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Comments of Public Citizen for the 2019 Special 301 Review

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

February 7, 2019

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 500,000 members and supporters. Public Citizen’s Access to Medicines Program works with partners across the United States and around the world to make medicines affordable and 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, on patent and other intellectual property (IP) rules to protect access to medicines. This submission proceeds in three parts. First we describe principles that should inform the 301 review process. Then we analyze several provisions of the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), including flexibilities we believe are sometimes overlooked. Finally we discuss countries’ use of TRIPS-compliant policies to advance public interests.

Drug Pricing

High prescription drug prices are a global concern.¹ Most governments recognize that expansive IP exclusivities facilitate manufacturers’ high prices. Many are reexamining how to safeguard public health in their IP regimes.² The Trump administration has noted, correctly in our estimation, that “the pharmaceutical market is almost the opposite of a real market” and that “fundamental changes to this

¹ See e.g., KFF, Public Opinion on Prescription Drugs and Their Prices (2018), <https://tinyurl.com/ydbsaj2e> (noting that 24 percent of Americans reported that they or a family member had not filled a prescription, cut pills in half, or skipped doses due to cost); World Health Organization, Pricing of Cancer Medicines and its Impacts (2019) (noting that high prices for cancer medicines are “impairing the capacity of health care systems to provide affordable, population wide access”) and Reuters, Trump says pharma 'getting away with murder,' stocks slide, January 11 2017, available at <https://tinyurl.com/yb6nqp33> (President-Elect Trump stating that pharmaceutical companies are “getting away with murder” in what they charge the government for medicines).

² See United Nations Secretary-General’s High-Level Panel on Access to Medicines (2016) (noting incoherence between intellectual property policy and health policy, and recommending use of TRIPS flexibilities).

system are necessary.”³ Unfortunately the administration’s focus on challenging lower prices abroad⁴ will not help people in the United States. Instead it risks harming public health and potentially costing people’s lives while alienating U.S. trading partners.

The 2018 Special 301 Report seemed to follow the administration’s aggressive approach by newly criticizing foreign practices designed to make medicines affordable.⁵ The Report reflects “the resolve of this Administration to call out foreign countries and expose the laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for U.S. inventors.” In doing so, the Report notes that:

USTR has been engaging with trading partners to ensure that U.S. owners of IP have a full and fair opportunity to use and profit from their IP, including by promoting transparent and fair pricing and reimbursement systems.⁶

There is no logical reason, let alone evidence, to think that people in the United States will pay less for medicine if the U.S. government works to compel other countries to pay more. Drug companies price to maximize revenue in each market, just like companies in other sectors.⁷ The Department of Health & Human Services (HHS) found that pharmaceutical corporations set prices based not on R&D spending, but rather profit maximization.⁸ There is no evidence to suggest that high prices are rooted in high research and development (R&D) costs that the rest of the world does not sufficiently support. One study found that prescription drug corporations receive 176 percent of global R&D costs from the excess profits they make charging high prices in the United States alone.⁹ What does make pharmaceutical pricing different

³ Alex Azar, Sec. Health and Human Services (HHS), Why drug prices keep going up — and why they need to come down (2019), STAT News, available at <https://tinyurl.com/y8doonjz>.

⁴ See e.g., Council of Economic Advisers, Reforming Biopharmaceutical Pricing at Home and Abroad (2018), available at (“Meaningful reforms would address the root of the problem: foreign, developed nations, that can afford to pay for novel drugs, free-ride by setting drug prices at unfairly low levels, leaving American patients to pay for the innovation that foreign patients enjoy”).

⁵ The 2018 Report generally adopts a more hostile approach. For example, the report includes a new passage challenging countries that “unfairly issue, threaten to issue or encourage others to issue” compulsory licenses. USTR, 2018 Special 301 Report, 12. But 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. It is necessary to respond to HIV/AIDS, cancer, hepatitis and other serious diseases. This marks a shameful departure in U.S. health and trade policy that places people’s lives at risk.

⁶ USTR, 2018 Special 301 Report, 12-13.

⁷ For example, a bipartisan Senate investigation into Gilead’s pricing of the hepatitis C treatment sofosbuvir (brand name Sovaldi) found that “[a] key consideration in Gilead’s decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price.” Senate Finance Committee, The Price of Sovaldi and its Impact on the US Health Care System (2015), available at <https://tinyurl.com/yavopfpv>.

⁸ HHS, Prescription Drugs: Innovation, Spending and Patient Access (2016), available at <http://apps.who.int/medicinedocs/documents/s23128en/s23128en.pdf>

⁹ Nancy Yu et al., *R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, Health Affairs Blog (2017), available at <https://tinyurl.com/ybt5fan4>

from some other sectors is that the patent-based industry operates without typical competitive constraints and, in the United States, without even government negotiating power as a check on price.

The Trade Act 1974 provides no clear mandate for USTR to discuss non-discriminatory pharmaceutical pricing in the Special 301 Report. The Act covers non-intellectual property policies only if they “deny fair and equitable market access to United States persons that rely upon intellectual property protection.” The statute clarifies:

A foreign country denies fair and equitable market access if the foreign country effectively denies access to a market for a product protected by a copyright or related right, patent, trademark, mask work, trade secret, or plant breeder’s right, through the use of laws, procedures, practices, or regulations which—

(A) violate provisions of international law or international agreements to which both the United States and the foreign country are parties, or

(B) constitute discriminatory nontariff trade barriers. (emphasis added)

As Professor Sean Flynn at American University has noted, if pricing policies neither discriminate against American firms nor violate an international agreement, it is inappropriate to include them in Special 301.¹⁰

Foreign practices criticized in the 2018 Special 301 Report are increasingly under active consideration in the United States. The U.S. politics of intellectual property and medicine pricing are changing quickly. 109 members of the House of Representatives so far and a number more senators endorse a bill introduced today that contains a compulsory licensing mechanism for medicines purchased by Medicare.¹¹ Presidential contenders in the Senate support compulsory licensing as a remedy for unreasonable pricing.¹² Confronting a hepatitis C epidemic, 18 members of Congress last year called the federal government to authorize generic competition for unaffordable cures.¹³ State and municipal officials, most acutely confronted by the gap between limited budgets and immense need, have issued similar calls. Louisiana requested the federal government to consider compulsory licensing for hepatitis C cures.¹⁴ In the midst of an opioid epidemic, the Baltimore City Department of Health requested the federal government to use compulsory licensing to increase access to an unaffordable overdose treatment.¹⁵ *The*

¹⁰ See Sean Flynn, Special 301 Post-Hearing Submission, Responding to Questions from the Committee, available at <http://infojustice.org/archives/35820>.

¹¹ The Medicare Negotiation and Competitive Licensing Act of 2019.

¹²S. 102, Prescription Drug Price Relief Act of 2019, available at <https://www.congress.gov/bill/116th-congress/senate-bill/102/cosponsors> (noting that sponsors include Sen. Sanders, Booker, Gillibrand, Harris & Warren).

¹³ Letter from 18 Members of Congress to Secretary Azar Requesting Use of Section 1498 (2018), available at <https://tinyurl.com/ychr5q9y>;

¹⁴ Kaiser Health News, Louisiana Proposes Tapping A Federal Law To Slash Hepatitis C Drug Prices (2017), available at <https://tinyurl.com/y8bx9ljt>; Drug Pricing Lab, Louisiana Budget Allocator (2018), <https://drugpricinglab.org/tools/louisiana-budget-allocator/> (showing the trade-offs faced by States seeking to increase access to high-priced treatment).

¹⁵ Letter from Baltimore City Health Department & Public Citizen to Trump Administration Requesting Use of 1498 to Increase Access to Naloxone, available at <https://tinyurl.com/yb83sp3j>.

New York Times editorialized in favor of the request. The interest of U.S. elected leaders, experts, and states and localities in these policies properly should lead to a softening of U.S. pressure against similar policies abroad.¹⁶

Technology Transfer

The 2018 Special 301 Report identifies several non-IP-related practices that may affect U.S. companies, which are either strategic industrial and R&D policies or regulatory practices, including some designed to support technology transfer. The Report suggests that these are not consistent with international practice and may raise concerns regarding consistency with international obligations. The Report does not spell out those international obligations and their enforceability as a matter of WTO law.

Various provisions in WTO agreements state the need for technology transfer.

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 acquisition, technology transfer and knowledge accumulation. Technology transfer remains important for innovation that drives economic development and the advancement of new technologies in developing countries. A significant element of the 2018 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.

¹⁶ Past Special 301 Reports have criticized countries for considering or issuing TRIPS-compliant pharmaceutical compulsory licenses. In some cases the criticism is direct. In others, the references are oblique or come in the form of pledges to monitor the situation. In each case, the mere reference is consequential; a form of sanction and an inappropriate warning against countries exercising established rights to promote public health. Public Citizen believes this is inconsistent with the Special 301 Report’s stated commitments and with United States commitments under WTO rules.

Principles

We believe the Special 301 Report should be discontinued, absent a radical shift in values. Nevertheless the balance of our comments addresses specific Special 301 practices that can and should be improved, to mitigate its negative impact. Taken together, the following principles should guide the review process:

1. The Special 301 Report should omit reference, whether express or implied, to countries' TRIPS-compliant policies that advance a public interest.
2. 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.¹⁷
3. 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.¹⁸
4. The Special 301 Report should not address ancillary policies such as pharmaceutical pricing unless those policies are specifically alleged to be discriminatory.
5. The Special 301 Report should treat public policy disagreement as a matter of clearly lower priority than criminal activity.¹⁹
6. 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. And even if the Special 301 Report subjects wealthy countries to criticism for TRIPS-compliant public interest policies, developing countries should be given greater leeway.
7. Criticism in the Special 301 Report should be accompanied by express and clearly articulated criteria.²⁰

Below, we describe the flexibilities available under TRIPS to protect public interests. Then, we apply these principles to analyze intellectual property issues in several countries.

¹⁷ 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.

¹⁸ The TRIPS Agreement provides not only substantive standards, but also standards for transparency and due process. It is clearly 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.

¹⁹ 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.

²⁰ 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.

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.²¹ Members are not obliged to adopt standards that are more extensive or onerous than the ones articulated in the TRIPS Agreement. The Agreement leaves countries room to adopt national policies that favor public interest, competition, foreign direct investment, 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.” The principles enumerated in Article 8 must be borne in mind during the national law legitimization process. Article 8 facilitates specific actions taken by the members regarding policy issues such as protecting public health or adopting measures against abuse of IP. Therefore, it is regarded as a tool that can potentially provide a basis for broader exceptions than Article 7.

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.²² WTO members including the 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.²³

²¹ 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.”)

²² SECTION27 and TAC, Standing Up For Our Lives: A History of the South African Access To Medicines Movement (2018), available at <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).

²³ Paragraph 4, Doha Declaration, Adopted November 14, 2001, available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

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.²⁴

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

The Doha Declaration states that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”²⁵ Procedurally, countries are not obligated to engage in prior negotiation with patent holders if licenses are designated for public non-commercial 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

²⁴ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (U.S. 2013).

²⁵ Doha Declaration, Paragraph 5(b).

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.

Country Recommendations

ARGENTINA

Argentina remained on the Special 301 Priority Watch List in 2018. The United States Trade Representative (USTR) asserts that “Pursuant to a highly problematic 2012 Joint Resolution establishing guidelines for the examination of patents, Argentina summarily rejects patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions, including in the United States”.

The USTR also says: “To be patentable, Argentina requires that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale. Industry also asserts that Resolution 283/2015, introduced in September 2015, also limits the ability to patent biotechnological innovations based on living matter and natural substances. These measures have interfered with the ability of companies investing in Argentina to protect their IP and may be inconsistent with international norms.”

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

Patent Examination Guidelines

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 imprecise but minimum standards set forth in the TRIPS Agreement.

In 2012, Argentina adopted guidelines for examining patent applications related to pharmaceutical products and processes (Joint Regulation Nos. 118/2012, 546/2012, and 107/2012, issued on May 2, 2012 by the Argentine Patent Office together with the Ministries of Industry and of Health; published in the Official Gazette on May 8, 2012). The guidelines 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. A proper and TRIPS-compliant application of patentability standards would prevent the grant of the “poor quality” secondary patents, and it would 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.”²⁶

Patent examination guidelines are key to ensuring thorough implementation of patentability criteria. 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.

The Special 301 Report should not cite Argentina for its TRIPS-compliant patent examination guidelines.

Data Protection

The USTR is asking Argentina to provide far greater protection to data than is required by the TRIPS Agreement. Argentina is not part of any regional or bilateral treaty that requires exclusivity over clinical trial data. 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).

According to Section 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 (Sections 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 Argentine legislation.²⁷

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

²⁶ Arias Eduardo, PPT on “Guidelines for the examination of patentability of chemical-pharmaceutical inventions,” INPI, Argentina, 2014

²⁷ See, Argentina – Certain Measures on the Protection of Patents and Test Data (WT/DS196)

BRAZIL

Brazil remained on the 2018 Special 301 Watch List. The USTR expressed concerns about the National Sanitary Regulatory Agency's (ANVISA) "duplicative" review of pharmaceutical patent applications. Furthermore, the USTR referenced "the April 2017 agreement between Brazil's National Institute of Industrial Property (INPI) and ANVISA that should expedite the processing of such applications." The USTR "will closely monitor the impact of ANVISA's new role as they implement the agreement."

The USTR also claims that "(...) while Brazilian law and regulations provide for protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for veterinary and agricultural chemical products, they do not provide similar protection for pharmaceutical products."

Transparency

Article 1.1 of the TRIPS Agreement 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." Members of the WTO are allowed to use principles and rules of their domestic legal systems for implementing their TRIPS obligations. This option has also been made available in several other provisions such as Article 16.1, Article 41.4, and Article 44.2. The members can introduce practices and change existing ones, provided that the new practices comply with the principles and provisions of the Agreement. Brazil created new practices aimed at implementing its TRIPS obligations to examine pharmaceutical patents.²⁸

After a request for examination is filed, patent applications that are filed for pharmaceutical products or processes are forwarded from the INPI directly to ANVISA for examination based on public health issues.

On May 13, 2013, ANVISA published an internal Orientation Guide detailing how pharmaceutical product and process patent applications are screened by its examiners. According to the Orientation Guide, a patent application falling within any of the therapeutic categories in Ordinance 1284/2010 will be subject to substantive examination on the merits by an ANVISA patent examiner.

ANVISA may deny "prior consent" for patent applications that are contrary to public health. ANVISA, prior to the Patent Office, analyzes patent applications involving pharmaceutical/chemical (i) products that have previously been rejected by the Agency, and thus present health risks; and (ii) compounds that are of interest to support Brazil's National Health System's access to medicines policy or a pharmaceutical care program, and that may not meet the patentability requirements set forth by the Patent Act (see Article 3, amending Patent Act Art. 229-C, and Article 5, amending Article 7 of Law No. 9782 of 26 January 1999). If a pharmaceutical product comprises or if a pharmaceutical process results in a substance prohibited for use in Brazil, then the application will be deemed to present a health risk.

In April 2017, the INPI and ANVISA reached an agreement on the "prior consent" procedure. The new procedure provides greater transparency and predictability and clarifies uncertainties around the double examination of pharmaceutical patent applications. The Resolution No.168/2017 established that

²⁸ Nuno Pires de Carvalho, *The TRIPS Regime of Trademarks and Designs*, Kluwer Law International, pp. 79-81

ANVISA's assessment would be limited to public health issues, and an application would be considered to be contrary to public health if it involves a health risk; i.e., if it refers to a substance whose use has been prohibited in the country.

According to the Resolution, the applicant should be notified if ANVISA issues either a preliminary opinion against the grant of a patent application or any other request. The applicant then has 60 days to file any arguments or documents to support the approval. The Resolution also established an appeal process for the ANVISA's decisions before ANVISA's Board of Directors. Upon the receipt of ANVISA's final health risk assessment, the INPI would make its final decision on the patent application. ANVISA's decision is not binding on the INPI and is considered a third-party observation.

If the INPI unreasonably delays the examination of a patent application for more than a period of 10 years, the term of the patent is 10 years from its grant.

The INPI and the ANVISA created an Interinstitutional Articulation Group (IAG) to share technical information and harmonize their understanding on pharmaceutical patents. The IAG's board is composed of three members from each public body. Researchers and public officials, as well as IP practitioners and representatives of pharmaceutical companies, can be invited to participate in the meetings to share their knowledge and experience. The first meeting was held in March 2018 with wide attendance both from the public and private sector. The IAG is an important step to overcome a pharmaceutical patent backlog.

The Special 301 Report should recognize Brazil's efforts and not cite Brazil for its TRIPS-compliant patent examination standards.

Data Protection

The USTR is asking Brazil to provide far greater protection to data than is required by the TRIPS Agreement. Brazil is not part of any regional or bilateral treaty that requires exclusivity over clinical trial data. 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.

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, § 2°, Law 9.279/96).

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

CHILE

Chile remained on the 2018 Special 301 Priority Watch List.

The USTR continued to raise concerns “regarding a number of longstanding implementation issues with the IP provisions of the United States-Chile Free Trade Agreement (Chile FTA).”

The USTR urged Chile “to make effective its system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products and to provide 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 Exclusivity

The U.S.-Chile Free Trade Agreement (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.²⁹ Chile enacted Law No. 19.996, which modified Chile’s Industrial Property Law³⁰ and Decree No. 107 from the Ministry of Health³¹ 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.³² 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.³³ 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, the 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. free-trade agreement. It is unclear from the language of the 2018 Special 301 Report what further protection the U.S. government perceives Chile is obligated to

²⁹ Article 17.10.01

³⁰ Articles 89 to 91 of the Industrial Property Law

³¹ Adopted December 18 2008, and available at

http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/DS_MINSAL_107-2010.pdf

³² *Cuando el Instituto de Salud Pública o el Servicio Agrícola y Ganadero requieran la presentación de datos de prueba u otros que tengan naturaleza de no divulgados, relativos a la seguridad y eficacia de un producto farmacéutico o químico-agrícola que utilice una nueva entidad química que no haya sido previamente aprobada por la autoridad competente, dichos datos tendrán el carácter de reservados, según la legislación vigente.”* Emphasis added.

³³ *“La naturaleza de no divulgada se entiende satisfecha si los datos han sido objeto de medidas razonables para mantenerlos en tal condición y no son generalmente conocidos ni fácilmente accesibles por personas pertenecientes a los círculos en que normalmente se utiliza el tipo de información en cuestión”.*

apply.

The Special 301 Report should not cite Chile for its U.S.-Chile FTA-compliant interpretation of data exclusivity standards.

Patent Linkage

The U.S.-Chile FTA requires parties to make the identities of registration applicants available to patent holders. Parties shall not grant marketing approval prior to expiration of the patent term, unless by “consent or acquiescence” of the patent holder (Article 17.10.2(b & c)). Black’s Law Dictionary defines “acquiescence” as “tacit or passive acceptance; implied consent to an act ... failure to make any objections ... binding legal effect is given to silence and inaction.”

Under the Chilean regulation, patent holders have the opportunity to pursue injunctions and block generic marketing approval after receiving information from the Institute of Public Health regarding “similar” registration applications (which includes the identities of applicants).³⁴ Logically, if a patent holder does not make use of this opportunity, he or she can be said to have acquiesced to marketing approval. Nothing in the FTA prevents Chile from assessing the merits of a patent holder’s claim in court. This merit analysis is important to prevent abuse; for example, to determine, at least as a matter of first impression, whether the claimed patent is indeed relevant to the generic seeking marketing approval.

Suggesting that Chile is obligated to implement a system with the same characteristics as the American patent linkage system is not consistent with the requirements of the FTA provisions, in particular Article 17.11.1.³⁵ An automatic injunction system would also be inconsistent with Chile’s continental law tradition. The Chilean legal system requires that for an injunction to be decreed, there must exist a “*periculum in mora*” (danger in delay), “*fumus boni iuris*” (some indication that there is a basis for what is claimed) and “*periculum in damni*” (danger of damages). It would constitute arbitrary discrimination to grant pharmaceutical patent holders the right to claim automatic injunctions while requiring other industries to present evidence. This kind of arbitrary discrimination is explicitly prohibited under Article 19.2 of the Chilean constitution.

Chile’s laws with regard to data exclusivity and pharmaceutical product marketing approval in relation to patents comply with the terms of the U.S.-Chile FTA.

The Special 301 Report should not cite Chile for its U.S.-Chile-compliant interpretation of patent linkage standards.

³⁴ Article 273 of the Chilean Civil Procedural Code and Article 106 of the Industrial Application Law allow for the pursuit of injunctions.

³⁵ “*Each Party shall ensure that procedures and remedies set forth in this Article for enforcement of intellectual property rights are established in accordance with its domestic law. Such administrative and judicial procedures and remedies, both civil and criminal, shall be made available to the holders of such rights in accordance with the principles of due process that each Party recognizes as well as with the foundations of its own legal system*”. Emphasis added.

COLOMBIA

Colombia was placed on the Priority Watch List in 2018 with an Out-of-Cycle Review focused on certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA) and monitoring the implementation of Colombia's National Development Plan (NDP).

Compulsory licenses

In Colombia, it is estimated that 400,000 people live with hepatitis C. In 2017, under the leadership of the Pan American Health Organization (PAHO) and the Colombian Ministry of Health, the country put into place the first strategic purchase of just 1,225 hepatitis C treatments (250 sofosbuvir, 725 sofosbuvir/ledipasvir and 250 daclatasvir).³⁶ Colombia's health care system still cannot afford to pay for the new hepatitis C cures.³⁷ Confronting a declared crisis in its general health system financing, the Colombian ministry decided to assess the burden of hepatitis C treatment in the country and determine whether there was sufficient evidence to support a public health declaration on compulsory licenses. Some pharmaceutical companies sought to intimidate Colombia, including by threatening Colombia's Organization for Economic Co-operation and Development OECD accession. In their Special 301 2018 submissions, the Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) called for Colombia to be placed on the priority watch list and given an out-of-cycle review.

Separately, in 2016 protracted talks broke down with the Swiss company Novartis over the price of the cancer drug Glivec. It was priced in Colombia at nearly double the country's GDP per capita. The Colombian health minister issued a declaration of public interest. This was only a declaration highlighting need and conditions; Colombia did not issue a compulsory license. Following the public health declaration, pharmaceutical companies applied pressure including threats to launch an investment dispute.³⁸

Leaked letters showed that after meeting with U.S. government officials, Colombian diplomats felt that U.S. financial assistance for the Paz Colombia peace initiative may be put at risk if they were to proceed with a compulsory license for Glivec.³⁹ More than 50 years of war in Colombia has claimed 8 million victims and 220,000 deaths. Colombia should not have been pressed to choose between support for peace and

³⁶ Colombia bought 1220 medicines (750 Harvoni, 250 Daklinza and 250 Sovaldi). "Strategic purchasing in the medicines to Hepatitis C in Colombia: equity and health financing innovations,"

<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/strategic-purchasingmedicineshepatitis-c-colombia.pdf>

³⁷ The price for 12 weeks treatment based on a combination drug of Sovaldi (sofosbuvir) + Daklinza (daclatasvir) was 136.000.000 COP (US\$48,960.00) in 2016.

³⁸ A Swiss company, Novartis threatened Colombia with an ISDS dispute:

https://www.publiceye.ch/en/media/pressrelease/compulsory_licensing_in_colombia_leaked_documents_show_aggressive_lobbying_by_novartis/

³⁹ "Colombia Fears U.S. May Reject Peace Plan To Protect Pharma Profits", 05.11.2016
https://www.huffingtonpost.com/entry/colombia-gleevec_us_5733d4ece4b077d4d6f224ee

its people's health. Eventually, the government announced that it would reduce the price of Glivec but stopped short of issuing a compulsory license.

Colombia's exploration of compulsory licensing and better pricing policies for high-priced cancer and hepatitis C products has attracted pressure from the patent-based industry despite an absence of credible assertions that Colombia acts against any of its treaty obligations. These pressure tactics put lives at risk.

The U.S. government should not criticize Colombia for domestic drug pricing policies or for considering compulsory licenses, both of which are consistent with their international obligations. Colombia has no obligation to consult with the U.S. government regarding either policy option.

INDIA

India remained on the Priority Watch List of 2018.

The U.S. expresses concerns about India's patent system: "India has yet to take steps to address longstanding patent issues that affect innovative industries. Companies across different sectors remain concerned about narrow patentability standards, the potential threat of compulsory licensing and patent revocations, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act. Further, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive Reporting requirements."

The USTR also states: "In the pharmaceutical sector, Section 3(d) of the India Patents Act restricts patent eligible subject matter in a way that poses a major obstacle to innovators seeking timely entry into the Indian market and 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."

The USTR extends its critique beyond India's IP laws and practice and criticized even the mere positions India took in multinational forums. The USTR says "(...) as well as positions that India supports and voices in multilateral fora on IP issues, continue to generate skepticism about whether India is serious about pursuing pro-innovation and -creativity growth policies."

Patent-Eligible Subject Matter

Recent criticisms of Indian patent rules tend to take Article 3(d) as an impermissible fourth patentability criterion. This is not how the Indian law is structured. 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 (see "Antecedents," above).⁴⁰ Section 3(d) could permissibly prohibit any new form of a known substance. Instead, India allows new forms to be patent-eligible where they "result in the enhancement of the known efficacy of that [known] substance."⁴¹ Patent

⁴⁰ See, Burcu Kilic & Luigi Palombi, "The Question of Patent Eligible Subject Matter and Evergreening Practices", <http://infojustice.org/archives/30314#more-30314>

⁴¹ The following are not inventions within the meaning of this Act:

applicants have an opportunity to overcome this presumption.

The Supreme Court of India utilized the patent eligibility test under Section 3(d) in its recent 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.⁴² Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.⁴³

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.

Moreover, it should be noted that Article 1.1 of the TRIPS Agreement 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 TRIPS Agreement 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.⁴⁴ The definition of invention under Section 3 complies with the TRIPS Agreement. The Special 301 Report should not cite India for its TRIPS-compliant interpretation of patent-eligible subject matter.

Compulsory Licensing

In 2012, India granted a compulsory license for sorafenib, a cancer medicine patented by Bayer (and marketed as Nexavar). India has since deferred multiple compulsory license requests.

The TRIPS Agreement allows countries to grant compulsory licenses on grounds of their choosing. Section 84 of India's patent law is narrower, providing three separate grounds for compulsory licensing, any one of which suffices to support a license. The sorafenib license makes use of each of the three grounds. Some observers have raised concerns about the availability of a working failure grounds (or local manufacturing provisions) in the Indian rules. However, as a threshold matter, if working failure were objectionable as a matter of policy or law, India's other grounds—price and the reasonable requirements of the public,

“(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;”

⁴² *Ibid.*

⁴³ Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013, Supreme Court of India.

⁴⁴ De Carvalho, N.P. (2002) *The TRIPS Regime of Patent Rights*. Kluwer Law International, London, p.80

including health requirements—are clearly TRIPS-compliant and, indeed, are precisely the point of the WTO’s Doha Declaration and compulsory licensing in the public interest. The sorafenib license is valid and TRIPS-compliant on one of several theories, leaving little room for criticism.

➤ *Working Failure Is a Permitted Grounds for Licensing Under TRIPS*

Does the availability of working failure as grounds for a compulsory license in Indian law nevertheless merit criticism? No. 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.

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.

➤ *Compulsory Licensing Does Not Diminish Patent Rights*

Article 27 of TRIPS provides that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention ... and whether products are imported or locally produced.” It is important to note, however, that a compulsory license does not diminish patent rights. Local working is not a requirement for obtaining, or even maintaining, a patent in India, but rather failure to work a patent is grounds for government authorization of others to use the patented technology in exchange for payments of royalties to the patent holder.

Governments grant patents and, similarly, retain the sovereign authority to determine under what circumstances a patent should be licensed or publicly used to promote public interests. The right of the state to license third parties or make use of a patented invention is reserved in the grant of the patent—it is part and parcel of the patent right. Patent holders are not guaranteed that the state will not make use of a patent or otherwise license it. Rather, under TRIPS, the rights of patent holders in case of compulsory license include procedural protections (right of appeal and in some cases prior negotiation) and adequate remuneration (except where a license remedies anti-competitive practices). Notably, the sorafenib license affords a 7 percent royalty (revised up from an initial 6 percent royalty) to Bayer, which is high by industry averages.

Licenses are issued with enumerated conditions, and the patent holder retains the patent and its rights. We note that no compulsory licenses have been issued since 2012.

The Special 301 Report should not cite India for its TRIPS-compliant compulsory licensing practices.

Pharmaceutical pricing

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

Nevertheless, it should be noted that the National Pharmaceutical Pricing Authority, which enforces the Drug Price Control Order, covers only off-patent branded generic medicines. This is in line with public policy of making drugs affordable for people in India, where 40 million people are forced into debt every year due to out-of-pocket expenses on health care, 80 percent of which are for payments to procure medicines.

India's leadership on global access to medicines

The USTR condemns India for its leadership on global access to medicines, saying “India’s vocal encouragement and propagation of initiatives that promote the erosion of IP around the world, especially in the pharmaceutical sector, sends a concerning signal about India’s commitment to strengthening its IP regime.”

India’s vocal participation at international fora and support for access to medicines policies are excellent examples that showcase the India’s commitment to saving the lives of those with preventable and curable diseases.

We note that this is outside the scope of the Special 301 process and further than USTR has gone in past Reports. USTR should not criticize India for its active participation at international fora and discussions to improve global access to medicines for all. The U.S. government also should be a vocal supporter of global access to medicines.

INDONESIA

Indonesia remained on the 2018 Special 301 Priority Watch List.

The USTR expresses concerns that “Indonesia also lacks 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.”

The USTR also says: “In addition, revisions to Indonesia’s Patent Law in 2016 have raised concerns, including with respect to the patentability criteria for incremental innovations; local manufacturing and use requirements; the grounds and procedures for issuing compulsory licenses; (...).”

Data Protection

Indonesia is not part of any regional or bilateral treaty requiring exclusivity over clinical trial data. Indonesia 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 Indonesia's "Law Concerning Prohibition of Monopolistic Practices and Unfair Business Competition."⁴⁵

Therefore, since the Indonesian law on data protection is consistent with its existing international obligations, and the TRIPS Agreement allows for 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.

Local Working Requirement

Indonesia's first patent law went into effect on August 1, 1991. Local working requirements have formed part of Indonesia's patent system since then. The legislature has revised the law three times in 1991, 2001, and most recently in 2016. All three iterations have retained the local working requirement.

Article 20 of the amended patent law states that patent holders must "make or us[e]" the patented process in Indonesia. Further, the "use" of such patented process should support technology transfers, increases in domestic investment or employment.

This long-standing requirement in Indonesian law has been subjected to fierce criticism from the U.S. government since the early years of TRIPS. This criticism is mostly based on misconceived claims by the U.S. pharmaceutical industry that the local working requirement was not consistent with the TRIPS Agreement and that the WTO Dispute Board ruled out the local working requirement.

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.

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 21(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."

⁴⁵ Law n° 5 of 1999. UNCTAD "Development Dimensions of Intellectual Property in Indonesia: Access to Medicines, Transfer of Technology and Competition," 2011, available at http://unctad.org/en/docs/diaepcb2011d6_en.pdf

In July 2018, Indonesia introduced implementing regulations to provide more clarity on the working requirement. According to the regulations, a patent owner who fails to work his or her invention can file an application to the Ministry of Law to postpone the obligation for a maximum of five years. Further postponement (i.e., beyond the maximum period of five years) may be granted upon request.

Indonesia has a right to have local working requirements. These are not new provisions and they are consistent with the flexibility permitted within the TRIPS Agreement.

The 2018 Special 301 Report should not cite Indonesia for its TRIPS-compliant patent law and practice.

Patent-Eligible Subject Matter

Article 4(f) of Indonesian Patent Law is not structured as an impermissible fourth patentability criterion as it is claimed by the industry. Article 4(f) falls under the definition of invention. Before patentability criteria are applied, Indonesia asks whether the subject matter of a patent qualifies as an invention, per its right to define the term (the TRIPS Agreement Article 27, *see* “Antecedents” above).⁴⁶ Article 4 (f) could have permissibly prohibited any new form of a known substance. Instead, Indonesia allows new forms to be patent-eligible where they “result in increased efficacy and significant differences related chemical structures of the compounds are already known.” Patent applicants have an opportunity to overcome this presumption.

Moreover, it should be noted that Article 1.1 of the TRIPS Agreement 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 TRIPS Agreement 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 the TRIPS Agreement. The definition of “invention” under national law is recognized as a practice.⁴⁷ The definition of invention under Article 4(f) complies with the TRIPS Agreement.

The Special 301 Report should not cite Indonesia for its TRIPS-compliant interpretation of patent-eligible subject matter.

MALAYSIA

Malaysia has not been on the Special 301 Watch List since 2012.

In 2017, PhRMA and BIO requested in their Special 301 submissions that Malaysia be treated as a Priority Foreign Country for its “decision to expropriate patent rights” of Gilead Sciences. PhRMA said Malaysia exhibited a “blatant disregard of patent rights.”

In the 2018 Special 301 Report, the USTR announced that it will conduct an Out-of-Cycle Review of Malaysia to “consider the extent to which Malaysia is providing adequate and effective IP protection and enforcement, including with respect to patents.”

⁴⁶ Kilic, *supra* 15

⁴⁷ Carvalho, *supra* 19, p.80

Government use of a patent

The prevalence of *hepatitis C* virus (HCV) infection in *Malaysia* has been estimated at 2.5% of the adult population (as many as 500,000 people).⁴⁸ The disease burden is high and is projected to rise steeply over the coming decades due to limited levels of antiviral treatment and high treatment costs. Sofosbuvir (Sovaldi), when used with another drug, can virtually cure most cases of hepatitis C in 12 weeks with few side effects. The list price of Sovaldi set by the patent holder, Gilead Sciences, in the U.S. is \$84,000⁴⁹ per treatment and RM 300,000⁵⁰ (\$ 71,300 USD) in Malaysia. The price was beyond the reach of many Malaysians, as the household income per capita is \$4,571.17.⁵¹ At that price, only 500-550 patients per year had received treatment.

In 2014, Gilead Sciences signed non-exclusive licensing agreements⁵² with seven India-based generic pharmaceutical manufacturers to produce and sell Sofosbuvir in 91 least developed countries, where people cannot even afford malaria pills at \$1 per treatment.⁵³ Most of the middle-income countries where the vast majority of hepatitis C patients live were excluded from the licenses. Malaysia was one of those 41 middle-income countries. The Malaysian government engaged in negotiations with Gilead to be included in the licenses and reduce the price. Gilead was unwilling to reduce the price below \$12,000 for a complete course of 12-weeks treatment, and negotiations failed in 2016.

In July 2017, on World Hepatitis Day, the World Health Organization called on countries to turn their commitment into action to tackle hepatitis C. At the time, only one out of ten people living with hepatitis C had access to treatment.⁵⁴

Gilead's failure to register the drug in many of the 105 countries within the voluntary license's territory delayed or obstructed access to hepatitis C treatment.⁵⁵ As of July 2017, Gilead has registered Sofosbuvir in only 27 countries⁵⁶. Malaysia was not one of them.

⁴⁸ Malaysian AIDS Council Press Statement, 2017, available at <http://www.mac.org.my/v3/malaysian-aids-council-welcomes-government-move-to-issue-compulsory-license-on-lifesaving-hepatitis-c-medicines/>

⁴⁹ How an \$84,000 drug got its price: 'Let's hold our position ... whatever the headlines', The Washington Post, December 1, 2015 https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/?utm_term=.66492505a65c

⁵⁰ Malaysian AIDS Council Press Statement, 2017, available at <http://www.mac.org.my/v3/malaysian-aids-council-welcomes-government-move-to-issue-compulsory-license-on-lifesaving-hepatitis-c-medicines/>

⁵¹ Malaysia Household Income per Capita, available at <https://www.ceicdata.com/en/indicator/malaysia/annual-household-income-per-capita>

⁵² Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries, 2014, available at <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>

⁵³ Azzi Momenghalibaf, "License to Deceive? A Big Drug Company's Smokescreen on Hepatitis C", 2014, available at <https://www.opensocietyfoundations.org/voices/license-deceive-big-drug-company-s-smokescreen-hepatitis-c>

⁵⁴ Dr Gottfried Hirnschall, WHO's Director of the HIV Department and Global Hepatitis Programme, Eliminate hepatitis: WHO, 2017, available at <http://www.who.int/mediacentre/news/releases/2017/eliminate-hepatitis/en/>

⁵⁵ Hepatitis C - Not even close, Médecins Sans Frontières, available at <https://www.msfaccess.org/hep-c-not-even-close>

⁵⁶ <http://www.gilead.com/~media/files/pdfs/other/registration/sovaldi%20registration%20%20071917.pdf>

After almost a year of consultations with the relevant government bodies, the Malaysian parliament and other stakeholders, the Malaysian government authorized government use of hepatitis C treatment patents. The Health Ministry was aiming to import generics for RM1.000 (\$256.41 per patient).⁵⁷

Just before the Malaysian government authorization in September 2017, under public pressure to widen access to Sofosbuvir, Gilead announced on Twitter that the scope of licenses would be extended to cover Malaysia. There was no official announcement or notification to the Malaysian government.

Gilead's tweet seems to have been strategic – aimed to anticipate Malaysia's government use decision. By doing so, Gilead hoped to avoid reputational damage. However, governments do not act on tweets. The Cabinet decision to make use of an invention was taken long before Gilead's tweet. For two years during the price negotiations, Gilead neither reduced the price nor applied for regulatory approval of Sofosbuvir in Malaysia.

Under the TRIPS Agreement, governments can make use of patents to facilitate access to affordable medicines. In compliance with the TRIPS Agreement, Section 84 of the Malaysian Patents Act provides that

“in case of national emergency or public interest in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government (...)

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit a patented invention.”

Under TRIPS, public non-commercial use of a patent does not require prior negotiation with the patent holder. A government agency or a third party (e.g. a generics company) can be authorized to import or manufacture a generic version of a patented drug limited to use in public programs and hospitals. Government use does not override a patent. Rather, the right reserved by the government to make use of an invention is embedded in the initial grant of every patent.

Malaysian government use authorization covers only public hospitals and clinics. It is only for importation and not for local manufacturing. It does not override or nullify the patent rights of Gilead. Gilead is free to compete and sell Sovaldi and retains the exclusive privilege to do so in the private market.

The government use authorization has resulted in significant cost savings for the Malaysian public health system and saved the lives of many patients. It brought the cost of the 3-month treatment (sofosbuvir + daclatasvir) down to less than RM1,200 (US\$300). It has enabled the government to roll out free treatment in 23 public hospitals, starting in March 2018. More than 1,500 patients have been treated so far. Access to affordable treatment has also strengthened the government's resolve to screen and treat thousands more patients. The low affordable price of HCV treatment secured by Malaysia has become

⁵⁷ Health Minister Datuk Seri Dr S. Subra-maniam, Urgent action needed on Hepatitis C, 2017, available at <https://www.thestar.com.my/opinion/columnists/global-trends/2017/07/31/urgent-action-needed-on-hepatitis-c-its-not-acceptable-that-500000-msians-are-infected-with-the-dise/>

the benchmark price for many other middle-income countries seeking access to affordable HCV treatment.

Had Malaysia acted on Gilead's tweet and stopped the government use procedure, it would have taken at least two years (and possibly many lives) for Malaysian patients to access the medicines (due to drug registration procedures). The price still would have been high – as seen in the case of other countries with voluntary licenses. The price for Sofosbuvir is US\$240 in Indonesia, US\$220 in Myanmar, and US\$570 in Vietnam for a month supply.⁵⁸

The U.S. government should not criticize Malaysia for making use of an invention to protect public health. It is consistent with Malaysia's international obligations and long-established U.S. policy.

THAILAND

Thailand remained on the Special 301 2018 Watch List, after an Out-of-Cycle Review between September and December 2017 resulted in moving Thailand from the Priority Watch List to the Watch List.

The USTR encouraged "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 2545,⁵⁹ 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 offence, 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."⁶⁰ 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.

⁵⁸ India is getting sofosbuvir at very low prices (US\$55) because of intense generic competition [http://www.worldhepatitis summit.org/docs/default-source/presentations/strategic-direction-2/generic-daas-\(giten-khwairakpam\).pdf?sfvrsn=2](http://www.worldhepatitis summit.org/docs/default-source/presentations/strategic-direction-2/generic-daas-(giten-khwairakpam).pdf?sfvrsn=2)

⁵⁹ Trade Secrets Act B.E. 2545 (2002) (as amended by Trade Secrets Act (No. 2) B.E. 2558 (2015))

⁶⁰ Section 15, Trade Secrets Act B.E. 2545 (2002)

The USTR is asking Thailand to provide far greater protection to data than is required by TRIPS. Thailand is not part of any regional or bilateral treaty that requires exclusivity over clinical trial data. Thailand 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 Thai law.

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

TURKEY

Turkey remained on the Special 301 2018 Watch List. The USTR states, “U.S. pharmaceutical companies continue to complain that Turkey does not adequately protect against the unfair commercial use of pharmaceutical test data and has not done enough to reduce regulatory and administrative delays to granting marketing approvals for products.”

Data Exclusivity

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 far greater protection to data than is required by the TRIPS Agreement.

The originator’s data submitted to the licensing authority is protected for six years starting from the date of first registration of the product in the European Union–Turkey Customs Union (sub-paragraph of Article 9 of the Regulation on Licensing of Human Medicinal Products dated January 19, 2005, numbered 25705). During the exclusivity period, the manufacturers of similar products are prevented from relying on the data in their license applications.

Applications for new doses, formulations, and presentations of chemical entities do not include any new indications other than their known therapeutic indications, and thus the test data associated with them are considered part of the initial authorization and are not granted an additional period of data exclusivity. However, a new medicinal product that offers therapeutic uses different from the known therapeutic uses of each of its components in its compound form may benefit from six years of data exclusivity protection.

It is important to recognize that Turkey provides six years of exclusivity for pharmaceutical products including biologics. Turkey is not part of any regional or bilateral U.S. treaty requiring exclusivity over clinical trial data. Turkey is obligated only to protect undisclosed clinical trial data against unfair commercial use and disclosure under Article 39.3 of the TRIPS Agreement.

Six years’ data exclusivity is a regulatory policy that instructs the Ministry of Health not to approve generic drugs. It is widely used by brand-name pharmaceutical companies to bypass the balances and limitations of patent law. Thus, it should not outlast patent protection. To prevent longer monopoly protection for originator companies, Turkey ends the exclusivity period when the patent term ends.

Turkey 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 Agreement and EU-Turkey Custom Union Agreement.

The Special 301 Report should not cite Turkey for its beyond-TRIPS-compliant law and practices on data exclusivity.

Pharmaceutical pricing

Some recent complaints 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.

VIETNAM

Vietnam was placed on the Special 301 2018 Watch List. The Report states that Vietnam should clarify “[its] 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 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.

Data exclusivity is a separate rule, not required by the TRIPS Agreement that provides exclusive rights over test data to the originator company and prevents regulatory authorities from relying on test data for approval of generic medicines.

Vietnamese law protects the undisclosed data and trade secrets that are products of “remarkable investments.” 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.⁶¹ 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.⁶² Neither Vietnamese law nor the U.S.-Vietnam Bilateral Trade Agreement (U.S.-Vietnam BTA)⁶³ provides exclusive control over disclosed data.

⁶¹ See, Article 128(1) Intellectual Property Law of Vietnam 2005.

⁶² See, Article 128(1) Intellectual Property Law of Vietnam 2005

⁶³ See, Article 9.5. US-Vietnam Bilateral Trade Agreement, Chapter II, Intellectual Property Rights “If a Party requires, as a condition for approving the marketing of pharmaceutical or agrochemical products, the submission of undisclosed test or other data, the origination of which involves a considerable effort, the Party shall protect such data against unfair commercial use. In addition, each Party shall protect such data against disclosure, except where necessary to protect the public”

It is clear that Vietnamese IP law is compliant with the TRIPS Agreement and the U.S.-Vietnam BTA. Vietnamese law protects against the unfair commercial use and authorized disclosure of undisclosed test data, but it does not protect disclosed data, for the purposes of obtaining marketing approval for pharmaceutical products.

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

Conclusion

We appreciate this opportunity to comment. Public Citizen invites USTR and all agencies engaged in the Special 301 Report process to make meaningful U.S. commitments, including commitments to protect public health, by omitting express or implied references to countries' public interest policies that comply with international obligations.