholar>

known efficacy of that [known] substance.”³⁴ Patent applicants have an opportunity to overcome this presumption.

Section 3(d) is a TRIPS-compliant safeguard that protects against patent evergreening. In 2023, the Indian Patent Office based its decision to reject Janssen Pharmaceuticals’ secondary patent applications for a fumarate salt form of its TB drug bedaquiline in part on noncompliance with Section 3(d).³⁵

Further, evidentiary requirements and principles for 3(d) application have previously been stipulated by the Supreme Court of India in its 2013 decision in *Novartis AG vs. Union of India*. In this case, the Supreme Court of India utilized the patent eligibility test under Section 3(d) in its 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.³⁶ Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.³⁷

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.

Patent Linkage

In 2023, USTR listed seven countries over concerns related to a lack of “an effective mechanism for the early resolution of potential pharmaceutical patent disputes,” and/or lack of an effective system for “notifying interested parties of marketing approvals for follow-on pharmaceuticals.” USTR urges countries to provide avenues for patent owners to stop potentially infringing products from reaching the market. This appears to favor a “soft” linkage system in which a party must either create a system to provide notice to a “patent holder” (the authorized holder of marketing approval) of a competing product, claimed under a patent. This also compels expedient resolution in which a party must provide adequate time and opportunity for a patent holder to seek remedies including judicial and administrative proceedings, preliminary injunctions or equivalent effective provisional measures.

Under patent linkage, even spurious patents may function as barriers to generic drug registration. Patent linkage can facilitate abuse, since the financial benefits to patent holders of deterring generic market

³⁴ The following are not inventions within the meaning of this Act:

“(d) 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 or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;”

³⁵ Indian Patent Office Decision In the matter of Patent Application No 1220/MUMNP/2009, https://www.patentoppositions.org/en/drugs/bedaquiline/patent_office_decisions/641c1136d2708f00050ab275

³⁶ See Footnote 31 above, “The following are not inventions within the meaning of this Act...”

³⁷ *Novartis AG v. Union of India and others*, Civil appeal 2706-2716 of 2013, Supreme Court of India.

entry may outweigh risks of penalties. Linkage allows patent holders to obtain de facto injunctions with low standards on assessment of merit, lending itself to abuse which prevents the approval of generics after the original patent has expired.³⁸

The TRIPS Agreement does not require that countries link drug regulatory status with patent status nor notify patent holders of potentially infringing products. Additionally, authorities in developing countries may not have the same resources for preventing abuse as in the U.S. The Special 301 should not list a country for the absence of a policy that it is not bound to uphold.

Select examples from the 2023 Special 301 Report

India

“Pharmaceutical stakeholders also express concerns as to whether India has an effective mechanism for the early resolution of potential pharmaceutical patent disputes, particularly shortcomings in notifying interested parties of marketing approvals for follow-on pharmaceuticals, and view the further restricting in 2019 of transparency of information about manufacturing licenses issued by states as a step backward.”³⁹

Patent linkage, which is not part of Indian law, is a TRIPS-plus provision. USTR is asking India to provide far greater protection than it is required by TRIPS. India has sovereign rights to adopt various standards on patents and pharmaceuticals while nonetheless maintaining baseline compliance with the imprecise, but minimum standards set forth in the TRIPS.

Patent Term Extensions

Special 301 points out delays in patent examination and advocates for patent term extensions. For example, in its highlighting patent application pendency and the “impact on the effective patent term” in Brazil.⁴⁰

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.

Patent adjustments extend the original right-holder’s monopoly, potentially keeping prices high for patients and providers.

TRIPS Article 33 holds that patent protection term shall be at least 20 years from the date of filing. The TRIPS Agreement does not require patent terms extensions for regulatory or administrative delays. USTR should not list countries for refusing to provide patent term adjustments.

³⁸ Son, K, Lopert, R, Gleeson, D, Lee, T. Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States, (2018),

<https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0#Fn4>

³⁹ 2023 Special 301 Report, at 56.

⁴⁰ 2023 Special 301 Report, at 70.

Technology Transfer and Local Working Requirements

In Section I of the 2023 Special 301 Report, under the subsection titled “Forced or Pressured Technology Transfer, Indigenous Innovation, and Preferences for Indigenous Intellectual Property,” USTR notes:

“Right holders operating in other countries report an increasing variety of government measures, policies, and practices that require or pressure technology transfer from U.S. companies. While these measures are sometimes styled as means to incentivize domestic “indigenous innovation,” in practice they disadvantage U.S. companies, effectively requiring them to give up their intellectual property (IP) as the price of market entry. These actions serve as market access barriers and deny U.S. companies reciprocal opportunities to access foreign markets relative to market access provided to foreign companies operating in the United States. Such government-imposed conditions or incentives for technology transfer to domestically owned companies may also introduce non-market distortions into licensing and other private business arrangements, resulting in commercially suboptimal outcomes for the firms involved and for innovation in general. ...

“These government measures often have the effect of distorting trade by forcing U.S. companies to transfer their technology or other valuable commercial information to domestically owned entities. Examples of these policies include: Requiring the transfer of technology as a condition for obtaining investment and regulatory approvals or otherwise securing access to a market or as a condition for allowing a company to continue to do business in the market; ... Requiring the submission of unnecessary or excessive confidential business information for regulatory approval purposes and failing to protect such information appropriately.”⁴¹

This section then goes on to highlight Indonesian pharmaceutical policies, citing reports “that foreign companies’ approvals to market pharmaceuticals are conditioned upon the transfer of technology to Indonesian entities or upon partial manufacture in Indonesia.”⁴²

The TRIPS Agreement makes explicit reference to IP protection and enforcement contributing “to the promotion of technological innovation and to the transfer of and dissemination of technology.”⁴³ Though the Agreement provided no clarity on how this should be carried out in practice. Meanwhile, some developing countries have implemented initiatives to encourage technology transfer. The dissemination of technology and knowledge can encourage innovation, drive development, and promote local production of pharmaceuticals in developing countries.

The Special 301 Report’s characterization of technology transfer and local working policies as a market access barrier and an opportunity for “non-market distortions” may inadequately account for legitimate policies and regulatory practices that intend to promote access to medicines in developing countries. Objections in the Special 301 Report against “requiring the submission of unnecessary or excessive confidential business information for regulatory approval purposes and failing to protect such information appropriately” may not account for the public interest in disclosure of information relating to patents and other exclusivities, pricing, safety and efficacy. Submission of evidence showing patent working increases visibility of potential patent system abuse and can be used as grounds for compulsory licensing in the public interest.

⁴¹ 2023 Special 301 Report, at 24.

⁴² 2023 Special 301 Report, at 25.

⁴³ TRIPS Article 7.

USTR should take steps to encourage legitimate competition and technology transfer by ensuring that IP protection, including trade secrets, does not impede these aims.⁴⁴

Select examples from the 2023 Special 301 Report

Indonesia

“In November 2020, Indonesia amended its 2016 Patent Law through the Omnibus Law on Job Creation to remove requirements for patents to be worked in Indonesia. However, due to a ruling by the Indonesia Constitutional Court that the Omnibus Law was unconstitutional for procedural reasons, in December 2022, Indonesia revoked the Omnibus Law and issued a new regulation to replace it, which Parliament passed in March 2023. The United States continues to urge Indonesia to undertake a more comprehensive amendment to the 2016 Patent Law to address remaining concerns. As Indonesia amends the 2016 Patent Law and other legislation and develops implementing regulations, the United States also urges Indonesia to provide affected stakeholders with meaningful opportunities for input.”⁴⁵

Indonesia's first patent law went into effect on August 1, 1991. The legislature revised the law in 2001 and 2016. Each iteration retained the local working requirement. Article 20 of the amended patent law states that patent holders must “make or use” the patented process in Indonesia. The “use” of such patented processes should support technology transfers, increases in domestic investment or employment.

If the invention is not worked (i.e. the patent owner does not make products or use processes in Indonesia covered by the patent) within 36 months after the grant of a patent, a third party can file an application for a compulsory license (Article 82). The patent owner is not expected to regularly notify the patent office that the patent is being implemented. However, he is expected to prove that his invention has been implemented in the event that an application for a compulsory license is filed by a third party. The Ministry of Law will examine each application and decide whether or not to grant the compulsory license based on the facts of each case.

In November 2020, Indonesia amended the 2016 Patent Law through the Omnibus Law on Job Creation.⁴⁶ This was subsequently revoked and replaced by the 2023 Omnibus Law on Job Creation. Among other things, the Omnibus Bill amended Article 20 and Article 82 of the Patents Act. The amended Article 20 now only requires implementation of the patent in Indonesia, which can be satisfied by importation or licensing of the patented product/process in Indonesia.⁴⁷ Article 82 was also amended to include this broader definition of “use.” The Article maintained that if the patent was not “used” in Indonesia (now including importing or licensing products granted a patent) within 3 years, the patent is open to revocation or compulsory licensing.

⁴⁴ Tundang, RE. US–China Trade War An Impetus for New Norms on Technology Transfer, *Journal of World Trade*, Volume 54, Issue 6 (2020) pp. 943 – 960, <https://doi.org/10.54648/trad2020040>

⁴⁵ 2023 Special 301 Report, at 60–1.

⁴⁶ Lexology, Indonesia: New amendments to IP laws, (Nov. 3, 2020), <https://www.lexology.com/library/detail.aspx?g=099eb106-00aa-45d5-8b1a-f020458cba55>

⁴⁷ Indonesia: Omnibus Law’s Patent Regime Overhaul Raises Questions About Practical Implementation, (Dec. 8, 2023), <https://www.iam-media.com/review/the-patent-prosecution-review/2024/article/indonesia-omnibus-laws-patent-regime-overhaul-raises-questions-about-practical-implementation>

Given the TRIPS negotiating history and the ambiguity of the final TRIPS text, local working requirements are consistent with the flexibilities permitted within the TRIPS Agreement.

Trade Secrets and Business Confidential Information

“Undisclosed information” broadly refers to trade secrets. In addition to persistent citations for inadequate protection “against the unfair commercial use, and unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products,” USTR has also given greater emphasis to trade secret protection more broadly in recent Special 301 Reports. The Report touts the robust trade secret protection provided under the United States-Mexico-Canada Agreement (USMCA), which “includes a number of commitments addressing the misappropriation of trade secrets, including by state owned enterprises: civil procedures and remedies, criminal procedures and penalties, prohibitions against impeding licensing of trade secrets, judicial procedures to prevent disclosure of trade secrets during the litigation process, and penalties for government officials for the unauthorized disclosure of trade secrets.”⁴⁸

The 2023 Special 301 Report also notes:

“Certain data governance regimes (whether proposed or implemented) also raise concerns for intellectual property protection in general and trade secret protection of proprietary data in particular. The United States continues to monitor this trend and its impact on incentivizing innovation and market access.”⁴⁹

The TRIPS Agreement does not require U.S.-style trade secret protection. Companies often claim data is “confidential information” but that does not make them trade secrets. For example, in bilateral deals for COVID-19 vaccines, pharmaceutical companies pressed governments to maintain secrecy around details such as prices and delivery schedules.⁵⁰ Another example is clinical trial data, access to which is vital for understanding the safety and efficacy of drugs.

Further, whether these claims over trade secrets are correct or not, disclosure of data may be necessary to protect the public. To that end, countries are free to advance public interest policies promoting access to information and medicines. For example, in 2013, the European Union adopted an open access policy toward clinical trial data in response to pharmaceutical companies withholding safety information. Pharmaceutical companies proceeded to sue the European regulatory authority over the disclosure of confidential commercial information.⁵¹ Industry pressure against disclosure of commercial information contributes to the rising floor of what is considered trade secret.

TRIPS Article 39.2 provides that “natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices.” The TRIPS Agreement provides flexibility in how countries protect trade secrets.

⁴⁸ 2023 Special 301 Report

⁴⁹ 2023 Special 301 Report, at 22–3

⁵⁰ The New York Times, Governments Sign Secret Vaccine Deals. Here’s What They Hide. (Jan 28, 2021) <https://www.nytimes.com/2021/01/28/world/europe/vaccine-secret-contracts-prices.html>

⁵¹ Mintzes, Lexchin, Santos Quintano, Clinical trial transparency: many gains but access to evidence for new medicines remains imperfect, *British Medical Bulletin*, 116(1), December 2015, pp. 43–53, <https://doi.org/10.1093/bmb/ldv042>

TRIPS Article 39.3, regarding data submitted to governments, states that “Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.” Under the TRIPS Agreement, protection of “undisclosed information” does not entail application of U.S.-style trade secret protection, instead providing exceptions for disclosure where reasonable steps are taken to protect data or where there are public interest considerations.

USTR should employ clear health exceptions when discussing trade secret protection so as not to equate public interest access to undisclosed data with trade secret theft. Public interest policies are not the target of the Special 301 Report and this distinction would clarify that such policies are clearly less objectionable than the prevalence of criminal activity, such as alleged trade secret theft.

Select examples from the 2023 Special 301 Report

India

“Companies also continue to face uncertainty due to insufficient legal means to protect trade secrets in India. The Department Related Parliamentary Standing Committee on Commerce (DRPSCC), in its July 2021 Report titled “Review of the Intellectual Property Rights Regime in India,” recommended “to consider enacting a separate legislation or a framework” and “to examine the relevant and best practices” for protection of trade secrets. However, as of 2023, no civil or criminal laws in India specifically address the protection of trade secrets. Criminal penalties are not expressly available for trade secret misappropriation in India, and civil remedies reportedly are difficult to obtain and do not have a deterrent-level effect. U.S. and Indian companies have identified trade secret protection as a growing concern and expressed interest in India eliminating gaps in its trade secrets regime, such as through the adoption of trade secret legislation that comprehensively addresses these concerns. ...

“While some stakeholders have welcomed the revised version of Form 27, concerns remain with respect to whether Indian authorities will treat as confidential sensitive business information that parties are required to disclose on Form 27. The United States welcomes India’s ongoing domestic consultations regarding the treatment of business confidential information related to working of patents, including the requirements on Form 27, and will continue to engage with India on this issue.”⁵²

Under TRIPS, India is not obligated to implement specific trade secret protection laws. India does not have separate legislation for trade secret protection. India provides an avenue for protection of commercial secrets through contract law.⁵³

In 2023, India’s Department for Promotion of Industry and Internal Trade published proposed amendments to India’s Patent Rules, which included changes to the statement of patent working submitted through Form 27.⁵⁴

⁵² 2023 Special 301 Report, at 57–9.

⁵³ Durkin, A, Sta Maria, PA, Willmore, B, Kapczynski, A. Addressing the Risks That Trade Secret Protections Pose for Health and Rights, 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233014/>

⁵⁴ *Draft Patent (Amendment) Rules*, India Department for Promotion of Industry and Internal Trade, (Aug. 22, 2023), https://dpiit.gov.in/sites/default/files/draft_PatentRules_2023_25August2023_1.pdf

In 2020, the revised Form 27 referenced in the 2023 Special 301 Report, replaced useful information on quantities, value, manufacturing/importing specifics, licensing details and working of inventions with a broad disclosure of information on value and whether the patented invention is manufactured or imported. Under the newly proposed Draft Patent Rules, this information will be removed, further diminishing the only reliable source for information on patent working.⁵⁵

The timely disclosure of detailed information concerning the working of a patent is crucial to understanding whether a patented medicine is meeting the needs of the public. In return for exclusive patent rights, patentees are required not only to disclose the patent to the public but also to work them. When patent holders refuse or fail to show their patents are worked, it hinders the scrutiny of market practices that can foster monopolies, stifle competition, and could be detrimental to the public interest. In order to prevent the abuse of patent rights, section 83 of the Patents Act ensures that a patented invention is being utilized (worked) sufficiently and does not impede protection of public health. Failure to sufficiently work a patent serves as one of the grounds for a compulsory license and revocation of the patent under the Indian Patents Act.

In the past, the Form 27 working statement has played a key role in ensuring access to medicines, including in the grant of India's first medicines compulsory license in 2012.⁵⁶ More recently, in 2017, Form 27 information was used by health groups to show that Otsuka Pharmaceuticals' drug-resistant tuberculosis drug delamanid, was not being made available in India, despite patent claims.⁵⁷ Due to this action, Otsuka filed for registration in India.

We appreciate this opportunity to comment. Thank you.

⁵⁵ See, Public Citizen, Comments to the Government of India on the Proposed Patent Rule Amendments, (Sept. 21, 2023), <https://www.citizen.org/wp-content/uploads/Public-Citizen-Comment-on-Indias-Draft-Patent-Amendment-Rules2023.pdf>

⁵⁶ See, MSF, Background Information on India's First Compulsory Licence, (April 10, 2012), <https://msfaccess.org/background-information-indias-first-compulsory-licence>

⁵⁷ See, TB Online, Health groups call on Indian Government to urgently make life-saving TB drug available, (Jan. 27, 2017), <https://www.tbonline.info/posts/2017/2/1/health-groups-call-government-india-urgently-make-/>