

Submission of Knowledge Ecology International to the WIPO SCP: Constraints faced by developing countries and least developing countries (LDCs) in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs.

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October 2017

Knowledge Ecology International (KEI) submits the following paper on “constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impacts” on access to medicines pursuant to the decision of the World Intellectual Property Organization’s (WIPO) Standing Committee on the Law of Patents (SCP) at its twenty-sixth session (document SCP/26/7, paragraph 19, first bullet point under "Patents and Health").

Mapping political pressure over the years

This submission documents some notable examples of pressure brought to bear against countries who employed or contemplated using the flexibilities afforded to them under the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Protection (TRIPS).

Brazil

As noted by KEI in June 2012:

On January 9, 2001, a few days before leaving office, President Clinton requested the establishment of a panel at the WTO, to challenge Article 68 of Brazil's 1996 industrial property law, which contained provisions regarding the local manufacturing of products. After Clinton left office, the Bush Administration withdrew the WTO case against Brazil on June 25, 2001. (Source: USPTO and Congress bash India over the Nexavar compulsory license, <https://www.keionline.org/node/1447>).

The New York Times reported the decision as follows:

The United States unexpectedly withdrew a patent complaint against Brazil in the World Trade Organization today and agreed to settle out of court a dispute widely seen as symbolic of the debate over who may manufacture and sell drugs to treat AIDS in poor countries.

Coming on the first day of a United Nations General Assembly debate on the AIDS crisis, the decision was welcomed by campaigners for cheaper medications for developing nations, where AIDS is taking a devastating toll. Brazil, which had been

moving to the forefront of an international challenge to large Western pharmaceutical companies and their high-priced anti-retroviral medicines, has sharply cut its mortality rate from AIDS in recent years with an aggressive campaign to make drugs available cheaply and effectively, experts say.

American officials, who had threatened Brazil with trade sanctions, said two months ago that this case was important to uphold the general principle of protecting intellectual property rights and that Brazil was using a provision in its law to pressure patent owners to make products there. Brazil's AIDS chief, Dr. Paulo Roberto Teixeira, responded on May 2, saying that his country was being punished for challenging American companies in ways that other nations did not. (Source: U.S. Drops Case Over AIDS Drugs in Brazil, <http://www.nytimes.com/2001/06/26/world/us-drops-case-over-aids-drugs-in-brazil.html>).

A different interpretation was that the United States did not believe it would win the dispute, given the uncertainty over the status of local working obligations in the TRIPS Agreement.

- January 9, 2001. Document submitted to the WTO by the United States. [Request for the Establishment of a Panel by the United States.](#)
- February 1, 2001. Document submitted to the WTO by Brazil. [Measures Affecting Patent Protection.](#)
- February 6, 2001. Consumer Project on Technology. [Statement on the Trade Dispute Between the United States and Brazil.](#)

Colombia

The following link on the KEI website, <https://www.keionline.org/colombia>, reports on some of the pressure faced by Colombia during the course of the imatinib (marketed in Colombia by Novartis as Glivec) compulsory licensing case, including specifics such as these:

May 2015: As noted by the authors (Goldman and Balasubramaniam):

On 18 May 2015 - on the margins of the 68th World Health Assembly in Geneva - the Swiss State Secretary and Director of the Federal Office of Public Health, Pascal Strupler, confronted Colombia's Minister of Health and Social Protection, Alejandro Gaviria, in a bilateral meeting and presented Switzerland's concerns with Colombia's impending move to issue a public interest declaration on the patent of imatinib. Switzerland's keen interest in Colombia's public policy likely stems from the fact that Novartis, a Swiss pharmaceutical company, had obtained a patent on the crystalline form of imatinib mesylate in February 2012, after 9 years of litigation.

Following the bilateral meeting at the World Health Assembly, on 26 May 2015, Ambassador Livia Leu, the Swiss Head of Bilateral Economic Relations and Delegate of the Federal Council for Trade Agreements, sent a letter to Colombia's Ministry of Health

and Social Protection explicitly referring to the Novartis patent, and asserting that compulsory licenses are a "policy tool of last resort" that are "tantamount to an expropriation of the patent owner and constitutes a deterrent to future research and development of innovative medicines and their placing on the market in Colombia." (Source: Switzerland pressures Colombia to deny compulsory license on imatinib, <https://keionline.org/node/2312>).

June 2015: As noted by KEI:

In February 2016, KEI submitted a FOIA request to the United States Trade Representative requesting "all correspondence and notes sent internally by the Office of the US Trade Representative as well as with Colombian government officials, other foreign government officials, and non-governmental persons or entities regarding efforts in the government of Colombia to issue compulsory licenses on medical technologies. Of particular interest is any correspondence, documents, memoranda, presentations, or talking points regarding the request for a compulsory licenses on the drug imatinib (marketed by Novartis as Gleevec or Glivec), a chemotherapy drug used to treat leukemia."

KEI received the response to this FOIA from USTR on June 5, 2017. Among the documents returned was an email of June 3, 2015 from Maria Fernanda Hurtado, the Public Affairs and Social Responsibility Head for Novartis de Colombia, S.A., to Michael McGee and Paola Lugari of the Department of Commerce, requesting that the U.S. Embassy send a communication to the Colombian Ministry of Health to discourage the compulsory license that was then under consideration for the leukemia drug Glivec. The email attaches, for reference, the controversial letter sent by Switzerland's Ambassador, Livia Leu, to the Ministry of Health on May 26, 2015, and notes that although the formal comment period was closed, Novartis "thinks it is highly valuable to have a communication from your Embassy and count with your support on this important case taking into consideration that if granted the Compulsory License could establish a serious precedent for R&D companies doing business in Colombia."

Paola Lugari then forwards this email to Angel Ventling and Laura Ebert, who then forwarded to Christine Peterson as the "IPR expert" at the Department of Commerce, who then forwarded the email chain to Leslie O'Connor at USTR. (Source: <https://www.keionline.org/node/2802>).

April 2016: Following a recommendation by a technical committee in Colombia's Ministry of Health in February 2016 that the Minister of Health should declare that a compulsory license on imatinib would be in the public interest¹, as a legal prerequisite to the compulsory license itself,

1

<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/informecomiteimatinib-22022016-vf.pdf>

Minister Gaviria announced on April 11, 2016 that he would open price negotiations with Novartis.² On April 20, 2016, Novartis refused to negotiate.³ On April 26, 2016, *El Espectador* reported that the Minister would proceed in pursuit of the compulsory license, following Novartis's rejection⁴. Documents leaked by Knowledge Ecology International show that on April 27, 2016, and April 28, 2016, the Colombian Embassy in Washington, D.C. sent letters revealing pressure being placed in Colombia to drop the pursuit of the compulsory license, including perceived threats to promised U.S. funding of \$450 million for the Colombian peace process during the reconciliation with FARC.

The April 27, 2016 letter sent from Deputy Chief of Mission Andrés Flórez to the Colombian Minister of External Affairs, María Ángela Holguín, describes pressure from the United States Trade Representative and the United States Senate Finance Committee under Senator Orrin Hatch, and specifically links U.S. funding for "Paz Colombia," an Obama Administration initiative in the Colombian peace process, to the granting of the compulsory license.⁵

The April 28, 2016 letter was likewise sent from Deputy Chief of Mission Flórez, but addressed to Colombian Minister of Health Gaviria.⁶ This letter more specifically named the Senate Finance Committee staffer referred to in the previous letter as Everett Eissenstat, and mentions Eissenstat's conversation with the Embassy in which he alleged that the proposed compulsory license would violate Novartis's intellectual property rights and the Colombia-US free trade agreement, worried that any such action would create a precedent, and stated that this "could tarnish Colombia's reputation regarding the respect of intellectual property rights and place Colombia among the countries that would receive a special treatment." According to the Embassy, Eissenstat also threatened that "if the Ministry of Health did not correct this situation, the pharmaceutical industry in the United States and related interest groups could become very vocal and interfere with other interests that Colombia could have in the United States." As with the letter of April 27, this letter once again explicitly links these threats to the loss of Paz Colombia funding.

Ecuador

In 2015, PhRMA requested USTR to place Ecuador on its Priority Watch List. The PhRMA submission was asking USTR to undertake "close monitoring of this subject" in Ecuador in order to "ensure" that compulsory licenses for medicines are "granted only when there is a true health

2

<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Procedimiento-declaratoria-int-eres-licencia-obligatoria-imatinib-Glivec.pdf#search=%252Cimatinib>

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<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/rta-novartis-oferta-minsalud-imatinib.pdf#search=%252Cnovartis>

4

<https://www.elespectador.com/noticias/salud/novartis-perderia-exclusividad-fabricar-imatinib-medica-articulo-629267>

⁵ <http://www.keionline.org/node/2504>

⁶ <http://www.keionline.org/node/2505>

emergency and as a measure of last resort." (Source: PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) SPECIAL 301 SUBMISSION 2015, https://www.keionline.org/sites/default/files/PhRMA_2015_Special_301_Review_Comment.pdf)

Compulsory licensing: The Ecuadorian Intellectual Property Institute has granted nine compulsory license petitions since 2010 and 12 applications are still pending. A compulsory license should only be granted when the need for such a license has been clearly demonstrated and in compliance with Ecuador's international obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

For these reasons and other emerging IP concerns, including Ecuador's Decree 522, PhRMA requests that Ecuador be placed on the Priority Watch List for the 2015 Special 301 Report. This is a change from PhRMA's requests in previous years to reflect the deteriorating IP environment in Ecuador. PhRMA urges the U.S. Government to continue seeking assurances that the problems described herein are quickly and effectively resolved. Source: (KEI Special 301 supplemental comments: Compulsory Licensing not restricted to "Emergencies" or "Measure of Last Resort", <https://www.keionline.org/node/2187>).

As noted in KEI's Special 301 supplemental comments: Compulsory Licensing not restricted to "Emergencies" or "Measure of Last Resort":

In practice, WTO members have used diverse grounds to permit non-voluntary use of patents, including to remedy anticompetitive practices (including but not limited to excessive pricing, refusals to license, failures to disclose patents to standards making bodies, etc.), for government use, and to protect the public interest or to promote access to health care.

Even though the United States does not have a general compulsory license statute (unlike nearly all other WTO members), it has numerous provisions that are used to grant non-voluntary uses of patents, for very diverse uses. Thus, for example, when Exxon successfully petitioned the U.S. Federal Trade Commission's (FTC) to obtain a compulsory license on the Unocal patent on low-emissions gasoline, the basis was Section 5 of the Federal Trade Commission Act.[2] The Unocal patent case also illustrates another nuance in the WTO patent rules. In some cases, the remuneration for non-voluntary use of a patent can be set to zero, when the use is to remedy an anticompetitive practice.[3] (Source: Ibid).

India

The following link on the KEI website, <https://www.keionline.org/node/1446>, reports some of the pressure faced by India during the course of the sorafenib (marketed in India by Bayer as

Nexavar) compulsory licensing case. Sorafenib is indicated for the treatment of liver cancer and kidney cancer.

On March 12, 2012, India's Controller General of Patents, Designs & Trade Marks, P.H. Kurian, "issued an order granting a compulsory license to patents on the cancer drug, sorafenib, in the matter of NATCO v. BAYER." (Source: KEI Statement on India's granting of compulsory license to patents on cancer drug sorafenib (NATCO Vs. BAYER),

<https://www.keionline.org/node/1384>) A copy of the decision can be found here:

https://keionline.org/sites/default/files/sorafenib_nexavar_compulsory_license_12032012.pdf.

As reported by KEI in March 2012:

KEI filed an affidavit in the case, which is available here. <http://keionline.org/node/1359>. The Bayer price in India for sorafenib was 69,000 USD per year. Bayer's main defense of the pricing was its program of discounts to lower income patients, and the fact that Cipla was selling an infringing product at a lower price.

Natco, an Indian generic firm, had sought a compulsory license under the following three grounds of Section 84 of the Patent Act:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(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.

All three grounds were upheld in the decision signed by P.H. Kurian.

The 62 page decision grants the CL for the life of the patent, and grants a 6 percent royalty, which was at the high end of the UNDP 2001 royalty guidelines.

The Bayer price of INR 3,411,898 per year (69 thousand USD) is more than 41 times the projected average per capita income for India in 2012, shattering any measure of affordability. Bayer tried to justify its high price by making claims of high R&D Costs, but refused to provide any details of its actual outlays on the research for sorafenib, a cancer drug that was partly subsidized by the US Orphan Drug tax credit, and jointly developed with Onyx Pharmaceuticals. Onyx told the SEC that the cost of R&D, pre-Orphan Drug tax credit, was \$275 million through the 2005 FDA approval of sorafenib, including outlays on other compounds, indications that were not approved for marketing, and for expanded access trials in the United States that had limited value as scientific experiments. Bayer has made billions from sorafenib, and made little effort to sell the product in India, where its price is far beyond the means of all but a few persons.

(Source: KEI Statement on India's granting of compulsory license to patents on cancer drug sorafenib (NATCO Vs. BAYER), <https://www.keionline.org/node/1384>).

Following the issuance of a compulsory license, Bayer appealed the decision before India's Intellectual Property Appellate Board (IPAB) which heard the case in January 2013 (<https://www.keionline.org/node/1640>).

On March 4, 2013, IPAB issued its ruling by upholding the compulsory license and rejecting Bayer's appeal.

The Indian compulsory license on an expensive cancer drug, sorafenib, was soon met with an onslaught of political and trade pressure.

A: Congressional hearing on International IP Enforcement: Protecting Patents, Trade Secrets and Market Access, June 2012

As reported by KEI:

On June 27, 2012, Teresa Stanek Rea, the Deputy Under Secretary of Commerce for Intellectual Property and the Deputy Director of the United States Patent and Trademark Office (USPTO), testified at a hearing on: "International IP Enforcement: Protecting Patents, Trade Secrets and Market Access", before the US House of Representatives, Judiciary Committee, Subcommittee on Intellectual Property, Competition, and the Internet, on International IP Enforcement: Protecting Patents, Trade Secrets and Market Access. During the hearing Chairman Bob Goodlatte (R-VA) and others criticized India for granting a compulsory license in the Nexavar case, and Teresa Stanek Rea responded with a lengthy and enthusiastic attack" [on the government of India].

Here is a [clip from the video](#) of the hearing where the compulsory licensing case was discussed. Rea mentions her background as a pharmacist and her knowledge that the case had been appealed, and discusses her own direct talks with India government officials.

Under prodding, Rea suggested India may have broken WTO rules. Although both Rea and the Members of Congress seemed unwilling to discuss important aspects of the case, for example by never discussing the excessive pricing issues that were at the center of the public debate in India, there was a suggestion that both the Committee and USPTO were critical of one of the grounds for the compulsory license -- the failure of Bayer to manufacture the product in India. (Source: USPTO and Congress bash India over the Nexavar compulsory license, <https://www.keionline.org/node/1447>).

B. USTR Special 301 reports

Following granting of the compulsory license on Nexavar, India came under scrutiny from the United States Trade Representative (USTR) and the bio-pharmaceutical industry.

2013

The Pharmaceutical Research and Manufacturers' Association of America (PhRMA) requested the USTR to place India on its Priority Watch List:

Compulsory Licensing (CL): In March 2012, India issued its first CL.⁴⁶ The decision was based on price differences and Indian “patent working” requirements. The decision held that local manufacturing is mandatory to fulfill working requirements, which is not consistent with India’s obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Additionally, recent media reports indicate that the Government of India has started the process of issuing CLs for the manufacture of three additional cancer drugs...For these reasons, PhRMA requests that India remain on the Priority Watch List for the 2013 Special 301 Report. In light of ongoing government reports recommending that India grant additional compulsory licenses, PhRMA also requests that the U.S. Trade Representative conduct an Out-of-Cycle Review of India during 2013 to develop a robust plan for quickly and efficiently addressing the problems described herein. (Source: PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) SPECIAL 301 SUBMISSION 2013, <https://www.keionline.org/sites/default/files/PhRMASpecial301Submission2013.pdf>).

In addition to its complaint about India’s compulsory license, the Biotechnology Industry Organization (BIO) complained to USTR about India’s system of post-grant opposition procedures and Section 3(d) of India’s Patents Act:

In 2012, the Indian Intellectual Property Appellate Board (IPAB) decided to revoke several pharmaceutical patents in post-grant opposition proceedings. Pfizer’s Sutent drug and Roche’s Pegasys treatment were revoked on multiple grounds including obviousness and inventive step even when these patents are valid in other patent offices around the world. If the Indian patent system is an outlier for granting patents it makes it very difficult for biotechnology companies to continue to invest in India....

Finally, the Indian Patents Act includes Section 3(d), which explicitly excludes from patentability new forms of a known substance that does not result in “enhancement of the known efficacy of that substance.” This requirement excludes from patentability many significant inventions in the pharmaceuticals area, e.g., new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits that may not result in “enhanced efficacy” per se. Even if not removed, new forms of a substance that has benefits to the patient with clear support for its therapeutic improvement should be central to the concept of “improved efficacy” yet are noticeably absent in consideration for granting a patent. In addition, this provision appears to be inconsistent with India’s obligations pursuant to Article 27 of the TRIPS Agreement, which requires that patents be made available to “any inventions ... in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” Section 3(d) also creates an additional hurdle to patentability that is applied only to certain chemical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27. We eagerly await a decision from the Supreme Court regarding this issue in the Novartis AG v. Ministry of Industry and Commerce case which may have a bearing on the interpretation of this provision. (Source: BIOTECHNOLOGY INDUSTRY

ORGANIZATION 2013 SPECIAL 301 SUBMISSION,
<https://www.bio.org/sites/default/files/2013%20BIO%20Submission.pdf>).

In the USTR Special 301 report of 2013, the USTR provided the following commentary:

The United States will also continue to monitor closely developments concerning compulsory licensing of patents in India, particularly following the broad interpretation of Indian law in a recent decision by the Indian Intellectual Property Appellate Board (IPAB), while also bearing in mind the Doha Declaration on TRIPS and Public Health, discussed in the Intellectual Property and Health Policy section of this Report. In particular, India's decision in this case to restrict patent rights of an innovator based, in part, on the innovator's decision to import its products rather than manufacture them in India, establishes a troubling precedent. Unless overturned, the decision could potentially compel innovators outside India--including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology, to manufacture in India in order to avoid being forced to license an invention to third parties. (Source: Notes on USTR's 2013 Special 301 Report, <http://www.keionline.org/node/1713>).

2014

In 2014, The Alliance for Fair Trade with India (AFTI) submitted the following comments to USTR with respect to India's decision to issue a compulsory license on nexavar:

India's compulsory licensing and forced tech transfer policies. In addition to being WTO non-compliant, India's approaches to compulsory licensing and the forced transfer of technology are clearly intended as tools of industrial policy, to be wielded against foreign companies for the benefit of domestic Indian enterprises. e direct beneficiaries of such policies are companies in industries in which India has become, or aspires to be, a global player, including in pharmaceuticals, green technology, telecommunications, and semiconductors. Since the Indian Controller General's decision to grant a compulsory license for Nexavar in March 2012, but particularly over the last twelve months, it has become apparent that the Indian government intends to use CL's as a tool for bolstering domestic innovation.

India's compulsory licensing practices clearly rise to the statutory threshold established for identification of a trading partner as a Priority Foreign Country. The Indian government's decision in March 2012 to grant a compulsory license ("CL") to an Indian pharmaceutical company to allow it to manufacture a generic copy of Nexavar, an anti-cancer medicine manufactured by Bayer, both i) denies Bayer adequate and effective protection of its intellectual property rights; and ii) denies Bayer fair and equitable market access in a manner that is in violation of India's WTO commitments.

The Indian Controller General of Patents ("Controller General") granted its first CL under the amended Patents Act in March of 2012.⁴ The CL related to a patent covering a product to treat liver and kidney cancer called Nexavar, produced by Bayer Group, a German-based drug company with extensive facilities in the U.S.⁵ The Controller

General granted the right to produce and sell Nexavar in India to the Indian generics producer Natco Pharma Ltd. ("Natco"). Bayer had initially extended its patent application to India for Nexavar in 2001, and had received a grant of registration in March 2008. Bayer did not sell any quantities of the drug in India in 2008, but did make sales in 2009 and 2010. All sales of Nexavar in India were of imported drugs, as Bayer chose not to manufacture in country given the initially low quantity of the drug being sold domestically. (Source: Alliance for Fair Trade with India (AFTI): Ground zero for trade sanctions against India, <https://www.keionline.org/node/1936>).

In the 2014 Special 301 report, the USTR designated India as a Priority Watch List country and provided a more elaborate critique of India's compulsory license on Nexavar:

In addition, the United States continues to be concerned with the rationale underlying a decision by India's Controller-General of Patents to grant a compulsory license under Section 84 of India's Patents Act (which allows private parties to initiate proceedings seeking a compulsory license of a patented article), as upheld by a recent judgment of the IPAB. The grant of the compulsory license was based, in part, on the innovator's failure to "work" the patent in India because it imported its products, rather than manufacturing them in India. The United States recognizes that, on appeal, the IPAB modified the Controller-General's reasoning to clarify that "in some cases" the "working" requirement could be met solely by importation. The IPAB, however, rejected the innovator's explanation that economic factors prevented manufacturing in India, stating, "the patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient[,] there must be evidence."³ The IPAB did not clarify the circumstances under which the "working" requirement would be met without manufacturing in India. The decision could inappropriately pressure innovators outside of India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being compelled to license an invention to third parties. The IPAB's decision is currently on appeal to the Bombay High Court.

Although the government has issued only one compulsory license under Section 84, India has made clear that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. (Source: 2014 Special 301 Report https://www.keionline.org/sites/default/files/USTR_2014_Special301.pdf).

In comments (February 2014) to USTR, the Intellectual Property Owners Association (IPO), a trade association which includes Johnson & Johnson, General Electric, Google, Monsanto, Qualcomm, Sanofi-Aventis, Pfizer, Roche, and Apple, the IPO addressed concerns with India's IP policy while also targeting multilateral fora including WIPO and the World Health Organization (WHO).

In relation to WIPO, the IPO specifically mentioned the activities of the SCP:

Publications and capacity-building activities of the World Intellectual Property Organization (WIPO) increasingly reflect IP-skeptic perspectives, despite its formal mandate and role as an IPR-focused organization. For example, WIPO has organized regional training sessions for government officials on the use of exceptions and limitations to patent rights. These sessions focus on public health, exploring the various possible ways that IPR for pharmaceuticals can be curtailed under national laws and regulations. Such training sessions could provide a basis for IP weakening and pose a threat to innovation and public health in the event that such policies are enacted. In addition to the training sessions, WIPO has also undertaken work to study “exceptions and limitations” to patents both within its Committee on Development & Intellectual Property (CDIP) and its Standing Committee on Patents (SCP).

At a minimum, it is crucial for WIPO to contextualize policies that would weaken patent rights by highlighting the negative impact that such policies have on innovation, partnership, investment, technology transfer, and other contributing factors to economic advancement, and by seeking evidence from a wide variety of stakeholders. Industry expressed concern on these issues as early as 2011, when the first training session on exceptions and limitations was organized in Bangkok; yet, sessions continue to be organized under WIPO’s auspices with no particular improvements or change in direction in sight. In addition, industry participation is often very limited, making it very difficult to ensure that a more neutral, balanced view is heard. (Source: USTR 2014 Special 301 Review, Request for Public Comment (79 Fed. Reg. 420), https://www.keionline.org/sites/default/files/IPO_Special_301_Submission_2-7-14.pdf).

With respect to WHO, the IPO stated:

*The text that was adopted as part of the U.N. Global Strategy for the Prevention and Control of Noncommunicable Diseases (NCD) and NCD Action Plan suggested IPR could be a barrier to countries’ and patients’ access to NCD treatment, despite a lack of supporting evidence. In general, the WTO should address IP-related trade issues, not the WHO or other non-specialized UN bodies. There is a lack of evidentiary support for IPskepticism in the NCD context, and there is broad support for the positive role IPR plays in a range of WHO and other international publications and studies. (Source: *Ibid*).*

For further detail on industry associations views (from 2014), please see:

https://www.keionline.org/sites/default/files/PhRMA_2014_Special_301_Submission.pdf and https://www.keionline.org/sites/default/files/IPO_Special_301_Submission_2-7-14.pdf).

2015

In its 2015 Special 301 report, the USTR noted that in the autumn of 2014, the United States conducted an out of cycle review “evaluate U.S.-India bilateral engagement on IPR areas of concern to the United States and U.S. stakeholders.” (Source: 2015 Special 301 Report, <https://www.keionline.org/sites/default/files/2015-Special-301-Report-FINAL.pdf>).

The report recorded the following:

In the course of the review, the United States concluded that the Government of India took steps that indicate that the Modi Administration is engaged and is examining key IPR issues. These steps include India's establishment of a domestic IPR-focused experts group, commitment to technical engagement on specific issues of concern, and the issuance of encouraging domestic policy pronouncements. India has continued its engagement with the United States on IPR issues of interest to both countries, including by establishing the High Level Working Group on Intellectual Property ("IPR Working Group"). The IPR Working Group, established by President Obama and Prime Minister Modi, operates under the auspices of the United States-India Trade Policy Forum, which exists to facilitate the enhancement of our overall bilateral trade relationship. In our bilateral dialogue, the United States is working with India to foster an environment that will enable India to achieve its important domestic policy goals of increasing investment and stimulating innovation through, not at the expense of, IPR protection and enforcement. Attention to our IPR priorities and action to resolve concerns through bilateral fora can benefit both the United States and India. Ultimately, however, recent positive developments on engagement should translate into substantive and measurable action. (Source: 2015 Special 301 Report, <https://www.keionline.org/sites/default/files/2015-Special-301-Report-FINAL.pdf>).

In relation to Section 3(d), USTR noted,

The United States continues to have concerns that Section 3(d) of India's Patents Act, as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations could include drugs with fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability. (Source: Ibid).

With respect to compulsory licensing, USTR echoed its previous arguments, expressing concern that the granting of once compulsory license for a cancer drug would have spillover effects into other fields of technology - including green technology.

Second, while emphasizing our continued commitment to the Doha Declaration on the TRIPS Agreement and Public Health, as discussed in the Intellectual Property and Health section of this Report (See Section I), the United States also continues to monitor India's application of its compulsory licensing law. The United States requests clarity from the Government of India regarding the compulsory license decision-making process as it affects U.S. stakeholders. Although the government has issued only one compulsory license under Section 84 of India's Patents Act, India has made clear in other policy statements that it views compulsory licensing as an important tool of industrial policy for green technologies, with the potential to be applied more regularly across economic sectors. Specifically, India has, in the past, promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector. (Source: Ibid).

C. US International Trade Commission Hearing, "Trade, Investment, and Industrial Policies in India: Effects on the US Economy"

In February 2014, the United States International Trade Commission (ITC) held a two-day hearing entitled, "Trade Investment, and Industrial Policies in India: Effects on the US Economy".

As reported by KEI in February 2014:

The hearing [was] part of a larger investigation launched by the ITC to examine a wide range of Indian policies and how they impact US trade and investment. The investigation was jointly requested by the US Senate Committee on Finance and the House Committee on Ways and Means. The ITC will perform quantitative analysis of the effects of various Indian policies, provide case studies, and will survey a sample of US firms to measure perceptions of India's policies and to gauge firms' business strategies towards India. (Source: US International Trade Commission Hearing, "Trade, Investment, and Industrial Policies in India: Effects on the US Economy", <https://www.keionline.org/node/1926>).

KEI recorded the two day hearing which can be found here:

https://www.youtube.com/playlist?list=PLLw9jWaZPEpwU_euETpPaVjdcFpKICxp-

D. Bayer CEO Marijn Dekkers explains: Nexavar cancer drug is for "western patients who can afford it."

On January 21, 2014, Bloomberg published an article on disputes over drug patents (link [here](#)) which quoted Bayer's CEO, Marijn Dekkers weighing in on the Indian compulsory licensing dispute - "We did not develop this medicine for Indians," Dekkers said Dec. 3. "We developed it for western patients who can afford it." (Source: Bayer CEO Marijn Dekkers explains: Nexavar cancer drug is for "western patients who can afford it.", <https://www.keionline.org/node/1910>).

From the Bloomberg story:

Under India's patent laws, compulsory licenses can be awarded for some products still under patent if the original isn't available locally at a reasonable price.

Natco Pharma Ltd. (NTCPH) applied directly to India's patents office and was awarded the nation's first compulsory license in March 2012 to make a copy of Bayer's Nexavar cancer drug at a 97 percent discount to the original product. In March last year, Bayer lost its bid to stop Natco from making the generic drug and is appealing the decision at the Mumbai High Court.

Bayer Chief Executive Officer Marijn Dekkers called the compulsory license "essentially theft."

"We did not develop this medicine for Indians," Dekkers said Dec. 3. "We developed it for western patients who can afford it." (Source: Bloomberg, "Merck to Bristol-Myers Face More Threats on India Patents," by Ketaki Gokhale. 28 January 2014, <https://www.bloomberg.com/news/articles/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-patents>).

As recounted by KEI in January 2014, the U.S. government had "weighed in on the side of Bayer in the patent case, at the highest levels". (Source: Bayer CEO Marijn Dekkers explains:

Nexavar cancer drug is for "western patients who can afford it.", <https://keionline.org/node/1910>).

For a full transcript of Dekkers' comments, please see: Transcript of Bayer CEO Marijn Dekkers quote at the December 3, 2013 FT Event, regarding India compulsory license of Nexavar, <https://www.keionline.org/node/1924>.

There is also a January 23, 2014 MSF response to Bayer CEO statement that its medicines are developed only for western patients. (Link [here](#)).

Indonesia

In 2013, the USTR placed Indonesia on the Priority Watch List of its Special 301 report partly due to Indonesia's granting of compulsory licenses.

The United States notes with concern statements in Indonesia's Special 301 submission indicating that Indonesia failed to abide by its procedures in issuing a compulsory license decree in 2012, and that its patent law does not require individual merit review in connection with the grant of compulsory licenses. The United States further encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States looks forward to working with Indonesia on these and other matters. (Source: 2013 Special 301 Report, https://www.keionline.org/sites/default/files/05_01_2013_Special301Report.pdf).

In 2014, the USTR repeated its concerns with respect to Indonesia's compulsory licensing regime:

The United States remains concerned by Indonesian government statements indicating that Indonesia failed to abide by Indonesian legal procedures in issuing a compulsory license decree in 2012, and indicating that Indonesian patent law does not require individual merits review in connection with the grant of compulsory licenses. The United States further encourages Indonesia to provide for judicial or other independent review of any compulsory license authorizations. The United States looks forward to working with Indonesia on these and other matters. Source: 2014 Special 301 Report, https://www.keionline.org/sites/default/files/USTR_2014_Special301.pdf).

In 2015 and 2016, the USTR expressed concerns about what it perceived to be a lack of clarity in relation to the procedures governing Indonesia's compulsory licensing regime. The US encouraged Indonesia to provide a judicial or independent review of compulsory licenses granted and noted the positive engagement of the Indonesian government with the US - through the IPR Working Group of the United States-Indonesia Trade and Investment Framework, as a mechanism to resolve outstanding issues. (Source: 2015 Special 301 report, <https://www.keionline.org/sites/default/files/2015-Special-301-Report-FINAL.pdf> and 2016

Special 301 Report,
<https://www.keionline.org/sites/default/files/USTR-2016-Special-301-Report.pdf>).

Philippines

In 2005, Senator Manuel Roxas, Chairman of the Senate Committee on Economic Affairs and the Committee on Trade and Commerce, introduced a bill in the Senate that would permit the parallel importation of medicines.

According to a State department cable dated November 22, 2005, the US Embassy in Manila wrote to Senator Roxas expressing concerns with his bill; the Economic Counselor requested a meeting with Senator Roxas to underscore their concerns.

According to US officials:

The Roxas bill is especially troubling to U.S. pharmaceutical rights holders who are trying to retain their market share and profitability in the Philippines. While the bill taps into more flexible provisions in TRIPS, it may not offer enough protection for drug makers. Passage of the bill would not reflect well on the Philippines' efforts to improve IPR and be removed from USTR's Special 301 Priority Watch List, following its out-of-cycle review this January. U.S. pharmaceutical patent holders, represented by PHAP, may defuse concerns about the high drug costs and the potential for an avian flu pandemic by focusing on alternate ways to reduce the cost of medicine, and support information exchange and planning to address any potential pandemic. JONES (Source: Wikileaks cables on the US opposition to Philippines legislation on affordable medicines, <https://www.keionline.org/node/1225>).

In 2006, Pfizer sued the Philippines government for importing and registering Norvasc (amlodipine besylate), a medicine for high blood pressure. More details can be gleaned from this IP-Watch piece: Pfizer Fights IP Flexibilities In The Philippines, <https://www.ip-watch.org/2006/04/30/pfizer-fights-ip-flexibilities-in-the-philippines>:

On 1 March 2006, Pfizer (Pfizer, Ltd. UK and Pfizer, Inc. Philippines) filed a case against the government-owned Philippine International Trading Corporation (PITC), the Bureau of Food and Drugs (BFAD) and two of the employees at the BFAD for having imported samples of Norvasc from India, sources say.

BFAD Director Leticia Barbara Gutierrez and Emilio Polig, BFAD officer in charge of the legal, information and compliance division, have been asked to pay damages to Pfizer, the Philippine lawyer said.

Some 200 tablets were imported and submitted to the BFAD for registration, according to the paper. BFAD granted the products approval in the form of a parallel import drug registration, and a government source said the country's rules required this registration even though it is not intended to be sold in the market until after patent expiry. The PITC has "repeatedly informed Pfizer in writing that it will not market its amlodipine besylate product until after the Pfizer patent expires," the paper said.

Pfizer sued two individuals as well, according to the spokesperson, because, "The two government representatives are named in the suit in their respective official capacities as director of the BFAD and officer in charge of the legal, information and compliance division of the BFAD," the spokesperson said.

It was perhaps not a good week for Pfizer, as company CEO Henry McKinnell personally met with resistance for his recent salary hike and reported \$83 million retirement arrangement, as well as for the Philippine case. Stanford alumni and graduate students in the United States have initiated a signatory campaign to "kick McKinnell off a Stanford advisory board over Pfizer's bullying of Philippine government drug regulators," according to CPTech's Judit Rius, one of the initiators of the campaign.

South Africa

The following entry is taken entirely from the following KEI blog: New leaked Merck missive reveals deep drug, medical device company opposition to South African patent reforms, <https://www.keionline.org/node/1908>:

In January 2014, KEI obtained an email sent out on January 10th, 2014, by Michael Azrak, Merck's Managing Director for Southern and East Africa, that illustrates the deep involvement of two dozen companies in the campaign to undermine patent reform in South Africa. The Merck email shed new light on industry lobbying to undermine South Africa patent reforms.

*The Merck email comes nearly 16 years after Merck and other companies sued Nelson Mandela on February 18, 1998, to block implementation of 1997 amendments to the South Africa Medicines Act. [Text of 1998 complaint [here](#)], and less than a year after the Sundance screening of *Fire in the Blood*, a documentary that focuses on the earlier opposition by big drug companies to affordable generic HIV drugs in developing countries, referred to by the Director of the film as 'the Crime of the Century'.*

The Merck email relates to a recently disclosed lobbying and public relations proposal by a US group named Public Affairs Engagement (PAE), headed up by Ambassador James Glassman. Glassman, now the head of a Washington, DC based lobbying and public relations firms, is a former Undersecretary of State for Public Diplomacy and Public

Affairs, and the former Chairman of the US Broadcasting Board of Directors, the entity that directed all non-military US taxpayer-funded international broadcasting including the Voice of America, Radio Free Europe and Alhurra TV. Glassman was also the founding director of the George W. Bush Institute. Glassman set out the campaign's objectives in a memo that was recently leaked to the media. Among the targets of the PAE campaign were MSF, and the South Africa based non-profit patient advocacy groups, the Treatment Access Campaign (TAC), and SECTION27. In the PAE proposal obtained by the South Africa Department of Health and the Mail and Guardian newspaper last week, Health Minister Aaron Motsoaledi described the proposal as genocidal conspiracy of satanic magnitude:

Health Minister Aaron Motsoaledi has accused a group of multinational pharmaceutical companies active in South Africa of conspiring against the state, the people of South Africa and the populations of developing countries – and of planning what amounts to mass murder.

"I am not using strong words; I am using appropriate words. This is genocide," Motsoaledi told the Mail & Guardian on Thursday, in response to a plan he described as a conspiracy of "satanic magnitude" – a plan he called on all South Africans to fight "to the last drop of their blood".

The plan in question is a nine-page document obtained independently this week by both the M&G and the department of health, blandly titled Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa.

After the PAE proposal was leaked, drug companies described the PAE proposal as something that they had rejected. (See IPASA statement below, for example.) But the email obtained by KEI illustrates the extensive role and buy-in to the proposal by Merck, and the engagement by nearly two dozen firms, including nearly all large pharmaceutical companies, but also several companies in the medical device business, including Baxter and General Electric, and the fact that budgeting for the campaign was approved in December 2013.

For context, note that the PAE/IPASA/PhRMA activities are related to South Africa's "Draft National Policy on Intellectual Property," including a recommendation that South Africa institute a pre-grant and post-grant opposition system for patents, as well new requirements for patent examination (RSA now has a registration system, without an examination), that South Africa exclude diagnostic, therapeutic and surgical methods from patentability, and improve the statutory framework for compulsory licensing. The policy is described in more detail [here](#).

In the email, Merck official Michael Azrak said:

As we agreed at the last Board meeting in December, we have moved ahead in identifying a high calibre consultancy group to work with us. The group selected is Public Affairs Engagement (PAE), a Washington DC based team led by former US Ambassador James Glassman. This group was selected after a detailed process where we received

proposals from a number of agencies both Local and International. The final selection was carried out in consultation with PhRMA. . . .

Key Objectives of the Campaign

The overall campaign is aimed at delaying the finalization of the IP policy by the Cabinet until after the 2014 election. . . .

Key elements of the Campaign

Mobilize voices inside and outside South Africa to send the message that the proposed IP policy threatens continued investment and thus economic well-being. This mobilization will occur through an energetic campaign, which will feel like a political campaign. . . .

Investment

The total investment for this 5 month campaign will be circa \$450K. PhRMA will contribute \$350K & IPASA will contribute \$100K. In addition, IPASA will be responsible for the remainder of IP activities in 2014, with a reserve of \$150K for any additional activities. So in total we will invest approx. \$600K in IP related activities in 2014. Our IPASA contribution will be R2.5m (slightly less to what we were agreed to invest at the December Board meeting).

I'm confident that this positive, forward thinking and proactive campaign is what we need to bring balance back to the entire discussion around IP and access to medicines. PAE have worked successfully with PhRMA in other countries with an established track record.

A list of the companies as recipients of the email include:

- *Alcon*
- *Allergan*
- *Amgen*
- *Astrazeneca*
- *Baxter*
- *Bayer*
- *BMS*
- *Boehringer-Ingelheim*
- *Covidien*
- *Galderma*
- *GE*
- *Johnson & Johnson*
- *Lilly*
- *Merck*
- *Merck group*
- *Murgatroyd*
- *Netgrs*

- *Norgine*
- *Novartis*
- *Novo Nordisk*
- *Pfizer*
- *Roche*
- *Sanofi*
- *Takeda*

In response, KEI issued the following statement on January 14, 2014:

"Nearly 16 years after Merck and 41 other applicants sued Nelson Mandela and the South Africa government to block implementation of amendments to its Medicines Law, Merck has emerged as a key figure in an industry effort to block new reforms. We call upon Merck to either fire Michael Azrak, Merck's Managing Director for Southern and East Africa, or have someone higher up in the company take responsibility for this action, and explain why Merck wants to use its power to stop South Africa and other countries in the region from expanding access to medicine. Merck and others should also stop lying about their involvement in this lobbying efforts. We also call upon all of the other companies copied in the email to make public statements about their involvement and future intentions, and stop hiding behind the untruthful and discredited front groups and trade associations that do their dirty works. General Electric, Baxter, and other medical device manufacturers also need to account for their involvement."
James Love, Director, Knowledge Ecology International.

For more detail, please see: <https://www.keionline.org/node/1908>

Thailand

In August 22, 2006, the *Financial Times (FT)* reported that William Aldis, WHO's representative to Thailand (WR), was removed from his post after writing an opinion piece in the Bangkok Post cautioning the Thai government against "surrendering its sovereign rights under the WTO — and access to cheap medicine." In his article, Aldis warned that "[g]iving up internationally agreed flexibilities in the implementation of intellectual property rights would put at risk the survival of hundreds of thousands of Thai citizens". (Source: It could be a matter of life and death, <http://www.bilaterals.org/?opinion-it-could-be-a-matter-of>).

According to the the *FT*:

William Aldis was agitated. As the World Health Organisation's top man in Thailand, he knew Thai officials were hosting their US counterparts in the northern city of Chiang Mai to negotiate what to many outsiders might seem an entirely worthy objective: a bilateral free-trade deal. But he saw dangers - and decided to make his views public....

That was in January. By the end of March, Dr Aldis - just 16 months into what is normally a four-year tenure - was abruptly transferred sideways to a job in India, raising concerns in Thailand about US efforts to curb the independence of the WHO's public health professionals.

The spat highlighted the tensions generated by a US drive to strengthen patent enforcement and intellectual property rights protection around the world - a campaign backed by some of the powerful drugs companies that produce Aids medicines but opposed by many public health specialists, patient groups and developing nations.

After the article appeared, Kevin Moley, then head of the US permanent representation to the United Nations in Geneva, called on Dr Lee. Both verbally and in writing, he registered Washington's displeasure with the statements of the WHO's Bangkok representative.

One US official familiar with the discussions says: "For someone on the WHO payroll to criticise a bilateral negotiation is not appropriate."

Yet the subsequent abrupt transfer of Dr Aldis (himself an American) brought alarm in Thailand. "If outside political pressure can influence an organisation which is supposed to be dedicated to the health of the people, it is a really bad sign," says Jiraporn Limpananont, a pharmaceutical sciences professor at Bangkok's Chulalongkorn University and an expert on intellectual property rights. "It will be a threat for people all over the world, not just for the Thai people"....

Last, the US has pushed Thailand to adopt more specific language on the terms and conditions under which it would engage in compulsory licensing of new drugs, although Washington promised to issue a "side letter" clarifying that the binding language in the bilateral trade deal was consistent with the WTO's 2001 Doha declaration on Trips and public health. (Source: Patent or patient? How Washington uses trade deals to protect drugs, Financial Times, August 22, 2006).

The FT article encapsulated the policy tensions and pressure faced by Thailand when it used the flexibilities of the TRIPS Agreement to issue three compulsory licenses between November 2006 and January 2007 including two AIDS drugs (efavirenz and the combination of lopinavir+ritonavir) and one anti-hypertension drug (clopidogrel).

On July 10, 2007, the European Trade Commissioner Peter Mandelson wrote to Thailand's Minister of Commerce, Kirik-krai Jirapaet, alleging that Thailand had embarked on a systematic policy of apply compulsory licensing "wherever medicines exceed certain prices" which Mandelson asserted were not justified by the TRIPS Agreement of the Doha Declaration. Mandelson encouraged the Thai authorities to engage in negotiations with Sanofi-Aventis, the manufacturer of clopidogrel. (Source: http://www.actupparis.org/IMG/pdf/Letter_from_Mandelson_to_Thailand.pdf).

On February 21, 2008, the European Trade Commissioner Peter Mandelson wrote to Thailand's Minister of Commerce, Mingkwan Saengsuwan, echoed his concerns over Thailand's compulsory licenses. Mandelson described compulsory licensing as an exceptional measure and expressed surprised that the outgoing Minister of Public Health, Dr. Mongkoi Na Songkhla, had authorized the granting of a "new set of compulsory licenses". (Source: https://www.ip-watch.org/files/Peter_Mandelson_letter_Febr_21_2008_to_Thai_Minister_of_Co_mmerce.pdf?f049a7).

The aforementioned material is a précis of the political and trade pressures Thailand faced in relation to its policies of promoting access to medicines and protecting public health through the use of TRIPS flexibilities. For detailed timelines and accounts of Thailand's compulsory licensing experience, please consult:

- 1) CPTEch page on Thailand - Efavirenz Compulsory License <http://www.cptech.org/ip/health/c/thailand/efavirenz.html>;
- 2) Timeline for US-Thailand Compulsory License Dispute, <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf>);
- 3) For a timeline detailing Trade Disputes involving Thailand and access to medicines from 1979 to 2001, please see: (Timeline of Trade Disputes involving Thailand and access to medicines, <http://www.cptech.org/ip/health/c/thailand/thailand.html>)