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## ***Comments of Public Citizen for the 2014 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 24, 2014

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 300,000 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. We begin with principles that we believe should inform any 301 review. We describe several relevant provisions of the World Trade Organization’s (WTO’s) 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.

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<sup>1</sup> See pages 22 and 23 of the 2013 Special 301 Report.

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 enacting TRIPS-compliant pharmaceutical compulsory licenses.<sup>2</sup> In some cases the criticism is direct. In others, the references are oblique or 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 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, Special 301 is used to inappropriately assert U.S. political influence, at the behest of private interests, to undermine public interests in developing countries. For these reasons, we believe Special 301 should be discontinued in its entirety. Nevertheless, the balance of our comments address specific Special 301 practices that can and should be improved.

General commitments to principle made 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 Office of the U.S. Trade Representative (USTR) and all agencies engaged in the Special 301 process to make meaningful U.S. commitments, including commitments to protect public health, by omitting express or implied references to countries' practices that comply with international obligations.

We suggest the following principles to support this modest reform:

**Special 301 should omit any reference, whether express or implied, to any country's TRIPS-compliant policies to advance a public interest.** USTR should not sanction policies directly. Nor should it sanction 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 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.

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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>

**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 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.

**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.

**Special 301 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 Special 301 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 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.

**At a bare minimum, even if Special 301 subjects wealthy countries to criticism for TRIPS-compliant public interest policies, developing countries should be given greater leeway.** This too-modest criterion reflects our understanding of USTR policy of differential treatment in the Trans-Pacific Partnership negotiations today. Though inadequate, Special 301 should, at a minimum, reflect this modest change.

**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 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 TRIPS enable governments to mitigate, by enacting 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...* [emphasis added]

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.

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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).

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

The United States excludes various subject matters from the definition of invention. For example, the U.S. Supreme Court recently ruled that isolated DNA is not an invention, and therefore not patent eligible<sup>6</sup>.

If the subject of a patent claim is not an invention -- not patent-eligible -- then by definition it may not be patented, even if the subject matter claimed is otherwise new, involves an inventive step and is industrially applicable. Patent-eligible subject matter analysis is separate from, and precedes, 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.’ According to Article 1.1, WTO Members may determine substantive requirements in accordance with their own local systems and practices. The Members are free to define these three patentability criteria.

### **Compulsory Licences**

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 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 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 TRIPS Final Act of 1994.

The refusal of TRIPS drafters to adopt the NAFTA provision is one of several factors

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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).

demonstrating their intention to provide for data protection, not data exclusivity, in TRIPS.

## **Country Recommendations**

### **CANADA**

Canada was placed on the Special 301 2013 Watch List. USTR expressed concerns about “the impact of the heightened utility requirements for patents that Canadian courts have been adopting recently.”

### **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.

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>

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 court argued: “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. Data obtained and submitted to the patent office after filing cannot cure the application’s defect.

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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

<sup>11</sup> *Id.*

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

<sup>13</sup> *Id.* at 69

The reasons for this rule include discouraging races to the patent office based on inadequate data. After all, patent filing and successful applications may cut off competing research efforts that might yield better results. Canada's patent system requires instead sound prediction (based on data) of utility at the time of filing.

Patent law is both statutory and judge-made. 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>14</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>15</sup>

Neither TRIPS nor NAFTA attempt to harmonize the utility requirement. Definitions and interpretation of utility are deliberately left to the discretion of member countries.

The notion of a patent's promise has deep historical roots going back to British Law.<sup>16</sup> It is not uniquely Canadian. It shares common elements with the laws of the U.S., Australia, New Zealand and Europe.<sup>17</sup> It has sound policy objectives, including preventing 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 2013 Priority Watch List. USTR urged Chile "to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products" and "to provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products."

### **Data Exclusivity**

The U.S.-Chile Free Trade Agreement (FTA) provides at least five years exclusive protection to undisclosed data concerning the safety and efficacy of a pharmaceutical product which utilizes a new chemical entity.<sup>18</sup>

Chile enacted Law number 19.996, which modified Chile's Industrial Property Law<sup>19</sup>, and

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<sup>14</sup> N. S. Sreenivasulu, C. B. Raju: *Biotechnology and Patent Law: Patenting Living Beings*, 2008, p.229

<sup>15</sup> Gold at 9

<sup>16</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>17</sup> Gold at 9

<sup>18</sup> Article 17.10.01

<sup>19</sup> Articles 89 to 91 of the Industrial Property Law

Decree number 107 from the Ministry of Health<sup>20</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>21</sup> The FTA only requires exclusivity for “undisclosed” data. The Chilean law goes beyond the FTA obligations by extending protection to disclosed data if it “has been object of reasonable measures to keep it” undisclosed.<sup>22</sup>

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 2013 Special 301 Report what further protection the U.S. Government perceives Chile is obligated to apply.

### **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>23</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.

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<sup>20</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>21</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.

<sup>22</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>23</sup> Article 273 of the Chilean Civil Procedural Code and Article 106 of the Industrial Application Law allow for the pursuit of injunctions.

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 Article 17.11.1<sup>24</sup>

An automatic injunction system, such as that which the United States has proposed for the Trans-Pacific Partnership, 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.

## **INDIA**

India remained on the Priority Watch List of 2013. The United States expressed concerns about compulsory licensing and patent rules.

### **Compulsory Licensing**

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

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 -- are clearly TRIPS-compliant and, indeed, 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

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<sup>24</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.

nevertheless merit criticism? No. During the TRIPS-negotiations, US-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 exclusio alterius*: express inclusion of one thing (the semiconductor limit) implies exclusion of others (no prohibition of local working grounds). This is a standard canon of statutory interpretation. Further, 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 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.

### **Patent Eligible Subject Matter**

Recent criticisms of Indian patent rules tend to take Article 3(d) as an impermissible fourth patentability criteria. 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>25</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

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<sup>25</sup> See, Burcu Kilic & Luigi Palombi, “The Question of Patent Eligible Subject Matter and Evergreening Practices”, <http://infojustice.org/archives/30314#more-30314>

[known] substance.”<sup>26</sup> Patent applicants have an opportunity overcome the 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>27</sup> Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.<sup>28</sup>

India’s Section 3(d) complies with the the TRIPS Agreement.

### **Pharmaceutical pricing**

Some recent complaints have focused on Indian pharmaceutical pricing policies. We note that these are not intellectual property complaints, and therefore are outside the scope of the Special 301 Review. Nevertheless, we have provided a rebuttal to one recent (and erroneous) complaint in an appendix, attached.

## **INDONESIA**

Indonesia was placed on the Special 301 2013 Priority Watch List. USTR encouraged Indonesia “to provide an effective system for protecting against unfair commercial use of undisclosed test data generated to obtain marketing approval for pharmaceutical products and remains concerned by measures restricting the importation of medicines.” USTR also noted “with concern statements in Indonesia’s Special 301 submission indicating that Indonesia failed to abide by its procedures in issuing compulsory license decree [sic] in 2012, and its patent law does not require individual merit review in connection with the grant of compulsory licenses.” USTR further encouraged “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 obliged 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>29</sup>

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<sup>26</sup> The following are not inventions within the meaning of this Act:

<sup>26</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>26</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>27</sup> Ibid

<sup>28</sup> Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013. Supreme Court of India.

<sup>29</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).

## **Compulsory Licences**

In 2012, Indonesian President Susilo Bambang Yudhoyono issued a presidential decree<sup>30</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>31</sup>

In accordance with Article 99 of Indonesian Patent Law No. 14/2001<sup>32</sup>, 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.

Government Regulation of the Republic of Indonesia Number 27, Year 2004<sup>33</sup>, establishes a procedure for the government use of patents. According to this procedure, the Ministry of Health files a written proposal to 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 opinion including the royalty rates for the exploitation of patents by the government. 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 the patent holder has an objection on the amount of the royalty paid by the government, he may file a lawsuit to the Commercial Court within a period of 3 months after the enactment of Presidential Decree.<sup>34</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 HIV/AIDS medicines. 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 2014 Watch List should include no references to Indonesia's government use of patents to advance

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<sup>30</sup> Presidential Decree Regarding Patent Exploitation of the Antiviral and Antiretroviral Drugs

<sup>31</sup> See, Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines -- Precedent-Setting Government Order has Extraordinary Life Saving Potential

<sup>32</sup> (1) If the Government is of the opinion that a patent in Indonesia is very important for the defense and security of the State and for an urgent need for the public interest, the Government may implement the relevant patent itself.

<sup>32</sup>(2) The decision to implement a patent itself shall be stipulated by a Presidential Decree after hearing the consideration from the Minister and from the minister or head of the agencies in-charge in the relevant field.

<sup>33</sup> Government Regulation of the Republic of Indonesia Number 27 Year 2004 Regarding the Procedure of Exploitation of Patent by the Government

<sup>34</sup> Article 10 Government Regulation of the Republic of Indonesia Number 27, Year 2004

AIDS treatment.

## **PERU**

Peru was placed on the Special 301 Watch List in 2013. Peru was requested to clarify its protection for biotechnologically-derived pharmaceutical products.

### **Data Exclusivity**

The U.S.-Peru Trade Promotion Agreement provides exclusivity to a product that utilizes a new chemical entity. Small molecule drugs are referred to as New Chemical Entities (NCEs). Large molecules (biologics) are not considered NCEs because they are not chemically synthesized. 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.”<sup>35</sup> Biologics are protected under trade secret rules in Peru.

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>36</sup>

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

## **TURKEY**

Turkey was placed on the Watch List in 2013. USTR encouraged Turkey to clarify its protection against unfair commercial use, as well as unauthorized disclosure, of test and other data generated to obtain marketing approval for pharmaceutical products.

### **Data Exclusivity**

Turkey fulfills its obligations under Article 39.3 of the TRIPS Agreement to provide protection against unfair commercial use of clinical trial data and takes necessary steps not to disclose the contents of these submissions to unauthorized third parties. In addition to protection against unfair commercial use, the Turkish system provides a *de facto* 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

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<sup>35</sup> See., Professor 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>36</sup> Ibid-

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.

According to Article 9.3 of the Regulation on Licensing of Medicinal Products, 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 Customs Union and the manufacturers of similar products are prevented from using / referring to the data in their license applications.

Under the Licensing Regulation, data exclusivity is granted to (i) original products that have been licensed for the first time in a Customs Union country following 1 January 2001 for which there have been no generic license applications in Turkey until 1 January 2005, and (ii) original products that are licensed for the first time in a Customs Union country following 1 January 2005.

Application 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 is 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.

### **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 Review.

## **PHILIPPINES**

Philippines was placed on the Watch List in 2013. The United States has concerns about data protection as well as recent amendments of 2008 to the Patent Law Act of 1997.

### **Data Protection**

Philippines has an effective system for protection of test data, indeed, section 7 of the Republic Act No 9502 of 2008 that amended Article 72.4 of the Patent Law Act of 1997 (Republic Act No 8293) established a data protection system in compliance with Article 39.3 of TRIPS. Section 7 provides that the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations to provide data protection. In that sense, the Intellectual Property Office in conjunction with the Department of Health,

Department of Trade and the Bureau of Food and Drug issued an Administrative Order No 2008-01, which regulates data protection on the same terms of Article 39.3 of TRIPS.

### **Patentable Subject Matter**

Like India, Philippines, as a WTO member, has discretion to determine what an ‘invention’ is and how the patentability requirements (novelty, inventive step, industrial applicability) are to be applied to decisions on whether to grant or not grant a patent.

Section 5 of the Republic Act No 9502<sup>37</sup> is structured as a subject matter eligibility threshold, not as a patentability test. According to Section 5, a new form of a known chemical substance is not considered an invention if it “does not result in the enhancement of the known efficacy of that [known] substance.” However, a derivative of a known substance can overcome this presumption against subject matter eligibility if it demonstrates a significant difference in its properties with regard to efficacy.

### **COLOMBIA**

Colombia was placed on the 2013 Watch List. The United States does not mention any substantial concerns related to Colombia’s patent law system, but encourages Colombia to pass pending legislation to implement the U.S.-Colombia FTA. The 301 Report states that the “United States urges Colombia to swiftly pass key pieces of currently pending IPR legislation in connection with the implementation of that agreement [the U.S.-Colombia FTA].” Notably, in the area of patents, Colombia’s legislation already complies with the intellectual property provisions of the FTA as well as the TRIPS Agreement. In 2012, the Government issued decree No 729 to implement Andean Community Decision No 486 of 2000 that was amended by Decision 632 of 2006, in order to be in compliance with the patent provisions of the FTA.

### **Conclusion**

We appreciate this opportunity to comment. Public Citizen invites the Office of the U.S. Trade Representative (USTR) and all agencies engaged in the Special 301 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>37</sup> Section 5 of R.A 9502: “ ...*Non-Patentable Inventions*. - The following shall be excluded from patent protection:

<sup>37</sup>“Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property 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 the mere use of a known process unless such known process results in a new product that employs at least one new reactant”.

## **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.