



## 2014 Special 301 Watch List Submission

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Health GAP submits these comments in response to written and oral submissions made by PhRMA and other trade associations attacking India's intellectual property regime, particularly its issuance of a compulsory license on a Bayer cancer medicine and the adoption of section 3(d) to the Indian Amended Patents Act and its Supreme Court decision thereunder denying a patent on a Novartis medicine. The referenced submissions by opponents to the India IP regime can be found at <http://www.keionline.org/ustr/Special301>.

We make the following three comments in opposition to listing India on the Special 301 Watch List:

- 1. India's adoption and one-time use of compulsory licensing is TRIPS compliant and does not justify elevation of India on the US's 2014 Special 301 Watchlist**
- 2. Section 3(d) of the Indian Patents Act is fully legal under the TRIPS Agreement and India's adoption and use of this provision does not justify elevation of India on the 2014 Special 301 Watchlist.**
- 3. The U.S. President's Emergency Plan for AIDS Relief and U.S. global AIDS programs are dependent for success on continued, robust Indian generic production of AIDS drugs through continued Indian use of WTO-compliant legal flexibilities. Listing India on the 301 Watch List would undermine President Obama's declared priority of creating an "AIDS Free Generation," waste U.S. taxpayer funds, and imperil the PEPFAR program.**

1. India's adoption and one-time use of compulsory licensing is TRIPS compliant and does not justify elevation of India on the US's 2014 Special 301 Watchlist

*India's Amended Patents Act allows both compulsory licenses and government use licenses, and it also authorizes licenses for export for countries with insufficient manufacturing capacity. In its entire history, India has issued just one compulsory license on Bayer's cancer medicine,*

*Nexavir, upon application by Natco. The initial decision of the Patent Office<sup>1</sup> was reviewed and modified by the Intellectual Property Appellate Board<sup>2</sup> and Bayer is now pursuing court review of that decision. India's compulsory licensing regime is fully TRIPS-compliant. Its issuance of a license in Nexavir was justified on several, alternative grounds and its also fully TRIPS-compliant. Thus, it is inappropriate for the USTR to base any decision on the India's listing on the 2014 Special 301 Watchlist based on any alleged abuse or protectionism by India with respect to its compulsory licensing legislation or the one license granted.*

Section 84 of the Indian Patents Act<sup>3</sup> allows the government to compulsorily license a patent three years after grant. Applicants seeking compulsory licenses should provide proof that the applicant attempted to negotiate a license with the patent owner as required under the TRIPS agreement, and must do so for a minimum period of six months.<sup>4</sup> As for the grounds, third parties can seek a license on the grounds that the (a) reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.<sup>5</sup> The term *reasonable requirements of the public* is broad and can be deemed to be not satisfied if an existing industry or trade in India is affected; the demand for a patented article is not met by the patent holder, or the market is affected directly or because of the patent holder's activities. The local working requirement, the grounds most criticized by India's critics, has been narrowly construed – as described further below – and is legally sufficient and justified under international and national law.<sup>6</sup> In sum, India's grounds under Section 84 are fully in accord with traditional grounds for compulsory licenses dating back to the earliest patent laws, and explicitly sanctioned in Paris Convention Article 5(A).

Under Section 92, a compulsory license can be granted where the government provides notice of the existence of a national emergency such as a public health crisis or where it intends to use the patented subject matter for non-commercial public use.<sup>7</sup>

Section 90(1)(vii) allows for export of non-predominate quantities compulsorily licensed products and Section 92A requires export of patented pharmaceuticals to “any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.”

Compulsory licensing, which allows involuntary use of a patent under public interest circumstances when proper, designated procedures are followed, is an important legally sanctioned exception to patent rights under international law. Article 31 of the TRIPS Agreement specifies the prerequisites of such compulsory licenses. Generally, Article 31 requires WTO

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<sup>1</sup> [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf).

<sup>2</sup> *Bayer v. India*, OA/35/2012/PT/MUM, <http://www.ipab.in/045-2013.htm>.

<sup>3</sup> Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (hereinafter Patents Act).

<sup>4</sup> *Id.*, § 84(5)(4).

<sup>5</sup> *Id.*, § 84.

<sup>6</sup> Michael Halewood, *Regulating Patent Holders: Local Working and Compulsory Licenses Under International Law*, 35 Osgoode Hall L.J. 243 (1997).

<sup>7</sup> *Id.* § 92.

Member States to negotiate with the rightholder for a reasonable period of time to obtain a voluntarily license on reasonable commercial terms with the understanding that such licenses will cease once the grounds for the license ceased to exist. Article 31(b), however, waives the requirement to negotiate towards authorization from the patent holder “[i]n the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” Prior negotiation is also not required for competition based licenses (Article 31(k)). The TRIPS Agreement does require that certain procedures be followed: (1) licenses shall be considered on their individual merits (Article 31(a)); (2) the scope and duration of the license shall ordinarily be limited to the purpose[s] for which it was authorized (Article 31(c)) and should ordinarily be terminable when the conditions of its issuance no longer exist (Article 31(g)); (3) the license should be non-exclusive, meaning the right-holder can still exercise the patent, and non-assignable (Article 31(d)-(e)); (4) the use by the licensee shall be predominantly for supply of the domestic market (Article 31(f); and (5) there shall be rights of review by independent higher authorities (Article 31(i) and (j)). The TRIPS Agreement in Article 31 (h) requires that the right holder shall be paid “adequate remuneration” in the circumstances of each case. The adequacy of the remuneration is measured by taking into account the economic value of the authorization.

The TRIPS Agreement does not specify the grounds upon which a license can be issued, although the incorporation of the Paris Convention on Industrial Property does expressly cover the circumstances when a compulsory license can be issued for non-working (Paris Convention, Art. 5). The TRIPS Agreement was negotiated in circumstances where nearly 100 countries had compulsory licensing provisions in their national legislation with pluralistic grounds for issuing such licenses. Nonetheless, because of uncertainty about the rights of countries to define grounds for and to issue compulsory licenses, WTO Member States, including the U.S., unanimously adopted the Doha Declaration on TRIPS agreement and Public Health<sup>8</sup> (“Declaration”) which specifically enumerates and details the the flexibilities within Article 31 of the TRIPS agreement.

Paragraph 3 introduces the Declaration by highlighting that, “We [also] recognize the concerns about its [the TRIPS Agreement’s] effects on prices” and adds in Paragraph 4 that “[t]he TRIPS Agreement does not and should not prevent members from taking measures to protect public health...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. (Emphases added)”

The tenor set in the introductory paragraphs is complimented by the specific flexibilities outlined in paragraph 5, which clarifies flexibilities both with respect to compulsory licenses and parallel importation (international exhaustion).

First, paragraph 5 states that TRIPS will be interpreted in light of the objectives and principles outlined in Articles 7 and 8 in a manner conducive to “social and economic” welfare of member states. Article 7 states that “[T]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and

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<sup>8</sup> *The Doha Declaration Explained*, WORLD TRADE ORGANIZATION, at [http://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm) (last visited May 30, 2011).

dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” In gist, Article 7 emphasizes the welfare paradigm in asserting that the international obligations of protection and enforcement of IP rights should contribute to the national social and economic welfare of members. The meat of this provision is in ensuring mutual advantage to the producers and users. The provision also acknowledges social and economic welfare –and balancing the rights with the obligations of members. Any balancing of rights of an exclusive right holder will create a corresponding duty of the right holder to the society (as opposed to a correlative duty that the right holder generally becomes entitled to). Article 8, discusses the principles under which the objectives of Article 7 will be satisfied. Entitled “Principles,” Article 8 recognizes members’ rights to adopt public interest or public health measures consistent with the TRIPS provisions. Such objective-based interpretation bears wide social and political consequences for developing nations and allows them to tailor measures facilitating global trade while also achieving national goals.<sup>9</sup>

Second, paragraph 5(2), outlines the right of national governments to compulsorily license patents and the “freedom to determine the grounds of compulsory licensing,” including the use of grounds not specified in Article 31.<sup>10</sup> Thus, lack of local working of the patent, high prices charged by the patent owner, refusals to license, ensuring access to essential facilities, avoiding reliance on single sources of supply and supply interruption, allowing production of fixed-dose combination medicines, and others can be grounds for granting compulsory licenses.<sup>11</sup> In addition countries can articulate open-ended public interest or public health grounds to issue compulsory licenses.

Third, members have the right to determine what constitutes a national emergency or other circumstance of extreme urgency.<sup>12</sup> Further, the subparagraph clarifies that it is “understood” that tuberculosis, malaria, and other epidemic-causing illnesses could represent a national emergency or a circumstance of extreme urgency.<sup>13</sup> Thus, there is specific recognition that national emergencies or circumstances of extreme urgency can arise from diseases other than HIV/AIDS. Professor Carlos Correa makes two important comments with reference to the subparagraph: (1) that the use of malaria and tuberculosis as examples indicates an understanding that the emergency need not be a short-term problem,<sup>14</sup> and (2) that the expression “it being understood that public health crises, including . . . tuberculosis, [and] malaria . . . can represent a national emergency” is used to create a presumption in favor of the member.<sup>15</sup>

The Doha Declaration clarifies and broadens the interpretation Article 31. Article 31 is not primarily about achieving commercially reasonable licenses – it is instead about governments exercising retained sovereignty to define when exclusive rights that might otherwise prevent competition might be reduced to achieve a public-interest result. The rightholder can still

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<sup>9</sup> Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization (June 2002).

<sup>10</sup> Doha Declaration, at ¶5(2).

<sup>11</sup> See Correa, *supra* note 5, at 15; see also Doha Declaration, ¶ 5(2)

<sup>12</sup> Doha Declaration, ¶ 5(3).

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

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

produce and sell, but it might face competition. Moreover, the rightholder is guaranteed adequate remuneration. Finally, if the rightholder feels aggrieved, it can seek review from independent higher authorities.

It is important to appreciate that the compulsory license on Nexavir granted by the Controller General of Patents was based on three separate and independent grounds and provided for a royalty on generic sales. The Controller's compulsory licensing decision was reviewed at length on appeal by the Intellectual Property Appellate Board (IPAB). Indeed, the IPAB raised the royalty rate from 6% to 7% and generally accepted the Controller's findings that the reasonable requirements of the public with respect to the patented drug were not met as Bayer supplied the drug to only 2% of the patient population and that the pricing of the drug (\$5100 for a month's supply of the drug against Natco's proposed price of \$160) was excessive and did not constitute a "reasonably affordable" price. On the other hand, the IPAB modified the Controller's interpretation of local working requirement in section 84 of the Indian Patents Act while confirming that Bayer had not satisfied the statutory requirement. The Controller had held that "working" under section 84 could never include mere imports; given that Bayer was merely importing Nexavar capsules into the country, it could not be said to have "worked the patent". The IPAB took a differing interpretation that "working" was a flexible term and could be satisfied by "imports" only in some instances and by local production only in other.<sup>16</sup> This would depend on circumstances such as the technology in issue, whether the invention could be feasibly and practicably manufactured in India in light of projected sales,<sup>17</sup> and other relevant issues. However, the IPAB held that it was not clear that "imports" in the Bayer case had satisfied the working requirement, given that Bayer did not furnish any credible reasons whatsoever for not manufacturing in India despite having a local plant. The IPAB also noticed the distinction in the Paris Convention on Industrial Property between revocation for non-working and compulsory licenses for insufficient work, which was explicitly allowed. Similarly, in addressing the non-discrimination against import rule in TRIPS Article 27, the IPAB correctly noticed that that provision addresses non-discrimination in the granting of patents based on import, not the issue of allowing the granting of compulsory licenses based on the absence of local working.

By all appearance, Bayer remains upset by the decision of the IPAB decision. However, since the possibility of judicial review of IPAB decisions is well preserved in India, Bayer is in fact currently exercising its appeal rights.

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<sup>16</sup> "So, with regard to Section 84(1)(c), we find that the word 'worked' must be decided on a case to case basis and it may be proved in a given case, that 'working' can be done only by way of import, but that cannot apply to all other cases. The patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence. Therefore, while we are of the opinion that the word 'worked' has a flexible meaning, and to that extent we differ from The Controller. The appellant has not proved working and so his conclusion is right. Working cannot mean that the requirement of working would be satisfied by having import monopoly for all patented inventions. We also look at Section 84(7)(iii) which says that the reasonable requirements of public shall be deemed not to have been satisfied if a market for export of the patented article manufactured in India is not being supplied or developed. Therefore, 'working' could mean local manufacture entirely and 'working' in some cases could mean only importation. It would depend on the facts and evidence of each case." *Bayer v. India*, OA/35/2012/PT/MUM, ¶ 52.

<sup>17</sup> *Id.* ¶ 51.

Provisions for compulsory licenses are not alien even in the United States. The government use provision in Title 28 below provides an easy-to-use license that has been used on hundreds of occasions in the U.S.

*28 USC § 1498 deals with the right of the US Government over any patented or copyrighted product. It provides that the US government is not required not seek a license or negotiate for the use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.*

This provision empowers the United States government, or those authorized by it, to make any use or manufacture of a patented product or process “without license.” While the right holder is entitled to “compensation,” he cannot enjoin the government to prevent the use or use for infringement. This provision can be used against foreign as well as U.S.-based rightholders. Similarly, the Bayh-Dole Act<sup>18</sup> codified under Title 35, in section(s) 200 and 203 outlines the reservations of government rights with a view to ensure that the patent holders of research that were originally funded by agencies of the federal government would use the research towards public benefit. Under these provisions, the federal government retains a non-exclusive, non-transferable, royalty-free license to use the invention. The objective is to retain the right to commission further research on patents acquired from research originally funded research by the federal agencies. In line with this, the federal agency that funded the research retains a “*march in*” right, under some circumstances, to compel a license where the patent owner is suspected of not using the invention for the benefit of the public. Once such instances where march-in rights can be initiated are to “alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees” – which is very similar and remains comparable to the compulsory license provision in India. Similar provisions are found in the Clean Air Act at Title 42 USC section 7608 allowing compulsorily licensing of a technology was funded by U.S. government grants if the patented technology becomes necessary to meet the requirements in certain sections of the Clean Air Act.<sup>19</sup>

2. Section 3(d) of the Indian Patents Act is fully legal under the TRIPS Agreement and India’s adoption and use of this provision does not justify elevation of India on the 2014 Special 301 Watchlist.

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<sup>18</sup> 35 USC section 200

<sup>19</sup> There are other examples of limitations and exceptions to patent rights in U.S. law including the so-called early-working or Bolar provision, 35 U.S.C. § 271(e)(1), which states that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”

Granting secondary patents is a controversial issue, not just in India but even in the United States.<sup>20</sup> The term *evergreening* refers to strategically patenting different forms of a medicine's active ingredients, new uses, and/or new formulations and staggering such protection to extend patent exclusivity over various forms/uses of the medicine beyond the basic 20-year term of protection. Such strategic secondary patenting became commonplace in the United States thanks to the steady lowering of patentability standards, especially for determining nonobviousness, which is now subject of much scrutiny in the United States. The struggles of the United States with a barrage of secondary patents on medicines have served as a lesson to other countries, including India.<sup>21</sup>

India's Section 3(d), enacted in the 2005 amendment,<sup>22</sup> prohibits patenting of new uses of known substances, including medicines. Similarly, patenting new forms of known substances is not allowed unless there is evidence of significantly enhanced efficacy. The logic of this interesting provision is along the exact lines of the opinion of the Court of Appeals for the Federal Circuit (CAFC) in the case of *Pfizer v. Apotex* involving the Pfizer's patenting of the besylate form of amlodipine (salt form) which Apotex claimed was obvious in the light of Pfizer's own patent on the base compound amlodipine.<sup>23</sup> The Court of Appeals, in agreeing with Apotex that the patent on the besylate form was invalid, highlighted the besylate form lacked the *unexpected superior results* from the base compound in order for the salt form to be patented.<sup>24</sup> Indeed, the Manual for Patent Examination Procedure in section 716.02 and in 2144.09 specifically memorializes *unexpected results* as a test to demonstrate nonobviousness of structurally similar compounds like isomers and homologues.<sup>25</sup> Thus, India's standard is well within the lines of what has been allowed in the United States.

The Novartis judgment, which has become central to Congressional criticism of India's IP regime, was decided significantly on the basis of the absence of any evidence of enhanced efficiency, a valid criteria for assessing patentability as described above.<sup>26</sup> In essence, the Supreme Court of India, in a well-reasoned decision, found that beta-crystalline form of imatinib mesylate, was revealed and claimed in a pre-TRIPS patent and thus was time barred from patentability in India unless it showed significantly enhanced efficacy.<sup>27</sup> Unfortunately for Novartis, the Supreme Court of India found that Novartis offered no evidence of increased efficacy of the relevant compound whatsoever, and thus that the patent was unmeritorious under section 3(d).

The Novartis judgment is a long one. It combines a meticulous examination of the legislative context within which India passed its amended Patents Act in 2005 and a painstaking analysis of the claims and disclosures in the original patent application on Glivec's base ingredient,

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<sup>20</sup> See GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY. FEDERAL TRADE COMMISSION 2002

<sup>21</sup> See Thomas Faunce and Joel Lexchin, *Linkage' Pharmaceutical Evergreening in Canada and Australia*, Aust - New Zealand Health Policy (Biomed Central) (2007); EVERGREENING OF PHARMACEUTICAL MARKET PROTECTION, EUROPEAN GENERIC MEDICINES ASSOCIATION.

<sup>22</sup> Patents Act, *supra* note 3, § 3(d).

<sup>23</sup> *Pfizer v. Apotex*, 488 F. 3d 1377 (Fed. Cir. 2007); *see also* *Pfizer v. Apotex*, 480 F.3d 1348 (Fed. Cir. 2007).

<sup>24</sup> 480 F.3d at 1368; *see also In re Swain*, 33 C.C.P.A. 1266, 156 F.2d 246, 247-48 (1946).

<sup>25</sup> Manual for Patent Examination Procedure § 2144, § 716 (8th ed., rev. 2012).

<sup>26</sup> *Novartis AG v. Union Of India & Ors*, Civil Appeal No. 2706-2716 of 2013.

<sup>27</sup> *Id*

imatinib, the details of its regulatory filing when it first sought product registration in the US and in India, and its subsequent application on the beta crystalline form of imatinib mesylate. It also clarifies the interrelationship between standards for invention found in section 2(1)(j) and (ja) of the Act and section 3(d) addressing the patentability of previously known substances including medicines.

In terms of the successive patent applications, the Supreme Court held that the original patent application, filed in the United States in 1994 before the effective date of India's amended Patents Act (the so-called Zimmerman patent), had claimed and had covered the imatinib mesylate as well as imatinib (paragraphs 133, 157). It held further that the second application, filed in India's "patent mailbox" in 1998, on the beta crystalline form was a rough cut and paste version of the original patent (paragraph 164). It found that Novartis's application for approval of Glivec/Gleevec in the United States had claimed that the active pharmaceutical ingredient was imatinib mesylate rather than only the beta crystalline form thereof (paragraphs 116-120), that Novartis' exclusive marketing rights application in India had been based on imatinib mesylate as well (paragraph 193), and that all of the pharmaceutical properties of the beta crystalline form were equally possessed by imatinib in free base form or its salt (paragraph 163). In terms of properties, the Court found that the beta crystalline form had better flow properties, was more thermodynamically stable, and was less hygroscopic (paragraph 172), but none of these characteristics were relevant to the section 3(d) analysis which focuses on increased efficacy in term of treatment (paragraph 187). It found that there was no evidence that the beta crystalline form had better bioavailability than the imatinib mesylate itself, the relevant comparison (paragraph 170).

In terms of its legal ruling, the Supreme Court clarified several important points. First, by examining the legislative context and history, the Court confirmed that India's amended Patents Act was intended to prevent evergreening patents (paragraphs 75-86). Second, it confirmed that India had incorporated strict standards of patentability, especially with respect to medicines, and that section 3(d) encapsulated that intent and was a clarification of basic standards of invention and inventive step found in section 2(1)(j) and (ja) of the Act (paragraph 104). Third, it held that Novartis' attempt to differentiate the "coverage" of a patent from what is "disclosed" in patent claims and specifications was unacceptable and that there should be no significant gap between the two (paragraphs 136-156). Finally, it confirmed an interpretation of section 3(d) that focuses on the therapeutic impact of modifications rather than simply physical properties such as solubility, flow, or stability (paragraphs 158-187). It rejected an interpretation that section 3(d) requires that the full therapeutic efficacy of the original compound be known and demonstrated at the time of filing and stated further that evidence of increased bioavailability alone would not necessarily show increased therapeutic efficacy (paragraph 188-189). The Court declined to further specify the exact meaning of increased efficacy even while acknowledging divergent opinion offered by counsel (paragraphs 182-186).

At the end, the Court summarized the legal standard that should be applied in assessing secondary patent applications: Section 2(1)(j) defines "invention" to mean, "a new product or ...", but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind". However, in case of chemicals and

especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation. (Paragraph 192.)

The Court was quite patient with the "creative" arguments advanced by Novartis' high priced lawyers. But in the end, it found the case incredibly easy to decide: the beta crystalline form failed both tests of invention found in section 2(1)(j) and (ja) and standards of patentability further set forth in section 3(d) (paragraph 195). The Court further stated that "the case of the appellant [Novartis] appears in a rather poor light and the claim for a patent for the beta crystalline form of Imatinib Mesylate would only appear as an attempt to obtain patent for Imatinib Mesylate, which would otherwise not be permissible in this country." (Paragraph 194.)

TRIPS does not require its member countries to be persuaded by the issue patents of other countries. The argument that several other countries agreed that Gleevec was patentable despite being a mere variation of an existing, previously patented chemical entity is inconsequential to India's own patent determination. If a country chooses to adopt a higher bar for determining patentable subject matter and/or inventive step under TRIPS, it is well within the member's rights to do so. Indeed, Japan has a record of allowing approximately 14% of patents that are granted in the United States. Having a higher bar with standards is well within the rights of a sovereign nation and well-established under the principles of the World Trade Organization. India's Section 3(d) and the Novartis judgment fall well within the ambit of the TRIPS agreement.

3. The U.S. President's Emergency Plan for AIDS Relief and U.S. global AIDS programs are dependent for success on a continued, robust Indian generic production of AIDS drugs through continued Indian use of WTO-compliant legal flexibilities. Listing India on the 301 Watch List would undermine President Obama's declared priority of creating an "AIDS Free Generation," waste U.S. taxpayer funds, and imperil the PEPFAR program.

*In 2014 the United States will spend \$6.54 billion on global anti-HIV programs,<sup>28</sup> largely through PEPFAR bilateral programs and the Global Fund to Fight AIDS, TB, and Malaria. Through largely-U.S.-funded research, it has become possible to talk, as President Obama has, about beginning to end the AIDS pandemic.<sup>29</sup> Doing so requires access to large quantities of low-cost, high quality antiretroviral medicines—which are in large part supplied by Indian generic drug makers through the very legal flexibilities for which PhRMA proposes India should be listed on the 301 Watch List.*

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<sup>28</sup> Henry J. Kaiser Family Foundation, U.S. FEDERAL FUNDING FOR HIV/AIDS: THE PRESIDENT'S FY 2014 BUDGET REQUEST (2014), <http://kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hiv-aids-the-presidents-fy-2014-budget-request/>.

<sup>29</sup> The White House, FACT SHEET: THE BEGINNING OF THE END OF AIDS (2011), <http://www.whitehouse.gov/the-press-office/2011/12/01/fact-sheet-beginning-end-aids> (last visited Mar 7, 2014).

Both President Bush and President Obama have made fighting AIDS in Africa a chief priority—investing many billions in U.S. taxpayer dollars in treatment, care, and prevention programs that have been one of the signature foreign policy achievements of both administrations. Under President Bush, however, it was recognized that the cost of anti-AIDS medicines would be a major barrier to getting drugs to all those in need of them. For this reason, PEPFAR began to transition to using generic versions of those drugs, largely made in India. The US Food and Drug Administration (FDA)'s process was modified to expedite review and approval of generic antiretrovirals (ARVs) quickly, making a large number of FDA–tentatively approved ARVs available for use by the US President's Emergency Plan for AIDS Relief. By 2008, 76% of the drugs purchased by PEPFAR were generic, saving the program over \$323 million.<sup>30</sup> U.S. taxpayer funds were used much more efficiently and effectively as cost of medicines bought by PEPFAR dropped from \$1,100 per person annually in 2004 to \$335 per person annually in 2012 due to the availability of effective generic antiretrovirals.<sup>31</sup>

In recent years NIH-funded research revealed that AIDS drugs are not only life-saving, but they also prevent new HIV infections. A randomized controlled trial demonstrated a 96% reduction in transmission between serodiscordant couples when the HIV-positive partner was on antiretroviral drugs,<sup>32</sup> which has recently been confirmed in the field.<sup>33</sup> This is already being shown to have an effect—with the population effect of ART on HIV transmission so strong that one analysis has shown that, in high burden settings, for every 1% increase in ARV coverage risk of acquiring HIV declines by 1.4%.<sup>34</sup> Meanwhile, ARVs have already resulted in life expectancy gains of over 11 years in hyper-endemic settings.<sup>35</sup>

This led Secretary of State Clinton in 2011 to announce a new U.S. policy goal: creating an “AIDS Free Generation.” A key pillar of this policy move was increasingly rapid expansion of access to ARVs, made possible by low-cost affordable generics.

Today India supplies 80% of generic antiretroviral AIDS drugs.<sup>36</sup> In developing countries, largely outside Africa, unable to access generic versions of these medicines due to patent barriers the costs have remained about ten times this generic price.<sup>37</sup> PEPFAR and the Global Fund are

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<sup>30</sup> Charles B. Holmes et al., *Use of generic antiretroviral agents and cost savings in PEPFAR treatment programs*, 304 JAMA J. AM. MED. ASSOC. 313–320 (2010).

<sup>31</sup> Kartik K. Venkatesh, Kenneth H. Mayer & Charles CJ Carpenter, *Low-Cost Generic Drugs Under The President's Emergency Plan For AIDS Relief Drove Down Treatment Cost; More Are Needed*, 31 HEALTH AFF. 1429–1438 (2012).

<sup>32</sup> Myron S. Cohen et al., *Prevention of HIV-1 infection with early antiretroviral therapy*, 365 N. ENGL. J. MED. 493–505 (2011).

<sup>33</sup> Samuel Biraro et al., *HIV-1 Transmission within Marriage in Rural Uganda: A Longitudinal Study*, 8 PLOS ONE e55060 (2013).

<sup>34</sup> Frank Tanser et al., *High coverage of ART associated with decline in risk of HIV acquisition in rural KwaZulu-Natal, South Africa*, 339 SCIENCE 966–971 (2013).

<sup>35</sup> Jacob Bor et al., *Increases in adult life expectancy in rural South Africa: valuing the scale-up of HIV treatment*, 339 SCIENCE 961–965 (2013).

<sup>36</sup> Brenda Waning, Ellen Diedrichsen & Suerie Moon, *A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries*, 13 J. INT. AIDS SOC. 35 (2010); P. Gwynne, *Biotech in the BRICyard*, SCI. AM. WORLDVIEW, <http://www.saworldview.com/article/biotech-in-the-bricyard>.

<sup>37</sup> Waning, Diedrichsen, and Moon, *supra* note 36.

among the largest purchasers, directly or indirectly, of these drugs—without which the global AIDS policy goals of the U.S. government would not be possible. The U.S. clearly recognizes the value of production of these key drugs, and yet this production is made possible directly because of the policies opposed by PhRMA in their 301 submission.

The lives of people living with HIV as well as dealing with cancer, tuberculosis, heart disease, and many other diseases around the world depend on continued policy space in India. There is no legal or ethical basis on which India should, thus, be listed on the Special 301 list for pharmaceutical related IP policy.