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Comments of Public Citizen for the 2018 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 8, 2018

Public Citizen submits the following comments in response to the request by the Office of the United States Trade Representative (USTR) for “written submissions from the public concerning foreign countries’ acts, policies, or practices that are relevant to the decision whether a particular trading partner should be identified under Section 182 of the Trade Act.”

Public Citizen is a national, 501(c)3 nonprofit consumer advocacy organization founded in 1971 to represent consumer interests in Congress, the executive branch and the courts. We have 400,000 members and supporters. Public Citizen’s Global Access to Medicines Program works with partners worldwide to improve health outcomes through use of pharmaceutical cost-lowering measures including generic competition.

The following comments are drawn from our experience providing technical assistance to public agencies, particularly in developing countries, with regard to patent and other intellectual property (IP) rules, to protect access to medicines. We begin with principles that we believe should inform any 301 review. We describe several relevant provisions of the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), including flexibilities we believe are sometimes overlooked. Then we proceed to discuss several countries’ use of TRIPS-compliant flexibilities to advance public interests.

Principles

Public Citizen takes note of commitments articulated in past Special 301 Reports that “the United States respects a trading partner’s right to protect public health and, in particular, to promote access to medicines for all,” and “the United States respects its trading partners’ rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement.”¹ We support these commitments, which echo the WTO’s unanimous 2001 Doha

¹ See pages 24 of the 2017 Special 301 Report, *available at*: <https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF>.

Declaration on the TRIPS Agreement and Public Health.

Nevertheless, past Special 301 Reports have cited countries for exercising public health rights and other flexibilities enshrined in the TRIPS Agreement and Doha Declaration.

For example, 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.

Invoking the power of the United States to monitor another country's legitimate health policies, at the suggestion of U.S. corporations, makes our country appear petty. In some cases, it may even communicate cruelty. Worse yet, it can harm efforts to protect people's health and save lives.

The Trade Act does not require an exercise akin to the Special 301 Report. Too frequently, the Special 301 Report is used to inappropriately assert U.S. political influence, at the behest of private interests, to undermine public health measures in developing countries. For these reasons, we believe the Special 301 Report should be discontinued in its entirety. Nevertheless, the balance of our comments addresses specific Special 301 Report practices that can and should be improved, to mitigate its negative impact.

General commitments to principles asserted by the United States in the Special 301 Report are not necessarily meaningful unless borne out by the Report's review of specific country practices. Public Citizen invites the USTR and all agencies engaged in the Special 301 Report process to make meaningful U.S. commitments to protecting public health, by omitting expressed or implied references to countries' public interest practices that comply with international treaty obligations.

We suggest the following principles to support this reform:

The Special 301 Report should omit reference, whether express or implied, to countries' TRIPS-compliant policies that advance a public interest. TRIPS-compliant policies should not influence a country's watch list status.

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 United

States expressly and specifically requiring the same.

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 clearly inappropriate to list (and thereby sanction) a country for an allegedly non-transparent practice, if the criteria for the listing is itself non-transparent and not articulated.

The Special 301 Report should not address ancillary policies such as pharmaceutical pricing unless those policies are specifically alleged to be discriminatory. The Trade 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.” As pointed out by Sean Flynn at American University,² if such a policy does not discriminate against American firms or violate an international agreement, it is not appropriate to mention it in the 301 Report.

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.** The 301 Report should not conflate policy disagreement and allegedly criminal activity.

At a bare minimum, even if the Special 301 Report subjects wealthy countries to criticism for TRIPS-compliant public interest policies, developing countries should be given greater leeway.

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.

We apply these principles to our analysis regarding intellectual property issues in the several countries noted below.

Antecedents: The TRIPS Agreement

The WTO’s TRIPS agreement reserves to signatory nations certain sovereign rights and flexibilities. TRIPS allows for diversity in the methods of implementing its provisions. Members are not obliged to adopt standards that are more extensive or onerous than the ones articulated in the TRIPS Agreement. TRIPS leaves countries room to adopt national policies that favor

² See Sean Flynn, Special 301 Post-Hearing Submission, Responding to Questions from the Committee, *available at* <http://infojustice.org/archives/35820>.

public interests, competition, encouragement of foreign direct investment (FDI), technology transfer, and stimulation of local innovation.

The ‘objectives’ introduced by TRIPS Article 7 as well as the “principles” within Article 8 accommodate factors that are necessary for the interpretation and implementation of the rights and obligations under the Agreement. These provisions are as effective as the other provisions of the TRIPS Agreement which indicate its object and purpose.

The objectives of Article 7 explicitly reference “the promotion of technological innovation and ... the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge.”

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.

At the 2001 WTO Doha Ministerial Conference, WTO Members, including the United States, unanimously agreed upon a Declaration on the TRIPS Agreement and Public Health.³ 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.*⁴

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 the realization of the right to health.

Patent-Eligible Subject Matter and Patentability Criteria

Article 27.1 of the TRIPS Agreement employs the substantive notion of “invention”:

³ Adopted November 14, 2001, and available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (emphasis added).

⁴ Doha Declaration, Paragraph 4.

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 is the ability of a WTO Member to determine for itself what constitutes an "invention."

The United States excludes certain subject matter from its definition of invention. For example, the U.S. Supreme Court has ruled that isolated DNA is not an invention, and therefore not patent eligible subject matter.⁵

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 is separate from, and precedes, the analysis of whether a claimed invention satisfies these 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 either term means. Nothing prevents WTO members from applying rigorous patentability criteria to ensure high-quality patents.

Compulsory Licenses

The Doha Declaration states:

*Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*⁶

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 only requires "protection of undisclosed test data on new chemical entities, (the collection of which involved considerable effort) against disclosure unless steps are taken

⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (U.S. 2013).

⁶ Doha Declaration, Paragraph 5(b).

to ensure that the data is protected against “unfair commercial use.” In other words, it is a 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 was placed on the 2017 Special 301 Priority Watch List. The 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, limits the ability to patent biotechnological innovations based on living matter and natural substances, including biologics (aka vaccines). These measures limit the ability of companies investing in Argentina to protect their IP rights and appear inconsistent with international practice.”

The USTR “remains concerned that Argentina does not appear to be providing adequate protection against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.”

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 TRIPS.

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), that advise patent examiners in assessing 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—so-called evergreening 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” evergreening patents, and it would promote the objectives introduced by TRIPS Article 7, as well as the principles within Article 8.

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.”⁷

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

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.

⁷ Arias Eduardo, PPT on “Guidelines for the examination of patentability of chemical-pharmaceutical inventions,” INPI, Argentina, 2014

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.⁸

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

BRAZIL

Brazil remained on the 2017 Special 301 Watch List. The USTR expressed concerns about the National Sanitary Regulatory Agency's (ANVISA) review of pharmaceutical patent applications and claimed that "the National Sanitary Regulatory Agency's (ANVISA) duplicative review of pharmaceutical patent applications has been a longstanding concern because it lacks transparency, exacerbates delays of patent registrations for innovative medicines, and has prevented patent examination by National Institute of Industrial Property (INPI)". Furthermore, the USTR referenced the "agreement between INPI and ANVISA, which is intended to expedite the examination of pharmaceutical patent applications and redefines ANVISA's role in that process" and expressed its interest in "reviewing the agreement and will closely monitor the impact of ANVISA's new role as they implement the agreement".

The USTR also claimed 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, similar protection is not provided 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 aiming at implementing its TRIPS obligations to examine pharmaceutical patents.⁹

⁸ See, Argentina – Certain Measures on The Protection Of Patents and Test Data (Wt/Ds196)

⁹ Nuno Pires de Carvalho, The TRIPS Regime of Trademarks and Designs, Kluwer Law International, pp. 79-81

Patent applications that are filed for pharmaceutical products or processes are forwarded, after a request for examination is filed, 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 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. 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 Special 301 Report should not cite Brazil for its TRIPS-compliant patent examination standards.

Data Protection

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 TRIPS Article 39.3.

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 with which the owner can exercise his right of property. Accordingly, ANVISA can analyze the undisclosed data in order 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).

CANADA

Canada remained on the 2017 Special 301 Watch List. The USTR expressed concerns about “the lack of clarity and the impact of the heightened utility requirements for patents that have been imposed by Canadian courts.” The USTR urged Canada to engage meaningfully with affected stakeholders and the U.S. on patent utility issues.

The USTR also says: “With respect to pharmaceuticals, the United States continues to have serious concerns about the availability of rights of appeal in Canada’s administrative process for reviewing regulatory approval of pharmaceutical products.” However, absent an allegation of discrimination or violation of an international agreement, the Special 301 Report should address only intellectual property, not ancillary public policies. The administrative process for reviewing regulatory approval of pharmaceutical products is not an intellectual property issue and is therefore outside of the scope of the Special 301 review.

Utility Requirement

NAFTA, in parallel with TRIPS,¹⁰ requires that patents be granted when prototypical standards for patentability, novelty, inventive step, and industrial applicability, are satisfied. NAFTA and TRIPS do not specify how these criteria should be defined and applied. Given the latitude of NAFTA and TRIPS provisions in not providing any definitions, parties can determine when an invention is deemed to be capable of industrial application or useful. Parties have sovereign rights not only to adopt varying patentability standards but to change and reinterpret them. This view has long standing support; the same terms in TRIPS are viewed as being ones that parties can self-define, and policy makers and scholars have in fact recommended that parties do so.¹¹

¹⁰ Although NAFTA was signed in 1992, three years before TRIPS, NAFTA Article 1709 (1) on patentability standards is based on the Article 27 of the “Dunkel Draft” from the GATT Secretariat which was presented in Geneva in December 1991. The text then became the Final Act of the TRIPS Agreement. Margaret Smith, *Patent Protection for Pharmaceutical Products In Canada - Chronology Of Significant Events*, Law and Government Division (March 30, 2000), available at <http://publications.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

¹¹ *E.g. Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS*, available at <https://www.mpg.de/8132986/Patent-Declaration.pdf>; UNCTAD-ICSTSD Capacity Building Project on IPRs, *Resource*

Canada is well within its rights under NAFTA and TRIPS to set its own industrial applicability and disclosure requirements. Under Section 2 of Canada's Patent Act, a patent is considered invalid if it has no utility "either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do." Canada requires utility to be demonstrated or soundly predicted at the time of the patent application. In the instance where the patent specification demonstrates utility, a mere scintilla of utility will suffice. However, where the patent specification instead makes a mere "promise" of future utility, then the utility will be measured against that promise and the evidence disclosed to support it.

The Supreme Court of Canada established the "sound prediction" test in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77. The "sound prediction" test recognizes likely utility when there is not enough evidence to prove it directly. The test creates a guide that increases efficiency in drafting patent applications and reduces litigation over ambiguity. In the meantime, it aims to balance the public interest in early disclosures of new and useful inventions even before the utility has been fully verified by tests. However, since the patent applicant is not able to prove immediate utility directly, the applicant has a heightened obligation to disclose underlying facts and his or her line of reasoning in support of the prediction of utility.

For example, in 2010 and 2011, the Federal Court of Canada invalidated Eli Lilly's Strattera (olanzapine) and Zyprexa (atomoxetine) patents for lack of utility. In each case, the court held that there was no sufficient evidence at the time of filing to demonstrate or soundly predict the promise of the patent. For instance, in the olanzapine case, the issue was purely factual: whether the compound possessed the advantages claimed in the patent specification at the time of filing. The court ruled that it did not: "one could not reasonably infer from the available evidence that olanzapine would treat schizophrenia patients in the clinic in a markedly superior way. Its antipsychotic effect was, at best, comparable to that of conventional antipsychotics."

The question is whether, at the time of the filing, the patent specification provided sufficient evidence to soundly predict that it would deliver the utility promised. Unfortunately, "a hope that these statements might someday turn out to be true" is not enough to secure another 20 years of exclusivity. The patent system is not designed to grant monopolies on the basis of hunches, guesses, or hopes. It is also not designed to allow actual verification of the alleged invention after the fact; data obtained and submitted to the patent office after filing cannot cure the application's defect.

The rationale behind this rule includes discouraging races to the patent office based on inadequate data. After all, patent filing and successful applications may halt competing research efforts that might otherwise have yielded better results. Canada's patent system instead requires a sound prediction of utility based on data at the time of filing.

Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement (2005); Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*, WHO-UNCTAD-ICTSD (2007); World Health Org. et al., *Promoting Access To Medical Technologies And Innovation: Intersections Between Public Health, Intellectual Property And Trade* 57 (2012); Chan Park et al., *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 41–46 (U.N. Development Programme 2013); Carlos M. Correa, *Patent Rights, in Intellectual Property and International Trade: The TRIPS Agreement* 189, 198–200 (2d ed. 1998); Straus, *Implications of the TRIPS Agreement in the Field of Patent Law*, From GATT to TRIPS – The Agreement on TRIPS 187 (Beier & Schriker eds., 1996).

Patent law is both statutory and judge-made. Neither TRIPS nor NAFTA prohibits patent law from changing over time; evolution in the law is an inevitable feature of any legal system. Courts routinely interpret and reinterpret patent rules. For example, in the U.S., the judiciary took the initiative in allowing the patenting of living organisms, and the legislature followed the judiciary's lead. Since the Supreme Court decision, the Canadian judiciary has held a patent invalid if a skilled reader, looking at the specification as a whole, would find that the patent does not live up to the promise that was claimed on the filing date.

Nothing in TRIPS or NAFTA should be interpreted as an intention to incorporate, by reference or implication, a single harmonized patentability standard. The inclusion of two alternatives—industrial applicability and utility—proves that the drafters of TRIPS and NAFTA deliberately left the definitions and interpretation of utility to the discretion of its member countries.

The notion of a patent's promise is particularly relevant for secondary patenting. In the case of "new use" and "selection patent," a promised utility is the only consideration that the public receives in exchange for 20 years of exclusivity.

A promise of a patent is not a recent standard applied by Canadian courts. It has been a well-established rule in Canadian jurisprudence and legal literature for at least sixty years that if a patent promises a certain utility; such utility must be attainable by the claimed invention. The notion of a patent's promise has deep historical roots going back to British law. It is not uniquely Canadian, either. It shares common elements with the laws of the U.S., Australia, New Zealand, and Europe. It has sound policy objectives, including the prevention of pharmaceutical patent evergreening.

In 2017, the Supreme Court of Canada struck down the "promise of the patent" in favor of a far lower standard. The decision puts an end to 60-year-old Canadian case law, and dramatically alters the balance between encouraging innovation and promoting the use of and dissemination of new technology.

The Special 301 Report should not cite Canada for its TRIPS-compliant interpretation of utility standards.

CHILE

Chile remained on the 2017 Special 301 Priority Watch List. The USTR urged Chile "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" and "to implement an effective system for addressing patent issues expeditiously in connection with applications to market 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.¹²

Chile enacted Law number 19.996, which modified Chile's Industrial Property Law¹³, and Decree number 107 from the Ministry of Health¹⁴ 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 by protecting 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.¹⁵ The FTA requires exclusivity only for "undisclosed" data. The Chilean law goes beyond the FTA obligations by extending protection to disclosed data if it "has been the object of reasonable measures to keep it" undisclosed.¹⁶

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 which 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 2017 Special 301 Report what further protection the U.S. government perceives Chile is obligated to 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."

¹² Article 17.10.01

¹³ Articles 89 to 91 of the Industrial Property Law

¹⁴ Adopted December 18 2008, and available at http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/DS_MINSAL_107-2010.pdf

¹⁵ "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.

¹⁶ "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".

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).¹⁷ 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 17.11.1.¹⁸

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.

COLOMBIA

Colombia remained on the 2017 Special 301 Watch List. USTR also selected Colombia for Out-of-Cycle review. Colombia’s exploration of compulsory licensing and better pricing policies for high-priced cancer and hepatitis C products has attracted pressure tactics 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. Public Citizen has provided technical assistance to Colombian organizations since 2008 toward a robust and TRIPS-compliant access politics. In light of recent leaked documents and updates out of Colombia, and their importance to the global politics of access to medicines, we intend to supplement the below

¹⁷ Article 273 of the Chilean Civil Procedural Code and Article 106 of the Industrial Application Law allow for the pursuit of injunctions.

¹⁸ “*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.

information with analysis of continuing events in Colombia during our in-person testimony at USTR later this month, and through post-hearing written comments.

Compulsory licenses and pricing

On June 15, 2016, the Colombian Minister of Health announced that he would proceed with a public interest declaration to lower the price of Glivec (imatinib), a lifesaving leukemia drug marketed by Swiss company Novartis. Glivec was priced in Colombia at nearly double the country's GDP per capita, and Novartis persistently rejected the Colombian government's offer to negotiate a price reduction for the treatment. The public interest declaration was a step toward a compulsory license on the patent held by Novartis, facilitating generic competition and reducing prices.

The U.S. Ambassador to Colombia Kevin Whittaker publicly stated soon after that granting a compulsory license is something that Colombia should discuss with the U.S. first. The drug has generated more than \$47 billion in global sales for Novartis and already faces generic competition in the U.S.

In fact, Colombia's Ministry of Foreign Relations and its Ministry of Health each received letters in late April from their Washington, D.C. embassy describing pressure from U.S. Senate Finance Committee staff and USTR. The leaked letters expressed concern that Colombian interests in the U.S. might be at risk if the country issues the compulsory license for imatinib, including U.S. support for Paz Colombia, the Obama administration's signature \$450 million aid initiative to support the Colombian peace process.

On December 20, 2016, the Colombian government announced that it will reduce the price of Glivec, but stopped short of issuing a compulsory license.

More than 50 years of war in Colombia has claimed the lives of more than 220,000 people. Since 2000, more than 8 million victims have registered with the Colombian government's National Unit for the Integral Attention and Reparation of Victims (Unidad para la Atención y Reparación Integral a las Víctimas). Violent conflict within the country has internally displaced more than 6 million Colombians and has resulted in the forced disappearance of more than 25,000 Colombians since 1985.

Colombia should have not been put in a position to choose between support for peace and its people's health. 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. Nor does Colombia have an obligation to consult with the U.S. government regarding either policy option. Notably, Novartis is not even an American company, which on its own would seem to vitiate grounds for a 301 review of the pricing decision under the terms of the Trade Act.

INDIA

India remained on the Priority Watch List of 2017.

The U.S. expressed concerns about Section 3(d) of India's Patent Act. "Despite positive statements and initiatives upon which the Modi Administration has embarked, the pace of reform has not matched high-level calls to foster innovation and promote creativity. India has yet to take steps to address longstanding patent issues that are affecting innovative industries. These include the application of narrow patentability criteria, challenges faced by the pharmaceutical industry due to Section 3(d) of the India Patents Act."

The USTR also states: "Innovative companies remain concerned about the potential threat posed to their IP through the possible use of compulsory licensing and patent revocation, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act. Across all industries, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements. In the pharmaceutical and agricultural chemical sectors, India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products."

The U.S. "intends to continue to engage with India on these and other IP matters through the primary channel of the Trade Policy Forum."

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, 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 could have also 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.

For instance, some life-saving drugs are patented but not marketed in India. This is evident in the case of delamanid (sold under the brand name Delyba), a life-saving anti-tuberculosis drug. The patent for delamanid—its intermediate, formulation and combination—is held by Otsuka. Yet no regulatory submission has been filed for the drug, even though it was first patented in 2010. This long regulatory submission lag time poses a hurdle to people living with MDR and XDR-TB in accessing this drug, which is often viewed as salvage therapy in the worst cases. (Please see the attached letter sent by the drug-resistant TB (DR-TB) survivors, networks of people living with HIV, and public health organizations to the Indian Ministry of Health about delamanid). This is one of the many examples of how failure to work a patent can contribute to the loss of lives by denying them the access to life-saving treatments.

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

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. 3(d) falls under Chapter II of

the Act, “Inventions Not Patentable,” and Article 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 Article 27 right to define the term (see “Antecedents,” above).¹⁹

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.”²⁰ Patent applicants have an opportunity to overcome this presumption.

The Supreme Court of India utilized the patent eligibility test under Section 3(d) in its 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.²¹ Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.²²

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, as a result of weak application of inventive step/obviousness standards by patent offices around the world.

Moreover, it should be noted that 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.²³ The definition of invention under Section 3 complies with TRIPS.

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

¹⁹ See, Burcu Kilic & Luigi Palombi, “The Question of Patent Eligible Subject Matter and Evergreening Practices”, <http://infojustice.org/archives/30314#more-30314>

²⁰ The following are not inventions within the meaning of this Act:

²⁰“(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.”

²⁰“*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;”

²¹ Ibid.

²² Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013. Supreme Court of India.

²³ Carvalho, p.80

Pharmaceutical pricing

Some recent complaints have focused on Indian pharmaceutical pricing policies. We note that these are not intellectual property complaints, and unless they allege discrimination, 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 healthcare, 80 percent of which are for payments to procure medicines.

INDONESIA

Indonesia remained on the 2017 Special 301 Priority Watch List. The USTR expressed 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 “ remains concerned about a range of market access barriers in Indonesia, including requirements for domestic manufacturing and technology transfer for pharmaceuticals and other sectors.”

Data Protection

Indonesia is not part of any regional or bilateral treaty requiring exclusivity over clinical trial data. Indonesia is only obligated 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.”²⁴

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.

²⁴ 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.

Article 20 of the amended patent law states that patent holders must “make or use” 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 TRIPS and that the WTO Dispute Board ruled out the local working requirement.

The drafting history of TRIPS 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.

TRIPS 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’ inclusive of 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 the TRIPS agreement, 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 TRIPS 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.”

Indonesia has a right to have local working requirements. These are not new provisions and they are consistent with the flexibility permitted within TRIPS. The 2018 Special 301 Report should not cite Indonesia for its TRIPS-compliant patent law and practice.

MALAYSIA

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

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)³¹. 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. The hepatitis C medicine sofosbuvir, priced at around RM 300,000³² (\$ 71,300 USD), is beyond the reach of many Malaysians as the household income per capita is \$4,571.17³³. So far only 500-550 patients per year are receiving treatment.

In 2014, Gilead Sciences signed non-exclusive licensing agreements³⁴ 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 treatment³⁵. 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 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. At the time, only one out of ten people living with hepatitis C had access to treatment³⁶.

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)³⁷.

Just before the Malaysian government authorization in September 2017, under public pressure to widen access to sofosbuvir, Gilead added Malaysia to the territories covered in its licensing

³¹ 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/>

³² *Id.*

³³ Malaysia Household Income per Capita, available at <https://www.ceicdata.com/en/indicator/malaysia/annual-household-income-per-capita>

³⁴ 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>

³⁵ 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>

³⁶ Dr Gottfried Hirschall, 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/>

³⁷ 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/>

deal. Health advocates in Malaysia found that Gilead's licenses would not be as effective as Malaysia's own imports plan at reducing price and expanding access.³⁸

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. The patent owner can still sell the medicine, and retains the exclusive right to sell to private providers and hospitals.

In 2003, following the adoption of the Doha Declaration, Malaysia authorized use of patents for antiretrovirals (ARVs) to treat HIV. The monthly treatment cost for government hospitals and clinics fell 81% from US\$315 to US\$58. This lower cost encouraged the Ministry of Health to offer free treatment for HIV patients, which increased from 1,500 to 4,000 patients³⁹.

Malaysia's authorization should enable more hepatitis C patients to receive treatment and at the same time reduce the cost of treating complications arising from hepatitis C. The U.S. government should not criticize Malaysia for its TRIPS-compliant public health policy.

PERU

Peru remained on the Special 301 2017 Watch List. The U.S. continues to request that Peru clarify its protections for biotechnologically derived pharmaceutical products.

Data Exclusivity

The U.S.-Peru Trade Promotion Agreement (U.S.-Peru TPA) provides exclusivity to a product that utilizes a new chemical entity. Small molecule drugs are referred to as new chemical

³⁸ See, Global Hepatitis C Report 2017, World Health Organization, 2017, *available at* <http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf>

³⁹ Martin Khor, Patents, Compulsory Licences and Access to Medicines: Some Recent Experiences, Third World Network, 2007 <https://www.twn.my/title2/IPR/pdf/ipr10.pdf>

entities (NCEs). Large molecule drugs that are derived from living cells or organisms, such as animal or human blood, are called biologics or biopharmaceuticals. The General Directorate of Medicines, Inputs, and Drugs (DIGEMID) differentiates between new chemical entities and biologics. Peru does not provide exclusivity to biologics, and it does not have any obligation to do so, since biologics are treated differently from chemically synthesized pharmaceutical products both in relevant U.S. statutory and regulatory language and in regulatory pathway.⁴⁰

Moreover, in the European Union-Peru/Colombia Trade Agreement, Article 231 specifically provides for biologics data exclusivity. Yet Peru is expressly exempted from this provision in footnote 72. The European Union and Peru, at least, seem to have a clear understanding that Peru is not obligated to provide data exclusivity for biologics.⁴¹ Similarly, the provision on biologics exclusivity is suspended in the Trans-pacific Partnership Agreement after the U.S. withdrew from the Agreement on January 2017.

Peru provides data exclusivity for NCEs, and thereby complies with its FTA obligations.

The Special 301 Report should not cite Peru for its TRIPS and U.S.-Peru FTA-compliant interpretation of data exclusivity.

TURKEY

Turkey remained on the Special 301 2017 Watch List. The USTR states “concerns over IP protection and market access for pharmaceutical products continue to grow, including with respect to protection against the unfair commercial use of pharmaceutical test data and regulatory and administrative delays.”

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.

Medical products are defined as any natural and/or synthetic active substances or combination of substances. The definition also includes biological drugs and biosimilar drugs administered to a human for the purpose of treating and/or preventing disease, making a diagnosis, or correcting or modifying a physiological function.

The originator’s data submitted to the licensing authority is protected for six years starting from

⁴⁰ See Brook K. Baker, “With One Exception Current Trade Agreements Do Not Appear to Include Biologic Medicines in their Data Protection/Data Exclusivity Provisions – Implications for TPP Negotiation,” Infojustice, August 13, 2013, available at <http://infojustice.org/wp-content/uploads/2013/08/baker082013.pdf>.

⁴¹ *Id.*

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 (Regulation). During the exclusivity period, the manufacturers of similar products are prevented from using/referring to 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. In order 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, they should be outside the scope of the Special 301 Report.

VIETNAM

Vietnam was placed on the Special 301 2017 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 TRIPS, 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 in order to ensure that submitted data is neither used for unfair commercial purposes nor disclosed, except where the disclosure is necessary to protect the public.⁴² 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.⁴³ Neither Vietnamese law nor the U.S.-Vietnam Bilateral Trade Agreement (U.S.-Vietnam BTA)⁴⁴ provides exclusive control over disclosed data.

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.

⁴² See, Article 128(1) Intellectual Property Law of Vietnam 2005.

⁴³ See, Article 128(1) Intellectual Property Law of Vietnam 2005

⁴⁴ 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”

Appendices

1. Letter from Colombian Ministry to Civil Society Clarifying that Compulsory Licenses Do Not Constitute Expropriation under Colombian Law
2. Letter from 56 Non-profit Organizations and Academic Experts to Secretary Kerry Regarding State Department Pressure Against Access to Medicines Efforts
3. India's Patent System Plays by WTO Rules and Supports Global Health, Public Citizen, June 27, 2013.
4. The Non-Discriminatory Nature of India's National Pharmaceutical Pricing Policy, Public Citizen, August 2013.

ANNEX 1

May 16th 2016

Mr. President

JUAN MANUEL SANTOS

President of the Republic of Colombia

SUBJECT: Colombia's Right to Issue a Compulsory License for the Cancer Medicine Imatinib

Dear President Santos,

We are lawyers, academics and other experts specializing in fields including intellectual property, trade and health, writing to affirm that international law and policy support Colombia's right to issue compulsory licenses on patents in order to promote public interests including access to affordable medicines.

Colombia's Ministry of Health and Social Protection has proposed to declare access to the cancer medicine imatinib under competitive conditions to be a matter of public interest. A public interest declaration should lead to the grant of a compulsory license on a patent held by Novartis, facilitating generic competition and reducing prices. We encourage your administration, the Ministry of Health and the Superintendency of Industry and Trade to proceed with the public interest declaration.

Recent media reports suggest that staff for the U.S. Senate Finance Committee and potentially representatives of the U.S. government may have communicated incorrect beliefs about compulsory licensing to their Colombian counterparts.¹ If the reports are accurate, those officials have acted inappropriately, and contravened U.S. government policy, which supports trading partners' rights to issue compulsory licenses. We condemn any pressure levied against Colombia for its use of lawful policies such as compulsory licensing to promote public health.

Article 31 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS) permits all WTO members, including Colombia, to issue compulsory licenses at any time on grounds of their choosing². The only compensation due to patent-holders in instances of compulsory licensing is a reasonable royalty, which governments may determine at their discretion³.

¹ See <http://www.elespectador.com/noticias/salud/presiones-de-eeuu-colombia-no-regule-el-precio-del-imat-articulo-631535> and

² Available at: www.wto.org/spanish/docs/s/legal_s/27-trips_04c_s.htm. See also World Trade Organization, "TRIPS and Health: Frequently Asked Questions," available at: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

³ *Id.* Art 31 (b).

The WTO's Declaration on the TRIPS Agreement and Public Health affirms this interpretation of Article 31 and its importance to health.⁴ The "Doha Declaration" explicitly recognizes the impact of intellectual property on medicine prices and states that countries' patent obligations under WTO rules "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."

The issuance of a compulsory license on imatinib is entirely consistent with the terms of trade and investment agreements to which Colombia is a party.⁵ The U.S. "May 10th Agreement" of 2007, for example, expressly incorporated certain public health safeguards in the U.S.-Colombia Trade Promotion Agreement and preserved Colombia's right to issue licenses for patented inventions.

High prices for any important medicine impose a burden on the public health system responsible for providing it, and lead to the rationing of treatment and other health services. When a pharmaceutical company uses a patent to exclude competition, it can charge much higher prices.

A recent report by Colombia's Ministry of Health and Social Protection specifies considerable predicted cost savings through a compulsory license for imatinib.⁶ The report of the ministry's Technical Committee for the Public Interest Declaration states:

...The impact on health system financing of only a single manufacturer supplying imatinib in the market is important. Additionally, prices of Glivec, despite being subject to controls, are still very high compared with generics, which have been progressively leaving the market with the grant of the patent. Direct price controls ... will never match the results achieved by competition in the market. Without a doubt, the best way to reduce prices is competition.

Novartis has rejected the Colombian government's offer to negotiate a price reduction for imatinib.

Issuing a compulsory license does not expropriate the property rights of the patent holder. Rather, the right of a government to authorize other uses of a patented invention is embedded and reserved in the grant of a patent. Furthermore, a license does not prevent the patent holder from continuing to sell its product, prohibit non-licensed uses of the invention, or prohibit non-licensed parties from using the invention.

We hope this letter will support Colombia's ongoing efforts to increase access to affordable medicines and put to rest any concerns regarding the international legitimacy of compulsory licensing. Compulsory licensing is a key tool for protecting the financial stability of health systems and ensuring access to medicines and health services for all.

Sincerely,

Dr. Deborah Gleeson

School of Psychology and Public Health,
La Trobe University, Australia

Amy Kapczynski

Professor of Law
Yale Law School
USA

Andrew S. Goldman

Counsel, Policy and Legal Affairs
Knowledge Ecology International
USA

Suerie Moon

Harvard T.H. Chan School of Public
Health and Kennedy School of Gov.
USA

Warren Kaplan, PhD, JD, MPH

WHO Collaborating Center for
Pharmaceutical Policy
Center for Global H & D, Boston

Peter Maybarduk

Global Access to Medicines Program
Director Public Citizen
USA

Prof. Dr. H. Schellekens MD,PhD

Director WHO Utrecht Center of
Excellence for Affordable
Biopharmaceuticals
Utrecht University

Professor Brook K. Baker

Northeastern University School of Law
Program on Human Rights and the
Global Economy Honorary Research
USA

Luz M. Umbasia B.

Attorney Administrative Law Specialist
MSC (C) International Relations &
Business UMNG Colombia

Rachel Kiddell-Monroe LL.M

Professor of Practice
McGill University, Montreal, Quebec

Joel Lexchin MD

School of Health Policy & Management
York University
Canada

Sean Flynn

Program on Information Justice and
Intellectual Property
American University Washington USA

Dipl. Soz Hedwig Diekwisch
Managing Director
BUKO Pharma-Kampagne / Germany

Robert Weissman
President Public Citizen
Washington D.C USA

Rochelle Dreyfuss
Pauline Newman Professor of Law
Co-Director of the Engelberg Center on
Innovation Law and Policy
New York University School of Law

Ellen 't Hoen
Consultant Medicines Law and Policy
University Medical Centre Groningen,
Global Health Unit, University of
Groningen, The Netherlands.

Carlos Correa
Universidad de Buenos Aires
South Centre

Dr. Holger Hestermeyer
Shell Reader in International Dispute
Resolution, King's College London

Germán Velásquez
Special Adviser for Health and
Development, Switzerland

Professor Yousuf A. Vawda
School of Law, University of KwaZulu-
Natal, South Africa

**Prof. Dra. Perla Mordujovich-
Buschiazso** Directora Centro
Universitario de Farmacología Centro
Colaborador OPS/OMS, Universidad
Nacional de La Plata Argentina

James Love
Director
Knowledge Ecology International
USA

Srividhya Ragavan
Professor of Law
Texas A&M Schhol of Law
Fort Worth, TX

Dr.V.C.Vivekanandan
Ministry of HRD IP Chair Professor
NALSAR University of Law
Adjunct Visiting Professor, University
of Buffalo Business School, New York
Director- Institute of Global Internet
Governance & Advocacy (GIGA)-

Wilbert Bannenberg
MD and public health consultant.
Adviser on TRIPS and Access to
Medicines to SADC member states

Gawain Kripke
Policy Director
Oxfam America

Susan K. Sell
The George Washington University,
Washington, DC

Cynthia Ho
Loyola University of Chicago School of
Law, USA

Matthew B. Flynn
Georgia Southern University

**Dr. Ruth Lopert MD MMedSc
FAFPHM**
Adjunct Professor Department of
Health Policy & Management
Milken Institute School of Public Health
George Washington University

Fran Quigley
Clinical Professor of Law, Director,
Health and Human Rights Clinic
Indiana University McKinney School of
Law, USA

Michael Palmedo
Assistant Director, PIJIP
American University Washington
College of Law

César Rodríguez Garavito
Centro de Estudios de Derecho, Justicia
y Sociedad Dejusticia

Oscar Lizarazo
Associate Professor
Faculty of Law National University of
Colombia

Dra. Tatiana Andia
Profesora Universidad de los Andes
Bogotá Colombia

Jorge Augusto Díaz Rojas.
Universidad Nacional de Colombia.
Profesor Asociado
Colombia.

Carlos H Caicedo E.
Director del Programa Radial
Interacción Emisora UNRADIO 98:5FM
Bogotá, Colombia Suramérica

Martha Milena Silva Castro. PhD.
PharmD. MA.
Teaching and Research Group in
Pharmacy Practice,
University of Barcelona

Martín Cañas
Cátedra de Farmacología, Instituto de
Salud, Universidad Nacional Arturo
Jauretche, Argentina

Tahir Amin
Attorney I-MAK

Rubén Espinoza Carrillo
Universidad Peruana Cayetano Heredia
Lima - Perú

Gabriel Jaime Otalvaro Castro.
PhD(c)
Salud Colectiva Docente Facultad
Nacional de Salud Pública
Universidad de Antioquia, Colombia

Norberto Camacho García
QF.UN MAE.UN (c)
Colombia

David G Legge MD
Professor Emeritus in Public Health
La Trobe University
Melbourne, Australia

Gabriel R. Nemogá Ph.D.
Universidad de Winnipeg - Canadá
Inv. Int. Grupo de Inv. Política y
Legislación en Biodiversidad, Recursos
Genéticos y Conocimiento Tradicional
Universidad Nacional de Colombia

Samuel David Osorio Garcia
MD colombiano
Candidato a Maestro en Salud Pública
por la Universidad de São Paulo

Claudia Patricia Vaca González
Profesora Universidad Nacional De
Colombia.

Mario Esteban Hernández Álvarez
Coordinador Doct. Interfacultades en
Salud Pública Universidad Nacional de
Colombia.

Luis Jorge Hernández Flórez, MD,
PhD
Profesor Asociado Salud Pública
Universidad de los Andes-Facultad de
Medicina. Bogotá, Colombia.

Oscar Andia Salazar
OBSERVAMED-FMC
Colombia

**Roxana Patricia De las salas
Martinez**
Profesora de la Universidad del Norte
(Barranquilla, Colombia)

Prof. José-Luis Alloza, MD, PhD
Dep Biomedical Sciences
School of Medicine and Health Sciences
The University of Alcalá de Henares
Spain.

Jorge Costa
Technologist Oswaldo Cruz Foundation
- Fiocruz, Brazil

Tatiana Galofre
Ingeniero Industrial
Colombia

Shiba Phurailatpam
Asia Pacific Network of People Living
with HIV (APN+)

Maria Auxiliadora Oliveira
Researcher Oswaldo Cruz Foundation –
Fiocruz, Brazil

Liliana Sarmiento
C.C.31158538
Abogada
Colombia

Vinciane Servantie
Administradora de empresas
Colombia

Andrés Izquierdo
IP Practicing Attorney
Washington D.C USA

José Julián López G.
QF MSc PhD (c)
Director CIMUN, Fac. de Ciencias,
Bogotá, Colombia

Gabriela Costa Chaves
Researcher Oswaldo Cruz Foundation –
Fiocruz, Brazil

**Claudia García Serpa Osorio de
Castro**
Researcher Oswaldo Cruz Foundation –
Fiocruz Brazil

Jorge Machado
Universidad Tecnológica de Pereira,
Colombia

Prof. Saúl Franco Agudelo
Maestría en Salud Pública, Facultad de
Economía, Universidad Santo Tomás,
Bogotá, Colombia

Carlos Durán, MD
Empresa Pública Yachay
Quito-Ecuador

Vera Lucia Luiza
Researcher Oswaldo Cruz Foundation –
Fiocruz
Brazil

Angela Fernandes Esher Moritz
Researcher Oswaldo Cruz Foundation –
Fiocruz
Brazil

Thiago Botelho Azeredo
Professor and researcher,
Federal University of Rio de Janeiro –
UFRJ

Nina Lisleth Ojeda Sopo
Universidad Nacional
Medico

Adriana Mendoza Ruiz
Researcher Oswaldo Cruz Foundation –
Fiocruz, Brazil

José Gilberto Orozco Díaz
Profesor Asociado
Universidad Nacional de Colombia
Colombia

Everaldo Lamprea
Professor, Los Andes Law School
everaldolamprea@gmail.com

Giovanny Garavito QF MSc PhD.
Vicedecano Académico (Academic
Deputy Dean)
Colombia

Kimberlee Weatherall
Associate Professor Sydney Law
School, The University of Sydney

Joan Rovira Forns
Professor Emeritus
Department of Economics, University
of Barcelona, Spain

Patrick Durisch
Health Programme Coordinator
Berne Declaration, Switzerland

Karen Hussmann
Public Policies Expert

Dra. María Inés Sarmiento
Docente Fundación Universitaria de
Ciencias de la Salud FUCS

Prof. Álvaro Zerda Sarmiento, PhD
Facultad de Ciencias Económicas
Investigador CID. Universidad Nacional
de Colombia

Maria Cristina Latorre
Q.F. Sociedad Colombiana de Historia
de la Farmacia

Rondineli Mendes da Silva
Researcher Oswaldo Cruz Foundation –

Fiocruz, Brazil.

Sergey Kondratyuk
All-Ukrainian Network of PLWHA

Yolima Baena Aristizábal
Associate Professor of Pharmacy
Department
Universidad Nacional de Colombia

Benoit Marchand, MD
Empresa Pública Yachay
Quito-Ecuador

Adriana Mercedes Ardila Sierra
MD MPH PhD(c)

Claudia Cano Correa
Universidad Externado de Colombia
Colombia

Gabriela Delgado,
profesora asociada, departamento
de farmacia
Universidad Nacional de Colombia.

Ulpiana M. Tamayo
Financista
Colombia

Elvia Saenz Botero
Abogada
Colombia

Claudia Lozano Gamba
Abogada
Colombia

Nadia Kahuazango
Politóloga
Colombia

Paula Páez
Especialista en Gobiernos y Relaciones
Internacionales. Colombia

David Pinzon

Abogado Colombia

Ricardo Saravia

Servicio de Inf. de Medicamentos de El Salvador CIMES

Carlos Arturo Cadavid V.

Alianza Internacional De Habitantes (AIH) Medellín-Colombia

Xavier Maldonado Dávila

Profesor de la Universidad Central del Ecuador. Coordinador ALAMES núcleo Ecuador

Prof. Martín Uribe Arbeláez

Director del Observatorio de P. I y del Grupo de investigación "Derecho y Desarrollo" Prometeo, adscrito a Unijus Universidad Nacional de Colombia.

Alma de León

Regional Director International Treatment Preparedness Coalition Latin America and The Caribbean "ITPC-LATCA"

María Belén Mena. MD, MPH, PhD (c)

Profesor de Farmacología. Universidad Central del Ecuador.

Camila Gianella Malca

Post Doc fellow CMI, Post doc Fellow University of Bergen, Norway

Kajal Bhardwaj

Lawyer
India

Prof. Hernando Gaitán D MD MSc

Gynecology and Obstetrics Department
Clinical Research Institute
National University of Colombia
Co- Ed. Sexually Transmitted Infections
Cochrane Review Group

Dr. Kwadwo Appiagyei-Atua

Senior Lecturer School of Law,
University of Ghana
Legon, Accra, Ghana

Juana Camacho

Instituto Colombiano de Antropología e Historia, Colombia

Jorge Bermúdez

Researcher Oswaldo Cruz Foundation –
Fiocruz, Brazil

John T. Mitchell

Interaction Law
USA

Tapiwanashe Kujinga

Director Pan-African Treatment
Access Movement
Africa

Adam Schatten

Hibernation films
Boston, MA

Dr. Burcu Kilic

Global Access to medicines Program
Public Citizen
Washington D.C.

Akbar Noman

Senior Fellow and Adjunct Associate
Professor
at Columbia University, New York.

Umunyana Rugege

Attorney, SECTION27
South Africa

L Mtima

Law prof at the Howard University
School of Law
USA

Graham Dutfield

Professor of International Governance
School of Law
University of Leeds, UK

Marcela Fogaça Vieira

Coordinator GTPI/Rebrip
Brazil

Juan Pablo Morales

Políticas Farmacéuticas
Chile

Pedro Villardi

PhD student in Public Health
IMS/UERJ Brazil

PhD MD Marilena Correa

IMS/UERJ Brazil

Dr. Martin Santos

Región de Salud Central/Ministerio de
Salud El Salvador, C.A.

Dr. Giovanni Francisco Guevara

Director de Tecnologías Sanitarias
Ministerio de Salud de El Salvador

Lorena Di Giano

Fundación Grupo Efecto Positivo-
Argentina.
RedLAM
Argentina

Angélica Garzón Umerenkova

Docente-investigadora Universidad El
Bosque
Bogotá, Colombia

Germán Humberto Rincón Perfetti

Rincón Perfetti Abogados &
Consultores Internacionales
Asociación Líderes en Acción
Bogotá, Colombia

ANNEX 2

The Honorable Secretary of State John F. Kerry
U.S. Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Secretary Kerry:

We are writing to express our concern about recent statements made by representatives of the State Department on issues regarding intellectual property (IP) and access to medicines in various settings, including proceedings in Colombia, several important United Nations fora, and in India.

Colombia & Cancer Treatments

In May 2016, leaked memos from the Colombian Embassy suggested that the United States Trade Representative and others in the United States government and Congress have pressured the government of Colombia not to increase affordable access to imatinib, a leukemia drug marketed by Swiss company Novartis under the brand names Gleevec or Glivec. The drug has generated over \$47 billion in global sales for Novartis and already faces generic competition in the United States. The Novartis price for the drug in Colombia per patient is approximately twice the Colombian gross national income (GNI) per capita.

The government of Colombia has been asked by Colombian civil society organizations to issue a compulsory license on the patents, in compliance with the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in order to remove barriers to generic competition and to foster affordable access to this lifesaving drug.

The Colombian Embassy was sufficiently alarmed by the pressure from the United States to twice remark that it was concerned that proceeding with the compulsory license would put at risk the \$450 million committed for President Obama's initiative to support the Colombian peace process, *Paz Colombia*.

More recently, following a public announcement on June 9 by the Minister of Health that he would proceed with a public interest declaration to lower the price of the drug — only one of a series of enumerated steps toward a compulsory license under Colombian law — news outlets aired footage of United States Ambassador to Colombia Kevin Whittaker publicly stating that it is very important for the Colombian government to consult with the United States on this decision.¹

The declaration by the Minister was the result of over a year and a half of national consultations, and follows Novartis's complete rejection of efforts by the Colombian Ministry of Health to negotiate a more affordable price.

We were surprised and dismayed by Ambassador Whittaker's remarks, which were interpreted, in Colombia and elsewhere, as unwanted interference with a domestic dispute over the price of a drug sold by the Swiss corporation. The United States State Department should not interfere with the government of Colombia's efforts to increase access to affordable medicines. Colombia is under no obligation to consult the United States on a decision to use its national law, when its actions are consistent with trade agreements binding both the United States and Colombia.

United Nations (UN) Secretary General's (SG) High-Level Panel on Access to Medicines

In November 2015, UN Secretary General Ban Ki-Moon announced the convening of a High-Level Panel on Access to Medicines (HLP) "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."² The call for submissions for consideration of the HLP to inform its report welcomed participation from a wide array of organizations from a diverse collection of sectors including governments, industry, civil society, academia, and intergovernmental organizations. The panel itself consists of former heads of state, academics, generics and brand-name pharmaceutical industry leaders, treatment activists, civil servants and more.

We are troubled by public statements from United States State Department representatives regarding the mandate, composition and work of the HLP, including in its official submission to the panel, labeling it as possessing a "critical flaw." The U.S. submission went so far as to question the very premise of the panel, namely that a conflict exists between "the rights of inventors, international human rights law, trade rules, and public health."³ Such a sentiment is out of touch with the reality faced every day by patients in developing countries around the world and here in the United States faced with rising drug prices and lack of innovation for critical medical needs, such as antibiotic resistance and Zika.

In June 2016, the U.S. Mission to the United Nations criticized the HLP again in its statement at the UN High Level Meeting on Ending AIDS. The U.S. Mission cited amongst its concerns "the Panel's narrowly-defined mandate, the non-transparent manner in which it was constituted, and the presumption of a policy incoherence."⁴

We are deeply disappointed that the U.S. has expressed these views. Most disturbing was the fact that the U.S. mission questioned the notion of policy incoherence. This incoherence is both

straightforward and important. Policies that lead to higher prices create barriers for access. If governments rely upon high prices to fund innovation, then they have to accept limited and unequal access to new medicines, as well as no innovation when high prices through sales are not an option to recover R&D costs. In what sense does the Department of State see that as coherent and good policy?

The work of the UN HLP on Access to Medicines to advance conversations to remedy this policy incoherence is vital. The challenges caused by high prices of medicines and lack of innovation are not a developing country concern only and should become a global priority, as the G7/G20 and the UN is increasingly recognizing through the search for strategies to better respond to antimicrobial resistance.

India

We are concerned about the growing evidence that the United States continues to place pressure on the Government of India to adopt policies that result in higher drug prices and the elimination of production sources of affordable generic drugs. These pressures including attacks on India's use of compulsory licensing of patents on drugs that are not affordable, and efforts to change India's law on the granting of patents that expand, extend and "evergreen" drug monopolies.

The U.S. State Department has played an active role in this pressure: the U.S. Embassy in New Delhi regularly provides a forum for industry representatives to address Indian policymakers and stakeholders,⁵ works with the U.S. Patent and Trademark Office's Intellectual Property Rights Attachés to coordinate pressure on key officials, and delivers speeches designed to publicly push the Indian government to adopt restrictive IP policies.⁶ The Embassy also readily misinterprets requirements in the TRIPS agreement related to the protection of test data to argue that India should implement test data exclusivity measures.⁷

India's patent laws are compliant with the obligations and public health safeguards in the TRIPS Agreement. Even without the U.S. pressure, the WTO rules are severe and have limited the supply of affordable generic versions of most new drugs. The pressure from the U.S. seeks to go even further in limiting the supply of affordable generic medicines by preventing India from using provisions in its national law that facilitate expedited generic competition, including through the use of compulsory licenses. While these provisions are consistent with WTO rules, they are opposed by large pharmaceutical companies that seek to expand monopolies and raise drug prices worldwide.

Any policies or practices that India adopts to expand patent rights on medicines, restrict the use of compulsory licensing or other exceptions to patent rights, or introduce new exclusivity rules for data would have dramatic and negative implications for people across the globe that desperately need access to affordable life-saving medicines, including many global health programs funded by the United States government, such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Moreover, the same maximalist IP policies that the U.S. is promoting abroad are resulting in a growing and unsustainable crisis of unaffordable medicine prices right here in the United States.

We request that State Department refrains from further pressuring countries and the UN Secretary General High Level Panel on Access to Medicines.

We take note of the official U.S. government position as stated in the United States Trade Representative 2016 Special 301 Report, that "the United States respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all," and "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement." We contend that the incidents described in this letter contravene this U.S. government policy.

We await your written response to this letter (a) detailing whether the State Department sees these incidents as coherent with U.S. government policy; and (b) clarifying State Department commitments and position on the right of governments to use TRIPS flexibilities to protect public health and access to medicines. Please address how the State Department will prevent recurrences of this conduct in the future, including any guidance that might be provided to U.S. government personnel.

We are available for a meeting at your earliest convenience to discuss these issues in greater detail and ensure policy coherence and fulfillment of international commitments with State Department interventions.

Sincerely,

African Services Committee
Alianza LAC-Global por el Acceso a Medicamentos
All-Ukrainian Network of People Living with HIV/AIDS
American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)
American Medical Student Association
The Berne Declaration

Center for Study of Responsive Law
Centro de Información de Medicamentos de la Universidad de Colombia (CIMUN)
Comité de Veeduría y Cooperación en Salud (CVCS)
Comunicación Positiva
Prof. Carlos Correa
Essential Information
Foundation for Integrative AIDS Research
Fundación IFARMA
Health Action International (HAI)
Health Global Access Project (Health GAP)
Initiative for Medicines, Access & Knowledge (I-MAK)
Interfaith Center on Corporate Responsibility (ICCR)
International Human Rights Clinic, University of Chicago Law School
Just Foreign Policy
Karisma Foundation
KELIN
Knowledge Ecology International
La Conferencia Episcopal de Colombia
Latin America Working Group (LAWG)
LWC Policy Consulting
Maryknoll Office for Global Concerns
Médecins Sans Frontières/ Doctors Without Borders (MSF USA)
Medicines Law & Policy
Mesa de ONGs con Trabajo en VIH/SIDA
Misión Salud
Dr. Suerie Moon
National Physicians Alliance
NETWORK Lobby for Catholic Social Justice
Observatorio del Medicamento de la Federación Médica Colombiana (OBSERVAMED)
OXFAM
Pax Christi International
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
Prescription Justice Action Group
Presbyterian Church (USA)
Public Citizen
Prof. Susan Sell, George Washington University
Dr. Matthew Rimmer, Queensland University of Technology
Student Global Access Campaign (SGAC)
Union for Affordable Cancer Treatment
United Church of Christ, Justice and Witness Ministries
Universities Allied for Essential Medicines (UAEM)

Dr. Germán Velásquez, Former Director of the WHO Secretariat on Public health, Innovation and Intellectual property

Page 5 of 6

Washington Office on Latin America (WOLA)
Yale Global Health Justice Partnership
Young Professionals Chronic Disease Network
Prof. Peter K. Yu

ANNEX 3

June 27, 2013

INDIA'S PATENT SYSTEM PLAYS BY WTO RULES AND SUPPORTS GLOBAL HEALTH

PEOPLE ACROSS THE DEVELOPING WORLD DEPEND ON INDIA FOR ACCESS TO AFFORDABLE GENERIC MEDICINES. RECENTLY, SOME PHARMACEUTICAL INDUSTRY GROUPS HAVE CRITICIZED INDIA'S PATENT RULES AND PRACTICES. BUT INDIA'S PRACTICE COMPLIES WITH THE WORLD TRADE ORGANIZATION'S AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (WTO'S TRIPS). RECENT COURT CASES AND ADMINISTRATIVE ACTIONS IN INDIA HAVE STRUCK AN APPROPRIATE BALANCE BETWEEN PROTECTING THE RIGHTS OF PATENT HOLDERS AND THOSE OF THE PUBLIC, AND ARE CRITICALLY IMPORTANT TO ADVANCING GLOBAL HEALTH.

1. India's patent rules comply with WTO standards.

India's Supreme Court recently determined that a Novartis patent application, for a derivative of a known substance treating cancer, does not qualify as an invention. This has led to some speculation that India treats efficacy as a fourth patentability criteria; it does not.

Under WTO rules, countries are free to define what qualifies as an invention (patentable subject matter), subject to three basic requirements for standards of patentability (novelty, industrial application and inventive step).¹ Like the U.S., India excludes certain categories of subject matter from patentability.

For example, In India, combinations and derivatives of known substances are "considered to be the same substance," and therefore do not qualify as inventions, "unless they differ significantly in properties with regard to efficacy."² While this standard is most relevant to chemical and pharmaceutical inventions--and, as the Supreme Court noted, may indeed have been inspired by a concern for "evergreening" of chemical and pharmaceutical compounds--it applies uniformly to all known substances.³ This is in full compliance with WTO rules.⁴

2. Compulsory licensing promotes access to medicines and health, including in the context of non-communicable diseases.

Compulsory licensing allows governments to authorize generic competition with patented medicines in exchange for royalty payments to patent holders. It is a flexibility included in WTO rules. Generic competition has consistently proven the most effective way to reduce the price of medicines, and ensure prices continue to fall with time.

Too many cancer drugs on the market today are priced vastly beyond the ability of most people and many health programs to pay. This problem is especially grave in developing countries, including India as well as the many countries which rely on generic or biosimilar medicines sourced from India. Compulsory licensing can help bring the cost of life-extending and life-saving cancer treatments under control, combating artificially high monopoly prices and still contributing meaningfully to research and development.

India set a royalty rate of six percent when it licensed Bayer's patent on sorafenib (Nexavar), a treatment for kidney and liver cancer. This royalty rate is relatively high by industry standards.⁵

¹ The U.S. uses the concepts of utility and non-obviousness, respectively, which can be analogous in some cases.

² India Patents Act of 1970, Section 3(d).

³ Section 3(d) follows Section 3(c), which codifies the natural law doctrine recognized in the U.S. (which excludes abstract ideas, natural laws and products of nature from patentable subject matter). Section 3(d) of the Indian Patents Act excludes known substances from patent-eligible subject matter.

⁴ In fact, it was not until 1995 that the U.S. Federal Circuit ruled in *In re Brana* that utility for a pharmaceutical invention does not depend on FDA approval; and it was not until 2006 that the Federal Circuit ruled in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* that therapeutic utility does not depend on demonstrated effects on living humans.

⁵ James Love, World Health Organization & United Nations Development Program, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies," WHO/TCM/2005., 34, http://keionline.org/sites/default/files/who_undp_2005_royalty_guidelines.pdf.

3. India has the right to issue compulsory licenses on grounds of its choosing.

According to the WTO, "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."⁶ There are no WTO rules which limit compulsory licensing to HIV, epidemics or emergencies, and no rules which prevent India from issuing licenses to address high prices.⁷ According to the WTO, the TRIPS Agreement "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."⁸ U.S. courts issue compulsory licenses to remedy anti-competitive practices, and U.S. agencies have broad authority to make government use of patents.

4. Public and charitable institutions have contributed significantly to the research and development (R&D) of new cancer drugs, including Glivec.

Together, the taxpayer-supported National Institutes of Health (NIH) are the world's largest funder of biomedical research (roughly \$30 billion annually). NIH has contributed significantly to the invention of many cancer drugs, including Glivec, the subject of the Novartis litigation in India.

The research leading up to STI-571, Glivec's active chemical ingredient, was supported in large part through public funding.⁹ The National Cancer Institute at NIH provided 50% of the funding for this work compared to the 10% contributed by Novartis. Despite the significant public funding supporting Glivec's R&D, its price--which skyrocketed from \$30,000 per year to \$92,000 per year even though Novartis's former CEO explained that the original price was sufficient to recoup R&D costs and yield a sustainable profit¹⁰--has kept it out of reach of many patients.

In 2013, more than 100 physicians with expertise in chronic myeloid leukemia (the condition treated by Glivec)--including the lead scientific researcher in the development of STI-571, Dr. Brian Druker, published an editorial denouncing these exorbitant prices.¹¹

5. Stringent patent laws have not been shown to create more American jobs.

Last year's report by the U.S. Patent and Trademark Office (USPTO) and Department of Commerce finding that IP-intensive industries account for 18.8% of U.S. jobs has been widely cited in support of proposals to transform patent policies in the U.S. and abroad. However the report itself notes that, "The bulk of employment and value added correspond to the 60 trademark-intensive industries, which is a reflection of the nearly ubiquitous use of trademarks and logos in the marketplace."¹² Compared to the 2.5 million jobs annually attributed to the top job-supporting IP-intensive industry -- grocery stores -- the pharmaceutical industry accounts for only 291,300 jobs annually. Even so, the report, which has been widely criticized, offers no support for a causal connection between the IP-intensity of an industry and the creation of jobs in that industry, nor any consideration of the effects on job creation of varying levels of patent protection.¹³

For more information, contact Peter Maybarduk, (202) 588-7755, pmaybarduk@citizen.org.

ANNEX 4

THE NON-DISCRIMINATORY NATURE OF INDIA'S NATIONAL PHARMACEUTICAL PRICING POLICY

Clarification in Response to the Testimony of Ms. Linda Dempsey, House Energy and Commerce Committee Hearing on India's Industrial Policy

On June 27, 2013, [Ms. Linda Menghetti Dempsey](#) (Vice President of International Economic Affairs, National Association of Manufacturers) said the following with regard to the Indian government's new [National Pharmaceutical Pricing Policy 2012](#):

"India imposes price caps on hundreds of medications. However, those caps do not apply to drugs Indian researchers develop."

Patented drugs, including those exported from the U.S., are not subject to the price ceilings. India's price ceilings will primarily impact local manufacturers of generic medicines.

The new pharmaceutical pricing policy, which replaces the Drugs (Price Control) Order 1995, establishes a **price ceiling formula to be applied to generic drugs** included in the [National List of Essential Medicines](#), regardless of where they were developed (although the vast majority are locally manufactured). Other generic medicines are not subject to the price ceiling formula, but are limited to price increases of 10% per year (§4(xiv)).

The policy categorically excludes patented medicines from these price caps. Patented medicines exported from the U.S. to India are not subject to price ceilings imposed by the new policy. It is possible that patented medicines may, in the future, be subject to a system of reference pricing in accordance with the [recommendations of the Committee on Price Negotiation for Patented Drugs](#) (§4(xv)), which were recently open for public comments.¹ Because the Committee's report was issued six years after the Committee was formed, [commentators](#) remain quite uncertain whether the Indian government will adopt the Committee's recommendations.

The new policy also states that Indian drug manufacturers may request a five-year exemption from price controls for newly approved drugs developed with Indian investments and produced only in India (§4(xvi)). Notably, BIO explicitly supported an exemption for medicines developed and exclusively introduced in India from the pricing policy in its [public comment submission](#) to the Committee's report.²

A comprehensive consideration of India's rules affecting pharmaceuticals should acknowledge that India's new pricing policy primarily impacts generic medicines, as it explicitly excludes patented medicines from its pre-determined price controls.

For more information on India's IP policies, please see Public Citizen's [submission](#) to the hearing.

¹ Section 4(xv) Patented Drugs: There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

² "For medicines developed and introduced in India first (p. 32), BIO recommends that no price negotiation or controls be placed on these medicines by the Indian government whatsoever. This is to encourage, not discourage, the discovery of medicines primarily for the benefit of the Indian people. As noted before, placing limits on the returns of Indian biopharmaceutical companies will undoubtedly dissuade some investigators from pursuing promising discoveries" (pp.5-6).