



## ***Comments of Public Citizen for the 2016 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, 2016

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.”<sup>1</sup> We support these commitments, which echo the WTO’s unanimous 2001 Doha Declaration on the TRIPS Agreement and Public Health.

Nevertheless, past Special 301 Reports have frequently 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 frequently criticized countries for issuing TRIPS-

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<sup>1</sup> See pages 25 of the 2014 Special 301 Report.

compliant pharmaceutical compulsory licenses.<sup>2</sup> 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 important—it is a form of sanction and an inappropriate warning against countries exercising established rights to promote public health. It is inconsistent with the Special 301 Report’s stated commitments and with United States commitments under WTO rules. American University law professor Sean Flynn has suggested that the Special 301 Report’s practice of threatening unilateral trade sanctions for practices which comply with trade rules is itself a violation of WTO rules.<sup>3</sup>

The Trade Act does not require any 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.

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 modest reform:

**The Special 301 Report should omit any reference, whether expressed or implied, to any country’s TRIPS-compliant policies that advance a public interest.** USTR should not sanction such policies directly, nor should it sanction such policies indirectly, for example, through imprecise references to failings in transparency or intellectual property protection or through otherwise unwarranted elevation in a country’s watch list status.

**The Special 301 Report should only address intellectual property, not ancillary public policies.** Past Special 301 Reports have criticized country policies that do not relate to the categories of intellectual property under the TRIPS Agreement. For example, pharmaceutical reimbursement, pricing, or procurement decisions are not intellectual property issues and are therefore outside of the scope of the Special 301 review.

**The Special 301 Report should not list countries for not adopting U.S. policy preferences if those countries have no bilateral or international obligation to adopt the same.** Even if the Special 301 Report continues to cite countries for TRIPS-compliant policies, Special 301

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<sup>2</sup> See, e.g., Peter Maybarduk, “The U.S. Government’s ‘Watch List’ on Developing Countries’ Use of Health Rights,” *Citizen Vox*, May 2, 2013, available at <http://www.citizenvox.org/2013/05/02/us-governments-watch-list-on-developing-countries-use-of-health-rights>.

<sup>3</sup> See Sean Flynn, “PIJIP Statement on the Release of the 2010 Special 301 Report,” American University Washington College of Law, April 30, 2010, available at <http://www.wcl.american.edu/pijip/go/pijip04302010>.

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 not adopting 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 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 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 are detailed with an explicit reference to “the promotion of technological innovation and to 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.<sup>4</sup> 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.<sup>5</sup>*

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”:

*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,

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<sup>4</sup> Adopted November 14, 2001, and available at:

[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (emphasis added).

<sup>5</sup> Doha Declaration, Paragraph 4.

the U.S. Supreme Court recently ruled that isolated DNA is not an invention, and therefore not patent eligible subject matter.<sup>6</sup>

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.

Article 27.1 does not provide definitions for “novelty,” “inventive step,” or “capable of industrial application.” The article clarifies in a footnote that the term “industrial application” is meant to be synonymous with “useful.” Even though these terms have somewhat similar meanings, their application is slightly different in the patent laws & practices of countries.

According to Article 1.1, WTO Members may determine substantive requirements in accordance with their own local systems and practices. Therefore, WTO members are free to define these three patentability criteria.

### **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.*<sup>7</sup>

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 generally known as 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 to ensure that the data is protected against “unfair commercial use.”

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

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<sup>6</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (U.S. 2013).

<sup>7</sup> Doha Declaration, Paragraph 5(b).

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**

### **CANADA**

Canada was placed on the Special 301 2015 Watch List. USTR expressed concerns about “the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently.”

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, the Special 301 Report should only address 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**

Article 1709.1 of NAFTA<sup>8</sup>, addressing patentability requirements, is based on Article 27.1 of the Dunkel Draft of the TRIPS Agreement, which later became the final text. Each sets up criteria for patentability, including industrial applicability or utility, without harmonizing the way in which countries may implement these criteria. Thus, Members have considerable flexibility in determining what utility means. NAFTA and TRIPS parties have sovereign rights not only to adopt varying patentability standards but to change and reinterpret them.

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.”<sup>9</sup> Canada requires utility to be demonstrated or soundly predicted at the time of application. In a case 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.<sup>10</sup>

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<sup>8</sup> “Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful”, respectively”.

<sup>9</sup> *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* (1981), 56 C.P.R. 92d 145 (S.C.C.) at 160 (“Consolboard”)

<sup>10</sup> *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197

For example, in 2010<sup>11</sup> and 2011<sup>12</sup> 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 not 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."<sup>13</sup>

The question is whether, at the time of 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<sup>14</sup>. 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 reasons for this rule include 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 requires instead a sound prediction (based on data) of utility at the time of filing.

Patent law is both statutory and judge-made. Neither TRIPS nor NAFTA prohibit patent law from changing over the time; evolution in the law is an inevitable feature of any legal system. Courts routinely interpret and reinterpret patent rules. For example, in the United States, the judiciary took the initiative to allow patenting of living organisms, and the legislature followed the judiciary's lead.<sup>15</sup> For at least sixty years, 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.<sup>16</sup>

Nothing in TRIPS nor 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 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 the 20 years of exclusivity.

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<sup>11</sup> Id.

<sup>12</sup> *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288

<sup>13</sup> Id at 69

<sup>14</sup> Expert testimony of Dr. Healy, *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 , para. 159 (R-016).

<sup>15</sup> N. S. Sreenivasulu, C. B. Raju: *Biotechnology and Patent Law: Patenting Living Beings*, 2008, p.229

<sup>16</sup> Gold at 9

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 then such utility must be attainable by the claimed invention<sup>17</sup>. The notion of a patent's promise has deep historical roots going back to British Law.<sup>18</sup> It is not uniquely Canadian either. It shares common elements with the laws of the U.S., Australia, New Zealand and Europe.<sup>19</sup> It has sound policy objectives, including the prevention of pharmaceutical patent evergreening.

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

## CHILE

Chile was placed on the Special 301 2015 Priority Watch List. 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 which utilizes a new chemical entity.<sup>20</sup>

Chile enacted Law number 19.996, which modified Chile's Industrial Property Law<sup>21</sup>, and Decree number 107 from the Ministry of Health<sup>22</sup> 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.<sup>23</sup> The FTA only requires exclusivity for “undisclosed” data. The Chilean law goes beyond the FTA

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<sup>17</sup> Eli Lilly And Company v. Government Of Canada, (Case No. Unct/14/2)

Government Of Canada Counter Memorial, January 27, 2015, p. 40

<sup>18</sup> Gold, E. Richard and Shortt, Michael, The Promise of the Patent in Canada and Around the World (November 24, 2013). 30:1 Canadian Intellectual Property Review (June 2014, Forthcoming). Available at SSRN:

<http://ssrn.com/abstract=236114>

<sup>19</sup> Gold at 9

<sup>20</sup> Article 17.10.01

<sup>21</sup> Articles 89 to 91 of the Industrial Property Law

<sup>22</sup> Adopted December 18 2008, and available at

[http://www.ispch.cl/ley20285/t\\_activa/marco\\_normativo/7c/DS\\_MINSAL\\_107-2010.pdf](http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/DS_MINSAL_107-2010.pdf)

<sup>23</sup> “*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.

obligations by extending protection to disclosed data if it “has been object of reasonable measures to keep it” undisclosed.<sup>24</sup>

Article 90 of Law 19.039 defines ‘a new chemical entity’ broadly to cover any active ingredient that has not been included previously in health registrations or authorizations, or that has not been marketed in the national territory prior to the health registration or authorization application. Once again, going beyond the 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 2015 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 complaint interpretation of data exclusivity standards.

### **Patent Linkage**

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

Under the Chilean regulation, patent holders have an 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).<sup>25</sup> 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 U.S. linkage system is not consistent with the requirements of the FTA provisions, in particular

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<sup>24</sup> *“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”.*

<sup>25</sup> Article 273 of the Chilean Civil Procedural Code and Article 106 of the Industrial Application Law allow for the pursuit of injunctions.

Article 17.11.1<sup>26</sup>

An automatic injunction system would disregard 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.

## **INDIA**

India remained on the Priority Watch List of 2015 The United States "continues to monitor India's application of its compulsory license law" and "requests clarity from the Government of India regarding the compulsory license decision-making process as it affects U.S. stakeholders."

The U.S. addresses concerns that Section 3(d) of India's Patent Act may "limit the patentability of potentially beneficial innovation" since it does not consider "the mere discovery of a new form of a known substance" as an invention.

The U.S. urges India to "provide an effective system for protecting against unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products."

The U.S. remains concerned about "actions and policies in India that appear to favor local manufacturing or Indian IPR owners", such as drug pricing restrictions, compulsory licensing and application of requirements for local clinical trial data for approval of new drugs. The USTR claims that these policies "distort" competitive foreign drug manufacturing industry.

### **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.

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<sup>26</sup> "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.

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 any 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. Furthermore, TRIPS favors technology transfer (Article 7).

#### *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 seven percent royalty (revised up from an initial six 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. Bayer may continue to compete in the Indian market.

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).<sup>27</sup>

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.”<sup>28</sup> 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.<sup>29</sup> Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.<sup>30</sup>

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 decision of the court extended over more than 90 pages and 195 paragraphs. The paragraph quoted by USTR in recent Special 301 Reports must be considered in its full context if it is to provide any informative value for analysis of Section 3(d).

India’s Section 3(d) complies with the TRIPS Agreement. The Special 301 Report should not cite India for its TRIPS-compliant interpretation of patent eligible subject matter.

### **Pharmaceutical pricing**

Some recent complaints have focused on Indian pharmaceutical pricing policies. We note that

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<sup>27</sup> See, Burcu Kilic & Luigi Palombi, “The Question of Patent Eligible Subject Matter and Evergreening Practices”, <http://infojustice.org/archives/30314#more-30314>

<sup>28</sup> The following are not inventions within the meaning of this Act:

<sup>28a</sup>“(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.

<sup>28</sup> *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;”

<sup>29</sup> *Ibid*

<sup>30</sup> Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013. Supreme Court of India.

these are not intellectual property complaints, and therefore are outside the scope of the Special 301 Report. Nevertheless, we have provided a rebuttal to one recent (and erroneous) complaint in an appendix, attached.

## **INDONESIA**

Indonesia was placed on the Special 301 2015 Priority Watch List. USTR “continues to encourage Indonesia to provide an effective system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products.” USTR “also remains concerned about market access barriers in Indonesia, including measures that appear to condition permissions to import medicines on at least partial local manufacturing or technology transfer requirements.” Finally, USTR “remains concerned about the lack of clarity surrounding legal procedures under the Indonesian patent law in connection with the grant of compulsory licenses.” Accordingly, USTR “encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations.”

### **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.”<sup>31</sup>

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

### **Compulsory Licenses**

In 2012, Indonesian President Susilo Bambang Yudhoyono issued a presidential decree<sup>32</sup> authorizing government use of patents for seven HIV/AIDS and Hepatitis B medicines in order to meet the urgent need for antiviral and antiretroviral treatments.<sup>33</sup>

In accordance with Article 99 of Indonesian Patent Law No. 14/2001, in the case of public interest need, the Government has a right to make use of patents by Presidential Decree, after consulting with the Health Minister and heads of the agencies in charge in the relevant field.

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<sup>31</sup> 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](http://unctad.org/en/docs/diaepcb2011d6_en.pdf).

<sup>32</sup> Presidential Decree Regarding Patent Exploitation of the Antiviral and Antiretroviral Drugs.

<sup>33</sup> See Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines -- Precedent-Setting Government Order has Extraordinary Life Saving Potential.

Government Regulation of the Republic of Indonesia Number 27, Year 2004<sup>34</sup> establishes a procedure for the government use of patents. According to this procedure, the Ministry of Health files a written proposal with the Ministry of Justice through the Directorate General of Intellectual Property Rights for the exploitation of patents. The Ministry of Justice then establishes a committee chaired by the Director General of Intellectual Property Rights to provide an opinion on the details of this license, including appropriate royalty rates for the patents the government will exploit. The Committee provides an opinion to the Minister for each of the patents on its individual merits. The Minister submits the proposal to the President. The President may issue a Decree for government use licenses, as referred to in Article 5, paragraph 2 of the Constitution of the Republic of Indonesia of 1945, as amended by the Fourth Amendment of 1945. The patent holder is informed within seven days of the enactment of the Presidential Decree.

This is a considerably more involved process than any required by TRIPS, under which any government minister could make government use of patents at any time on any grounds.

If a patent holder has an objection to the royalty rate paid by the government, he may file a lawsuit in the Commercial Court within a period of 3 months after the enactment of the Presidential Decree.<sup>35</sup> The patent holder also has the right to apply to the Constitutional Court for the judicial review of the Presidential Decree.

Indonesia followed this procedure in making government use of patents on important HIV/AIDS medications. The process took more than a year and complied with TRIPS and national rules. Patent holders have the ability to challenge royalty rates and license authorizations. The 2016 Watch List should include no references to Indonesia's government use of patents to advance AIDS treatment.

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

## **PERU**

Peru was placed on the Special 301 2015 Watch List. The United States continues to request 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 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

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<sup>34</sup> Government Regulation of the Republic of Indonesia Number 27 Year 2004 Regarding the Procedure of Exploitation of Patent by the Government.

<sup>35</sup> Article 10 Government Regulation of the Republic of Indonesia Number 27, Year 2004.

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.”<sup>36</sup>

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.<sup>37</sup>

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 was placed on the Watch List in 2014 and remains on the Watch List in 2015. The U.S. encourages “Turkey to clarify how it protects against the unfair commercial use, as well as unauthorized disclosure of test and other data generated to obtain marketing approval for pharmaceutical products.” The U.S. is also concerned that “Turkey appears to shorten the term of data protection if the patent term ends first.”

### **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 an exclusive right to clinical trial data of medical products 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 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

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<sup>36</sup> 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>.

<sup>37</sup> *Id.*

applications. If a Turkish patent exists on the medicine, the data exclusivity will end when the Turkish patent expires.

Applications for new doses, formulations and presentations of chemical entities do not include any new indications other than its 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, which contains known constituents that do not individually have a medical uses established with reasonable efficacy and acceptably safety, but, in its combined form, offers a therapeutic uses different from the known therapeutic uses of each of its constituents 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 only obligated 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 TRIPS-compliant (even going beyond) interpretation of protection of undisclosed test data.

### **Pharmaceutical pricing**

Some recent complaints have focused on Turkish pharmaceutical pricing policies. We note that these are not intellectual property complaints, and therefore are outside the scope of the Special 301 Report.

## **VIETNAM**

Vietnam was placed on the Watch List in the 2015 Special 301 Report. The United States continues to request that Vietnam 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 exclusivity**

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, on the other hand, provides an exclusive right 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 assure that submitted data is neither used for unfair commercial purposes nor disclosed, except where the disclosure is necessary to protect the public<sup>38</sup>. Neither Vietnamese law nor the U.S.-Vietnam Bilateral Trade Agreement (U.S.-Vietnam BTA)<sup>39</sup> provides exclusive control over disclosed data.

Within five years from the date that market approval is granted on the basis of undisclosed data submitted in an application, a regulatory agency cannot grant market approval regarding any subsequent applications in which the same secret data are used without consent of the data submitter, unless the data are proved to be independently created before the end of a five year term<sup>40</sup>. It is clear that Vietnamese IP law is complied 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 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.

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<sup>38</sup> See, Article 128(1) Intellectual Property Law of Vietnam 2005.

<sup>39</sup> 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”

<sup>40</sup> See, Article 128(1) Intellectual Property Law of Vietnam 2005

## **Appendices**

India's Patent System Plays by WTO Rules and Supports Global Health, Public Citizen, June 27, 2013.

The Non-Discriminatory Nature of India's National Pharmaceutical Pricing Policy, Public Citizen, August 2013.

The Question of Patent-Eligible Subject Matter and Evergreening Practices, Burcu Kilic and Luigi Palombi, July 27, 2013.

Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines, Public Citizen, Fall 2012.