

Written Statement of James Love, Knowledge Ecology International (KEI), at the United States International Trade Commission Investigation into Trade, Investment and Industrial Policies in India, Investigation No. 332-543. February 14, 2014.

Thank you for the opportunity to testify today regarding Trade, Investment and Industrial Policies in India, and the United States trade relationship with India. I represent Knowledge Ecology International (KEI), a non-profit organization with offices in Washington, DC and Geneva, Switzerland, that follows global negotiations on knowledge goods, including patented inventions for new drugs and other medical technologies. KEI undertakes research and policy analysis, and often advocates for the interests of consumers, including persons with HIV, cancer or other diseases, living in developing countries.

I am also the Chairman of Essential Inventions, and the author in 2005 of Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, on behalf of UNDP and the World Health Organization. I was an expert witness in the compulsory licensing dispute between Bayer and Natco, for patents on the cancer drug Nexavar, worked with a number of developing country governments, including the South Africa Competition Commission's investigation into allegations of abuses of patents on AIDS drugs. I have been involved in four compulsory licensing cases in the United States, two of which were successful (West Publishing 1996, Microsoft 1997-2000) and two of which were not successful (2004 Xalatan/latanoprost, and 2004/2011-12 Norvir/ritonavir).

I also work on a number of new trade negotiations that involving R&D, including a proposed World Health Organization (WHO) medical R&D treaty, to increase sustainable levels of global funding for research and development, an initiative that US Government has generally opposed, and of which India has been generally been supportive.

More information about KEI is available on our web page at <http://keionline.org>, and my personal web page, <http://keionline.org/jamie>

My testimony today will focus on the manufacture and sale of generic drugs from India, the recent compulsory license on Bayer's patents on Nexavar, the decision to reject patent protection for Novartis' patents on Gleevec, and the consequences of trade pressure in curbing India's role in supplying affordable medicines.

There are many issues raised in this hearing, but there is a perception that this investigation is a direct consequence of (1) the March 9, 2012 India Comptroller General of Patents, Designs and Trademarks' decision to grant a compulsory license on Bayer patents for the cancer drug sorafenib (marketed under the trade name Nexavar), upheld on March 4, 2013 by the Indian Intellectual Property Appeals Board (IPAB), and (2) the Indian Patent Office rejection of a patent for the Novartis cancer drug imatinib (trade name Gleevec or Glivec), which was upheld by the Indian Supreme Court on April 1, 2013.

Before discussing the details of the Nexavar and the Gleevec cases, consider the wider context. From 1970 until 2005 India did not grant patents on pharmaceutical products, and many other developing countries limited or eliminated patent protection for pharmaceutical drugs. When the World Trade Organization (WTO) was created, it included a requirement that India and other countries grant patents on pharmaceutical drugs, and it created a new system to regulate the limitations and exceptions for patent rights, including the granting of compulsory licenses.

India and other countries were reluctant to accept the TRIPS agreement, but did so after threats of unilateral trade sanctions (highlighted by the creation in 1989 of the Special 301 list), as part of a larger bargain that offered great market access.

Since the WTO was created, the United States has reneged on that earlier bargain, not only with India, but with all developing countries, by pressing for endless demands to change intellectual property laws beyond that required by the WTO TRIPS agreement, and now, by complaining about price controls and other measures designed to control the prices of patented medicines.

A number of witnesses at this hearing and in a series of February 7, 2014 comments to the USTR Special 301 process (Docket USTR-2013-0040) have alleged that India's actions in the Gleevec and Nexavar cases violate the WTO rules for patents. If that was the case there would be no need for this hearing, and no need for the USTR Special 301 process. The United States could simply bring a case before the WTO and resolve the issue under the procedures and sanctions available through the WTO's Dispute Settlement Understanding (DSU).¹ The Indian patent law has been on the books since 2005, and the US has yet to bring a WTO case over the issues now raised in the Gleevec or Nexavar case, either because the United States has no case, or because the case is weak or could go either way. So long as the United States avoids the WTO dispute resolution, people should stop alleging India is operating outside of the WTO rules.

These bilateral pressures are designed to operate outside of the WTO rules, and the primary purpose of the pressures are to stop the manufacture and sale of affordable generic drugs. There is a history to these efforts. From 1997 to 2003, the United States was involved in a regrettable campaign to stop India from manufacturing and exporting inexpensive AIDS drugs to Africa and other developing countries. These pressures were highlighted by recent documentary films, Brian Wood's *Dying for Drugs*², and Dylan Gray's *Fire in the Blood*,³ and in number of books and articles.⁴ In 2001, outside of Brazil, only a few thousand persons were receiving HIV/ARV drugs in all developing countries, despite warnings from UNAIDS that tens of millions

¹ http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm

² <http://truevisiontv.com/films/details/81/dying-for-drugs>

³ <http://fireintheblood.com/>

⁴ For example, Greg Behrman, *The Invisible People: How the U.S. Has Slept Through the Global AIDS Pandemic, the Greatest Humanitarian Catastrophe of Our Time*. Free Press, 2009. Daniel Pearl, *At Home in the World*, Free Press 2002. Daniel Pearl and Alix Freedman, "The Catalyst: Behind Cipla's Offer of Cheap AIDS Drugs: Potent Mix of Motives," Published in the *Wall Street Journal*, March 12, 2001, reprinted in Daniel Pearl, *At Home in the World*, Free Press 2002.

were living with HIV and thousands were dying every day. Today, after breaking down barriers to the purchase of low cost affordable generic drugs for HIV, more than 8 million persons living in developing countries are receiving HIV drugs. Many of the key figures in the trade disputes over AIDS drugs today express regret for their actions to block access to affordable generic products.

Today there are huge disparities in access to new drugs for cancer, and the political situation is similar to the beginning of the battle over AIDS drugs. The few countries that have taken steps to expand access to patented cancer drugs have been subject to considerable trade pressures, including in particular the two countries -- Thailand and India -- that were seen as potential models for other countries.

If the USITC brings pressure on India to curb the manufacture and sale of generic cancer drugs, the actions will be directly responsible for the death of cancer patients living in developing countries, and this should be on everyone's mind.

For all the corporate propaganda about concern for global health, the fact is that nearly all companies manufacturing and selling cancer drugs have been indifferent to the inequalities of access, and only introduce measures to mitigate concerns over access when faced with compulsory licensing of patents or other actions against the patent monopolies.

India itself is a country with more than 1.237 billion residents, and given the rate of population growth, may become the most populous country the world. While India has a very large population, some drug companies talk as if most people living in India don't exist. For example, in a June 7, 2010 Bloomberg story⁵, Ranjit Shahani, vice chairman and managing director at Novartis India Ltd. in Mumbai, said Novartis was making its medicines available to 42 million persons, and planned to expand this to 100 million. 100 millions persons sounds like a big market to a company like Novartis, but this is also only 8 percent of the population.

More recently, on December 3, 2013, Bayer CEO Marijn Dekkers spoke to an audience at an event organized by the Financial Times. In discussing the Nexavar compulsory license, which he described as "theft", Dekkers said, "we did not develop this product for the Indian market, let's be honest. I mean, you know, we developed this product for Western patients who can afford this product, quite honestly."

In March 2012, when the compulsory license for Bayer's product, Nexavar, was granted, the price for Nexavar, in India, was \$5,626 (US dollars) per month, in a county where the per capita income was \$132 per month. To put this into perspective, if Bayer was charging a price for Nexavar equal to 42 times average incomes in the United States, as it was in India, the price in 2012 would have been \$183,190, per month, or \$2.2 million per year. Is there any wonder that given the facts in this case, that India granted its first compulsory license?

⁵ June 7, 2010. Subramaniam Sharma, Novartis, Sanofi Pursue 'Cash Machine' in Indian Countryside, Bloomberg, <http://www.bloomberg.com/apps/news?pid=2065100&sid=anBD9OWpEqsA>

Dekkers' blunt comment brings out into the open one issue in this investigation. Should the United States punish the people of India, by various forms of retaliation and trade sanctions, because their government broke the Bayer monopoly on Nexavar, when Bayer itself had no interest in even selling its drug in India?

India is an important country. India has a population that is larger than the United States, the European Union and South America combined. According to the World Bank, about one third all the "world's poor" live in India. India is also most feasible global source for generic drugs. India is currently the primary source for most HIV drugs used developing countries. India is the only source of generic versions of sorafenib, the drug Bayer sells under the brand name Nexavar. India is the only source for generic versions of several other cancer drugs, and the best source of generic versions of new drugs to treat asthma, diabetes, and many other diseases and conditions.

At the hearing today is Nina Mahmud. Nina is a nursing student living in Florida. Her father-in-law, Fathi Aboseada, lives in Egypt, has advanced liver cancer, and has been using Nexavar, a drug that has improved his health. Bayer's price for Nexavar in Egypt is about \$900 per week. Mr. Aboseada earns less than \$300 per month. In order to stay alive, Mr. Aboseada has spent his entire life savings on the drug, and he will run out of the drug on Saturday, February 15, 2014. Mr. Aboseada is contemplating selling his business, which he co-owns with his brother, at a fire sale price, in order to buy just 9 months more of the drug, at Bayer's prices. Bayer has not been willing to supply an affordable version of Nexavar to Mr. Absoeada.

In India, generic sorafenib is available for \$27 per week from two generic manufacturers. The compulsory license in India is regrettably limited to sale in the territory of India, undoubtedly to avoid criticism from the US Congress and government. Despite requests, Nina Mahmud has been unable to have generic sorafenib shipped from India to Egypt, an act that may be considered an infringement of the patent if undertaken by an Indian manufacturer. Perhaps due to pressure from the United States, third party shipping firms like DHL have made it quite complicated if not impossible for an individual to ship the drug from India to Egypt. According to his doctors, if Mr. Aboseada does not obtain the drug, his health will deteriorate very rapidly.

The situation that brought Nina Malmud to Washington, DC is not an isolated story. No one in Egypt, or any other country outside of India, has access to affordable versions of sorafenib, and the same is true for many other cancer drugs. Because of high prices, it has so far proved impossible to place patented cancer drugs on the WHO list of essential medicines.

My wife is a HER2+ stage four breast cancer patient. She is alive today because she has access to Herceptin, a very expensive drug that generates more than \$500 million in sales every month for the Swiss company Roche. Few women with the same condition (roughly 1 in 5 breast cancer patients are HER2+) who live in developing countries have access to this remarkable drug.

The USITC's investigation should include a questionnaire into the manufacturers of drugs for cancer, asking them about their sales, measured by dollars and units, in both high and low income countries, and compare the access, when considering the burden of the disease in the different countries. This U.S. policy regarding patents on pharmaceutical drugs in India should be informed by evidence, and the very companies pressing for trade sanctions against India should be asked to provide information that sheds light on the consequences of strong patent protection on cancer drugs in developing countries.

It is appalling that such disparities exist, and morally repugnant that they are in part the consequence of trade pressures by the United State executive branch and Congress.

Research and development

While it is true that drug development is expensive, the USITC should not simply accept bold assertions regarding the R&D costs associated with Gleevec or Nexavar.

In the case of Gleevec, Dr. Brian Druker of the Oregon Health and Science University estimated that 90 percent of the early work on the drug was funded by the US government, charities or his own university.⁶ Novartis played an important role in clinical development of Gleevec, but that was not expensive. The drug was approved by the FDA based upon evidence from three Phase II trials with a total of 1028 patients, the trials were completed in a very short period of time, and the FDA approval took only 2.5 months.⁷ The out-of-pocket costs by Novartis on the relevant Phase II trials were probably less than \$15 million, and even the most generous estimates of company overheads, risks of failures and capital costs would place the Novartis adjusted outlays at less than \$100 million.⁸ Note that last year, the Novartis sales of Gleevec were \$12.9 million -- per day.

Nexavar, which was approved by the FDA in 2005, was developed by Onyx Pharmaceuticals, and licensed to Bayer. According to page 36 of the Onyx 2005 annual report⁹, in the section that reports on research and development:

⁶ "Novartis was not 'the innovative force.' Not only was all the basic research done in academic institutions, but so were the initial clinical investigations that showed STI 571 to be specifically effective against CML cells in vitro and in vivo. In fact, it took a few years for Brian Druker, the investigator most responsible for these latter studies, to convince Novartis that it should invest in a crash program to develop Gleevec and to undertake large-scale clinical trials." Relman, A. (2003). Book Review: Magic Cancer Bullet: How a Tiny Orange Pill Is Rewriting. Medical History. JAMA, 290: 2194-2195. For the Druker estimates and other calculations, see: R&D costs for Gleevec, April 3, 2013. <http://keionline.org/node/1697>.

⁷ The NDA filing was February 27, 2001. The FDA approval as May 10, 2001.

⁸ R&D Costs for Gleevec, April 3, 2012, Ibid.

⁹ Onyx Pharmaceuticals, Inc. Annual Report Pursuant To Section 13 Or 15(d) Of The Securities Exchange Act Of 1934 For The Fiscal Year Ended December 31, 2005. Page 35-36. Research and Development Expenses.

“Aggregate research and development costs-to-date through December 31, 2005 incurred by Onyx since fiscal year 2000 for the Nexavar project is \$134.8 million.”

These outlays included expenditures on a large patient access program that did not benefit patients in developing countries. The development of Nexavar was also partly subsidized by the US Orphan Drug Tax Credit, which effectively funds 50 percent of the costs of qualifying clinical trials.¹⁰

It is ironic that two drugs with fairly small company outlays are at the center of a debate over how to protect investments in medical R&D, because for these two drugs, the company outlays were far below average, and the revenues were far above average. That said, to the extent that the US government wants to address R&D costs, it should not expect high drug prices to be the solution. The high prices for Nexavar has resulted in very small sales in developing countries, just like the high prices for HIV/ARV drugs led to almost no sales in developing countries. And, given the huge human cost of excluding people from access, people that place any value on life in developing countries should look to the new models for delinking R&D costs from drug prices as the way forward. In this regard, several countries have endorsed the idea of eliminating monopolies for cancer drugs, and replacing the monopolies with a reward fund for new drug developers, tied to some fraction of the cancer treatment budget. In this approach, the low prices of generic cancer drugs would be an incentive for greater investments in treatment -- just as low prices for HIV drugs led to greater investments in infrastructure and treatment for AIDS.

USITC Methodology

KEI proposes, as part of the USITC methodology for this study, that the ITC staff estimate the number of people who will or who have died, because of a lack of compulsory licenses in India and other countries.

Appendix

When United States government officials become indignant over developing countries' issuance of compulsory licenses over cancer drugs, the degree of hypocrisy expressed by some parties is worth noting. The United States is leading the world in the use of compulsory licenses.

Recent compulsory licenses in the United States

Remedies to anticompetitive conduct

¹⁰ IPAB hearing on the Nexavar compulsory license, part 1, R&D costs, January 19, 2013. <http://keionline.org/node/1640>.

The United States and other countries seek to limit and curb anticompetitive actions by businesses. One of the remedies available to curb anti-competitive acts are compulsory licenses on patents, copies, data or other types of intellectual property rights. The following are a few examples from the United States.

In 1996, the US Department of Justice, consumer groups and small publishers successfully pressed for a compulsory license to West Publishing's copyright claims on page numbers of court opinions.¹¹

In 1997, following complaints from consumer groups, the US Department of Justice brought an antitrust suit against Microsoft, dealing in part with the ability of other software developers to provide programs to work with the Windows operating system. The European Union, Japan, several state governments, private firms and others subsequently brought antitrust cases against Microsoft. The resolution to the United State's case included, as a remedy to unlawful conduct, a compulsory license to a number of Window's protocols.

In 1998, the US Department of Justice required Monsanto to license certain corn germplasm to over 150 seed companies, and the "spin-off of Monsanto's agrobacterium claims to the U.C. Berkeley" in order to ensure competition in biotechnology for new varieties of corn, as a condition of a merger with Dekalb Genetics.¹²

In 2000, the US Department of Justice obtained compulsory licenses to Miller Industry patents on tow truck technologies.¹³

In 2001, ExxonMobil and the National Petrochemical & Refiners Association asked the US Federal Trade Commission (FTC) to force Unocal, another oil company, to grant licenses to patents on reformulated gasoline. The patents were necessary to be in compliance with clean air regulations in California. In 2005, the FTC obtained a zero royalty compulsory license a portfolio of patents, as a condition of Chevron acquiring Unocal. In announcing the agreement, the FTC statement said: "if Union Oil were permitted to enforce its patent rights, companies producing this low-emission CARB gasoline would be required to pay royalties to Union Oil, the bulk of which would be passed on to California consumers in the form of higher gasoline prices.

¹¹ The compulsory license was available to any publisher, and later became moot when Hyperlaw, a small publisher of court legal information, successfully challenged the ability to claim copyright in the pagination of court opinions.

¹² Justice Department Approves Monsanto's Acquisition Of Dekalb Genetics Corporation, Divestiture of Transformation Technology Rights and Licensing of Corn Germplasm Implemented, Press Release, November 30, 1998

¹³ Justice Department Requires Miller Industries To License Important Towing Technology Decree will resolve Lawsuit Challenging Two Prior Acquisitions. Press Release. February 17, 2000. http://www.justice.gov/atr/public/press_releases/2000/4189.htm. Also, United States of America v Miller Industries, Competitive Impact Statement, Civil Action No. CV-00-0305-RWR, February 23, 2000.

The Commission estimated that Union Oil's enforcement of these patents could potentially result in over \$500 million of additional consumer costs each year."¹⁴

In 2008, the FTC obtained an open compulsory license to patents held by Negotiated Data Solutions LLC (N-Data), for use in Ethernet technologies. The FTC said "The settlement will protect consumers from higher prices and ensure competition by preventing the company from charging higher royalties for the technologies used in the standard."¹⁵

In 2011, the USDOJ, in collaboration with Germany's Federal Cartel Office (Das Bundeskartellamt), required Microsoft, Oracle, Apple and EMC to license 882 patents and patent application acquired from Novell, under "open source" licenses, including the GNU General Public License 2, and the Open Innovation Network (OIN) license.¹⁶

Additional Actions Regard Standards Relevant Patents

In 2012, the USDOJ issued a statement regarding a series of acquisitions of patents by Google, Apple, Microsoft and Research in Motion (RIM). The statement detailed a number of promises by the parties acquiring patents to provide licensing to competitors, and to forgo requests for injunctions in resolving disputes over infringements. USDOJ noted:¹⁷

"the division continues to have concerns about the potential inappropriate use of Standards Essential Patents (SEPs) to disrupt competition and will continue to monitor the use of SEPs in the wireless device industry, particularly as they relate to smartphones and computer tablets. The division's continued monitoring of how competitors are exercising their patent rights will ensure that competition and innovation are unfettered in this important industry. All three of the transactions highlight the complex intersection of intellectual property rights and antitrust law and the need to

¹⁴ See: ExxonMobil asks FTC to investigate Unocal's gasoline patents, *Oil and Gas Journal*. May 9, 2001. <http://www.ogj.com/articles/2001/05/exxonmobil-asks-ftc-to-investigate-unocals-gasoline-patents.html>, and Statement of the Federal Trade Commission In the Matter of Union Oil Company of California, Dkt. No. 9305, and, Chevron/Unocal, File No. 051-0125, June 10, 2005.

<http://www.ftc.gov/enforcement/cases-proceedings/0510125/chevron-corporation-unocal-corporation-matter>
¹⁵ "FTC Challenges Patent Holders Refusal to Meet Commitment to License Patents Covering 'Ethernet' Standard Used in Virtually All Personal Computers in U.S." FTC Press Release. January 23, 2008. <http://www.ftc.gov/news-events/press-releases/2008/01/ftc-challenges-patent-holders-refusal-meet-commitment-license>.

¹⁶ CPTN Holdings LLC And Novell Inc. Change Deal In Order To Address Department Of Justice's Open Source Concerns: Justice Department and Germany's Federal Cartel Office Cooperate Closely on Patent Matter, Investigation Continues. USDOJ Press Release. April 20, 2011 http://www.justice.gov/atr/public/press_releases/2011/270086.htm

¹⁷ Statement of the Department of Justice's Antitrust Division on Its Decision to Close Its Investigations of Google Inc.'s Acquisition of Motorola Mobility Holdings Inc. and the Acquisitions of Certain Patents by Apple Inc., Microsoft Corp. and Research in Motion Ltd. USDOJ Press Release, February 13, 2012. <http://www.justice.gov/opa/pr/2012/February/12-at-210.html>

determine the correct balance between the rightful exercise of patent rights and a patent holder's incentive and ability to harm competition through the anticompetitive use of those rights. “

On January 8, 2013, the US Department of Justice (DOJ) and the U.S. Patent and Trademark Office (PTO) issued a joint statement on "remedies for standards-essential patents subject to voluntary F/RAND commitments." The statement was directed to the United States International Trade Commission (ITC) which administers Section 337 of the Tariff Act of 1930 (19 USC 1337. Unfair practices in import trade) and it has the practical effect of introducing a policy of compulsory licenses for thousands of standards relevant patents.

DOJ and PTO were responding to growing criticism of the patent system as it relates to mobile computing devices and other technologies where product developers find it difficult if not impossible to obtain voluntary licenses on reasonable terms to the large number of patents covering various aspects of a product. A few quotes from the text of the DOJ/PTO statement follow:

. . . when a standard incorporates patented technology owned by a participant in the standards-setting process, and the standard becomes established, it may be prohibitively difficult and expensive to switch to a different technology within the established standard or to a different standard entirely. As a result, the owner of that patented technology may gain market power and potentially take advantage of it by engaging in patent hold-up, which entails asserting the patent to exclude a competitor from a market or obtain a higher price for its use than would have been possible before the standard was set, when alternative technologies could have been chosen. This type of patent hold-up can cause other problems as well. For example, it may induce prospective implementers to postpone or avoid making commitments to a standardized technology or to make inefficient investments in developing and implementing a standard in an effort to protect themselves. Consumers of products implementing the standard could also be harmed to the extent that the hold-up generates unwarranted higher royalties and those royalties are passed on to consumers in the form of higher prices. . .

The USITC has a mandate to consider the “effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers.” [19] As the USITC has observed, these public interest factors “are not meant to be given mere lip service,” but rather “public health and welfare and the assurance of competitive conditions in the United States economy must be the overriding considerations in the administration of this statute.” . .

The USITC may conclude, after applying its public interest factors, that exclusion orders are inappropriate in the circumstances described in more detail above. Alternatively, it may be appropriate for the USITC, as it has done for other reasons in the past, to delay

the effective date of an exclusion order for a limited period of time to provide parties the opportunity to conclude a F/RAND license. Finally, determinations on the appropriate remedy in cases involving F/RAND encumbered, standards-essential patents should be made against the backdrop of promoting both appropriate compensation to patent holders and strong incentives for innovators to participate in standards-setting activities.

On August 3, 2013, USTR head Ambassador Michael Froman wrote to the Chairman of the U.S. International Trade Commission (ITC), to "disapprove the USITC's determination to issue an exclusion order and cease and desist order" for Apple Inc. "smart phones and tablet computers that infringe a U.S. patent owned by Samsung Electronics," in the ITC Investigation No. 337-TA-794.¹⁸ According to press reports, this is the first time since 1987 that the White House has overturned an exclusion order by the ITC.¹⁹ Froman's letter cited the legislative history of USC § 1337, which includes a review of the impact on "(1) public health and welfare; (2) competitive conditions in the U.S. economy; (3) production of competitive articles in the United States; (4) U.S. consumers; and (5) U.S. foreign relations, economic and political."

By deciding that Apple would be allowed to import devices into the United States that infringe a patent held by Samsung, the USTR signaled that it would not back the exclusive rights in patents cases where there are abuses or conflicts with the public interest, or other domestic concerns. USTR's analysis of the Apple Samsung patent dispute focused on the harm associated with failures to license on reasonable terms "standards essential patents". Froman's letter said that the decision to permit Apple to infringe Samsung patents was made "after extensive consultations with the agencies of the Trade Policy Staff Committee and the Trade Policy Review Group as well as other interested agencies and persons." According to Froman, the decision was based upon "the effect on competitive conditions in the U.S. economy and the effect on U.S. consumers.

Bayh-Dole

In 1980, the U.S. Congress passed the Bayh-Dole Act, which sought to provide for more uniform policies as regards federally funded inventions. The Bayh-Dole act included among its safeguards and a royalty free license "to practice or have practiced for or on behalf of the United States any subject invention throughout the world," a requirement of 35 USC 202(c)(4), and a compulsory licensing procedure called "March-In Rights," set out in 35 USC 203, and the definitions in 35 USC 201, and the requirement of 35 USC 204, regarding "Preference for United States industry."

According to 35 USC 203(a), a federal agency can grant a compulsory license on a patent for an invention developed with federal funds:

¹⁸ Michael Froman's decision in the Apple/Samsung ITC patent dispute and the USTR trade agenda, August 5, 2013. <http://keionline.org/node/1785> Includes a copy of the August 3, 2013 letter.

¹⁹ Brian X. Chen, Obama Administration Overturns Ban on Apple Products, New York Times, August 3, 2013. <http://bits.blogs.nytimes.com/2013/08/03/obama-administration-overturns-ban-on-apple-products/>

if the Federal agency determines that such --

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The term “practical application” of the subject invention is defined in 35 USC 201(f) as “its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms,” an obligation quite similar to the requirement in the Indian patent law that patent are “reasonably affordable.”

The obligation mentioned in 35 USC 201(a)(4) is that normally, the invention must be “manufactured substantially in the United States.” (Referring to 35 U.S. Code § 204 - Preference for United States industry)

In the 33 years since the Bayh-Dole Act created a uniform system for federally owned or funded patents, the NIH has never exercised March-In Rights for an invention, and the same may be true for all federal agencies. However, while federal agencies have not formally granted March-In petitions, there are several instances where the threat of the compulsory license has been used to obtain concessions from the patent holders.

In 1997, a March-In rights petition by Cell-pro for Johns Hopkins patents on a medical device was denied, but since the infringing device was then the only FDA approved technology using the patented inventions, infringement was permitted for a period of time.

In 2001, DHHS used the threat of a March-In rights to expand access to patents on stem cell lines resulting from publicly funded research and held by the Wisconsin Alumni Foundation (WARF). Secretary Thompson, a former Governor of Wisconsin, reportedly communicated to

WARF the government's ability and willingness to grant March-In rights, as leverage to secure an open license on the patents.²⁰

In a 2004 case involving patents on ritonavir, a drug used in the treatment of HIV/AIDS, the concession by the patent holder to avoid the March-In was significant -- Abbott Laboratories agreed to reduce the price of ritonavir approximately 80 percent for HIV/AIDS patients on federally supported programs.

In 2006, the Centers for Disease Control may have threatened to use March-In rights or the government's royalty free license, to expand access to patented technologies used to manufacture vaccines for avian flu. KEI has an outstanding FOIA for the details of this case.

In 2010, a shortage in the US supply of Fabrazyme, an expensive treatments for Fabry's disease, was caused by manufacturing failures by Genzyme, a firm now owned by Sanofi. The patents were invented on an NIH grant, and were owned by Mount Sinai School of Medicines. Several Fabry's disease patients asked the NIH to grant a compulsory license for the patents on Fabrazyme, under the March-In rights provisions of the Bayh-Dole Act. At the time, Fabrazyme was severely rationed in the United States, and patients were getting sicker. The NIH rejected the patients' March-In petition, in part because the NIH found other IPR barriers to entry, such as the FDA monopoly on test data. However, the Director of the NIH reported that "Mount Sinai has assured us that it will not pursue an injunction against the marketing and sale of Replegal during any period of an existing or future shortage of Fabrazyme."²¹ The relevant injunction referred to by the NIH involved another similar treatment for Fabry's disease on the market in Europe, but not in the United States. Mount Sinai was suing Shire in Germany, for infringing the patent it had licensed to Genzyme for Fabrazyme. In Germany, Shire has responded by asking for a compulsory license to the Mount Sinai patent. An injunction to block the sale of Replagal in Europe would have increased European demand for Fabrazyme in Europe, making the US shortage of the drug more acute. The combination of the NIH induced restraints on a European injunction and the German compulsory licensing request, was to induce Mount Sinai to license its patent to Shire, and this effectively avoiding a more severe global shortage of treatments for Fabry's disease.²²

In 2013, Senator Patrick Leahy asked the NIH "to consider using March-In rights under the

²⁰ Resulting in these agreements: September 5, 2001, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement," <http://www.nih.gov/news/pr/sep2001/od-05.htm>. Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service: http://stemcells.nih.gov/staticresources/research/registry/MTAs/Wicell_MOU.pdf

²¹ Francis Collins, Director, NIH, Determination in the case of Fabrazyme, Manufactured by Genzyme Corporation. December 1, 2010.

²² Note that for this US funded invention, the drug was rationed in the United States, where there was no competition, but not in Europe, where competition existed.

Bayh-Dole Act to ensure greater access to genetic testing for breast and ovarian cancer."²³
According to Leahy:

“Myriad's genetic test, which was developed with federally-funded research, is truly important for public health. Myriad is the only provider of this test because it is covered by patent protection. Unfortunately, testimony before the United States Patent and Trademark (USPTO) revealed that Myriad does all of this testing in-house, and charges between \$3,000 and \$4,000. . . . the health needs of the public are not reasonably satisfied by the patentee in this situation because testimony presented to the USPTO made clear that many women are not able to afford the testing provided by Myriad.”

Compulsory licensing of patents under United States Energy Storage Competitiveness Act of 2007

In 2007 the US Congress enacted a new compulsory licensing program for “energy storage markets.”²⁴ In a program involving four energy storage research centers that “translate basic research into applied technologies” and which is designed to “advance the capability of the United States to maintain a globally competitive posture in energy storage systems for electric drive vehicles, stationary applications, and electricity transmission and distribution,” the statute creates two obligations as regards patents obtained by participants.

- (i) the patent holder shall not negotiate any license or royalty agreement with any entity that is not an industrial participant under this subsection; and
- (ii) the patent holder shall negotiate nonexclusive licenses and royalties in good faith with any interested industrial participant under this subsection.

The program is coordinated with an "Energy Storage Advisory Council" that "shall consist primarily of representatives of the energy storage industry of the United States."²⁵ The statute provides that "as a condition of participating in a center, a participant shall enter into a participation agreement with the center that requires that activities conducted by the participant for the center promote the goal of enabling the United States to compete successfully in global energy storage markets."²⁶

28 USC § 1498 Cases

²³ Donald Zuh, Senator Leahy Urges NIH to Use March-In Rights on Myriad BRCA Test, Patent Docs. July 17, 2013

<http://www.patentdocs.org/2013/07/senator-leahy-urges-nih-to-use-march-in-rights-on-myriad-brca-test.html>

²⁴ 42 USC 17231(h)(7).

²⁵ 42 USC 17231(e)(2)(B).

²⁶ 42 USC 17231(h)(3).

Another area where the United States permits uses of patented inventions (and copyrights) without permission of right holders are uses “by and for” the government, under 28 USC § 1498 - Patent and Copyright Cases. Under this statute, the federal government can authorize third parties as well as its own employees to use any patented invention (also applies to copyrights, plant variety protection and semiconductor designs), and the patent owners sole remedy is limited to compensation for the use.

The largest user of 28 USC § 1498 is the US Department of Defense, and indeed, the statute was amended in 1918 in order to address concerns by the U.S. Navy regarding patent litigation.

In an April 20, 1918 letter to the Chairman of the Senate Committee on Naval Affairs, Acting Secretary of the Navy Franklin D. Roosevelt wrote:

"manufacturers are exposed to expensive litigation, involving the possibilities of prohibitive injunction payment of royalties, rendering of accounts, and payment of punitive damages, and they are reluctant to take contracts that may bring such severe consequences. The situation promised serious disadvantage to the public interests, and in order that vital activities of this department may not be restricted unduly at this time, and also with a view of enabling dissatisfied patentees to obtain just and adequate compensation in all cases . . . I have the honor to request that the act be amended by the insertion of a proper provision therefore in the pending naval appropriation bill."

Until 1960, 28 USC § 1498 was limited to patents. In 1960, the Congress extended the act to cover copyright. William Patry²⁷ writes.

“Until 1960, the doctrine of sovereign immunity seemed to preclude recovery against the United States for infringement. This changed on September 6, 1960 when [the Congress passed] an act creating a new Section 1498(b) in title 28. This waiver of sovereign immunity came with attached strings: one can only recover "reasonable and entire recovery for such damages, including minimum statutory damages," no injunctive relief is available, nor attorney's fees. Moreover, corporations owned or controlled by the federal government, contractors and subcontractors, as well as "any person, firm, or corporation acting for the Government and with the authorization or consent of the Government" must be sued in the Court of Federal Claims, with the same limitations on relief. Authorization may be express (as in a contractual clause), extrinsic (as where evidence demonstrates the government's intention to assume liability), or implied (e.g., when the government makes the infringement by the contractor inevitable due to the conditions placed on the contractor). The reference to minimum statutory damages should scare off copyright owners from thinking they can get the enhanced amounts of up to \$150,000 per work. In short, monetary recovery is slight, injunctive relief and attorney's fees impossible; litigation against the federal government is not an attractive option. (These provisions do

²⁷ William Patry, The U.S. Government and Copyright. The Patry Copyright Blog, May 4, 2005.

not apply to actions against state governments, but there one has intractable sovereign immunity problems).”

Later the statute would be amended to apply to override exclusive rights for plant variety protections [28 USC § 1498(d)], mask works under chapter 9 of title 17, and designs under chapter 13 of title 17 [28 USC § 1498(e)]

Today any federal agency can rely upon to 28 USC § 1498(a) to limit remedies for the infringement of patents, copyrights, plant variety rights, mask works, and designs to compensation only. By removing the possibility of an injunction to enforce an exclusive right, the federal government has the equivalent of a compulsory license on all patents, copyrights and other intellectual property rights covered by the statute. Examples where this compulsory license has been used are quite diverse, and include such items as medicines, Blackberry smartphone services²⁸, software used by the Federal Reserve Bank to curb fraud²⁹, technology used by NASA to explore space³⁰ and weapons of all types.

In 2001, the US Department of Health and Human Services (DHHS) used the threat of a compulsory license for the patents on Bayer’s ciprofloxin, to successfully obtain a 50 percent price reduction in the drug.³¹

State Sovereign Immunity

In 1999, the United States Supreme Court ruled that state governments were not liable for

²⁸ NTP v. Research in Motion, Civil Action No. 3:01CV767.

²⁹ Advanced Software Design Corporation, Et Al., v. Federal Reserve Bank Of St. Louis, Case No. 4:07Cv185 CDP, Memorandum And Order. November 9, 2007. United States District Court, Eastern District Of Missouri, Eastern Division. Advanced Software Design Corporation v Federal Reserve Bank Of St. Louis, No. 2008-1152. September 30, 2009, United States Court of Appeals, Federal Circuit.

³⁰ For example, Boeing v United States, Opinion, No. 00-705C, March 16, 2009, United States Court of Federal Claims.

³¹ "A U.S. senator Tuesday called on the government to increase the supply of the antibiotic Cipro, the only approved oral treatment for anthrax, by purchasing cheaper generic versions of the drug. Sen. Charles Schumer, a Democrat from New York, said U.S. law allows the government to make purchases from manufacturers other than the patent holder, in this case Bayer AG. "So if we invoke this statute, we can greatly increase our supply of Cipro and greatly reduce the cost to the government by about 50 percent," Schumer told a press conference." NY Senator urges U.S. to purchase generic Cipro. Reuters, October 16, 2001. "Mr. Gardett, the spokesman for the Department of Health and Human Services, countered that Mr. Thompson has not actually infringed on any patents, and added that the secretary has said he wants to avoid that step. 'He has only talked about it,' Mr. Gardett said." Carter Dougherty, U.S. seeks cheaper Cipro stockpile," The Washington Times, October 24, 2001. "Congressional Republicans have traditionally been leery of interfering with patents. But Representative Christopher Shays, the Connecticut Republican who is the chairman of the House Government Reform subcommittee that held today's hearing, said that Congress would probably back any request from Mr. Thompson for permission to bypass the patent. "If the secretary asked for it, it would probably pass," he said. Keith Bradsher and Edmund L. Andrews. "U.S. Says Bayer Will Cut Cost of Its Anthrax Drug," New York Times. October 24, 2001.

damages for patent infringement, under the doctrine of state sovereign immunity. Florida Prepaid Postsecondary Education Ed. Bd. v College Savings Bank. 527 U. S. 627 (1999). Later this immunity was extended to infringements of copyrights and trademarks.

The immunity from damages for patent infringement has the practical effect of expanding the ability of state universities to engage in a wide variety of infringing activities, including those relating to medical research.

Affordable Care Act

In 2010, the Affordable Care Act [PL 111-148] created a compulsory license for patents associated with biologic drugs. The compulsory license goes into effect when the manufacturer of a biologic drug does not bring a timely action for infringement, or fails to disclose relevant patents for the drug. The statute limits the remedies for infringement to either a reasonable royalty, or no remedy at all, depending upon the failures of the patent holder to assert or disclose patent rights in a timely manner. The compulsory license is automatic and mandatory. The legal basis in the WTO TRIPS agreement for the elimination of the availability of an injunction and the limit of the remedy to a reasonable royalty is TRIPS Article 44.2.

PUBLIC LAW 111–148. March 23, 2010 [H.R. 3590]. An Act Entitled The Patient Protection and Affordable Care Act.

35 U.S.C. Title 35 - PATENTS. PART III - PATENTS AND PROTECTION OF PATENT RIGHTS. CHAPTER 28 - INFRINGEMENT OF PATENTS

28 USC 271(e)(6) (A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological

product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

Compulsory licensing of patents as a limitation of remedy, under *eBay v. MercExchange*

In 2006, the US Supreme Court ruled that notwithstanding the exclusive rights associated with a patent, a patent holder was not automatically entitled to obtain an injunction to prevent future infringements. The decision, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), states that the decision to grant an injunction is question of equity, and the court must consider a four part test, and require the plaintiff to demonstrate:

- (1) that the plaintiff has suffered an irreparable injury;
- (2) that remedies available at law are inadequate to compensate for that injury;
- (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

The practical impact of *eBay v. MercExchange* was to transform many infringement and injunction proceedings into compulsory licensing cases, and to include a public interest test.

Some judges and observers have sought to draw distinctions between the “running royalties”³² in the post eBay injunction cases, from compulsory licensing cases under European patent statutes, but the distinctions are primarily about the timing of the compulsory license. A European Union compulsory licensing proceeding can take place before or during an infringement. The post eBay injunction cases are compulsory licenses that normally take place after infringement has taken place.

Since 2006, the post eBay injunction cases have resulted in a very large number of compulsory licenses involving all sorts of technologies. The following are a few examples.

In a 2006 case, Dr. Jan K. Voda alleged that three patents concerning an angioplasty guide catheter were infringed by Cordis (a Johnson and Johnson company). A jury found for Dr. Voda on infringement, and determined that he was entitled to a reasonable royalty of 7.5% of Cordis’ gross sales of the infringing catheters.³³ Finding that Dr. Voda failed to demonstrate either irreparable injury or that monetary damages would be inadequate, the court denied his request for a permanent injunction.

³² Mark J. Feldstein Ph.D., Permanent Injunctions and Running Royalties in a Post eBay World, *Intellectual Property Today*, September 1, 2009. Stephen M. Ullmer, "Paice Yourselves: A Basic Framework For Ongoing Royalty Determinations In Patent Law," *Berkeley Technology Law Journal*, Vol. 24:75.

³³ *Voda v. Cordis Corp.*, 2006 U.S. Dist. LEXIS 63623 (W.D. Okla. 2006)

In a 2009 case, patentee Bard Peripheral Vascular, Inc. sued W.L. Gore & Associates in Arizona for infringement of a patent for a prosthetic vascular graft. Finding infringement, the jury awarded damages, including reasonable royalty set at 10 percent. The court denied Bard's motion for a permanent injunction, holding that a compulsory license was appropriate compensation; it wrote:

"The Court is satisfied that a fair and full amount of compensatory money damages, when combined with a progressive compulsory license, will adequately compensate Plaintiffs' injuries, such that the harsh and extraordinary remedy of injunction-with its potentially devastating public health consequences--can be avoided."³⁴

In 2009, US District Court Judge David Folsom issued an ongoing royalty rate in light of patent infringement by three of Toyota's vehicles. Paice filed a lawsuit in 2004 alleging that Toyota's Prius, Highlander SUV, and Lexus RX400h SUV vehicles infringed on patents held by Paice relating to the drive train for hybrid electric vehicles. Toyota was found to be infringing on the patent and a jury awarded Paice damages and established an ongoing royalty rate. In 2009, the court set an ongoing royalty rate as a percentage of wholesale vehicle price per model in question.³⁵ The rates decided were 0.48 percent on each Toyota Prius, 0.32 percent on each Toyota Highlander, and 0.26 percent on each Lexus RX400h sold for the remaining life of the patent.

In 2009, Boston Scientific Corporation (BSC) filed a patent infringement action against the Cordis Corporation for infringement of its US Patent No. 5,922,021, which is a patent involving cardiovascular stents. The court ruled in favor of BSC in this case, which follow several previous patent infringement claims and counterclaims between the two parties (which also were decided in favor of BSC). The claim in this case was ruled to be a separate instance of infringement from the previous cases (which also involved cardiovascular stents). The jury awarded \$18,531,022 in lost profits damages and \$1,000,470 in reasonable royalties to BSC. The court granted BSC's motion for ongoing damages in lieu of a permanent injunction at a rate of 32 percent.³⁶

In 2010, a Florida district court declined to grant a permanent injunction following a finding that the Johnson & Johnson's ACUVUE®OASYS contact lens product infringed patents owned by CIBA Vision Corporation. In consideration of the decision, the court included a thorough and considered discussion of the public interests at stake. Finding that approximately 5.5 million American patients presently wear the infringing lenses and that the total cost of refitting for all current users would be between \$275 million and \$687.5 million, the court stated that "millions of innocent lens wearers will suffer real adverse consequences if sale of ACUVUE®OASYS is

³⁴ Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., 2009 U.S. Dist. LEXIS 31328 (D. Ariz. 2009)

³⁵ Paice, LLC v. Toyota Motor Corporation, Civil Action No. 2:04-CV-211 (US District Court, E.D. Tex., April 17, 2009)

³⁶ Boston Scientific Corporation and Boston Scientific Scimed, Inc. v. Cordis Corporation, Civ. No. 10-315-SLR (US District Court, Del., March 13, 2012)

enjoyed.” The concerns, said the court, were not limited to “issues of comfort or cosmetics, as CIBA argu[ed], but rather deal[t] with the more substantive concerns of proper vision and eye care.”³⁷

In 2010, the US District Court found Wells Fargo to be in infringement of patents owned by Datatresury Corporation (US Patent Nos. 5,910,988 and 6,032,137). The patents in the case involved check image technology whereby customers deposit checks via image technology on mobile applications. The patents specifically dealt with the encrypting, processing, and verifying systems and data extraction limitations. The court decided in favor of Datatresury Corporation and set the ongoing royalty rate at 0.5 cents per check.³⁸

In 2012, Judge Richard Posner dismissed with prejudice the patent infringement suits filed in Apple Inc. and NeXT Software, Inc. v. Motorola, Inc. and Motorola Mobility, Inc. In this case, the judge cited the eBay decision noting that neither party was entitled to injunctive relief as neither party demonstrated that “damages would not be an adequate remedy”. In fact, the judge specifically noted that a “compulsory license with ongoing royalty is likely to be a superior remedy in a case like this because of the frequent disproportion between harm to the patentee from infringement and harm to the infringer and to the public from an injunction.”³⁹

In 2012, the US District Court decided that Varian Medical Systems had found to be infringing on two patents owned by the University of Pittsburgh and had been used in Varian’s Real-time Position Management Respiratory Gating System (RPM System). The RPM System is used in imaging and radiation therapy to target tumors during cancer treatment. The court ruled in favor of the University of Pittsburgh, awarding the university more than \$36.8 million in damages. Additionally, the judge found that the university was entitled to an ongoing royalty for the infringement, with a rate of 10.5% for the sales of Varian’s RPM Systems and a rate of 1.5% for its sales of the Clinac and Trilogy linear accelerators, which were sold in conjunction with the RPM Systems.⁴⁰

In 2012, the Activevideo brought a patent infringement action against Verizon on several of its patents. The jury found that Verizon had infringed on four Activevideo patents following the decision, a permanent injunction was entered (with a sunset royalty assessed). On appeal however, the court vacated the grant of a permanent injunction and awarded an ongoing royalty rate for future infringement by Verizon. The Court of Appeals upheld the royalty rate determined

³⁷ Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., Nos. 3:05-CV-135-J-32TEM, 3:06-CV-J-32TEM (US District Court, M.D. Fla., March 26, 2009)

³⁸ Datatresury Corporation v. Wells Fargo & Company, et al., Civil Action No. 2:06-CV-00072 DF (US District Court, E.D. Tex., August 2, 2011)

³⁹ Apple, Inc. and NeXT Software, Inc. v. Motorola, Inc. and Motorola Mobility, Inc., Nos. 2012-1548, 2012-1549 (US Court of Appeals, Fed. Cir. November 27, 2012)

⁴⁰ University of Pittsburgh of the Commonwealth System of Higher Education d/b/a/ University of Pittsburgh v. Varian Medical Systems, Inc., No. 08-CV-1307 (US District Court, W.D. Pa., April 25, 2012)

by the district court and awarded Activevideo an ongoing royalty rate of \$2.74 per Verizon FiOS-TV subscriber per month.⁴¹

In 2012, the court awarded Mondis supplemental damages, prejudgment interest, and an ongoing royalty rate for Chimei-Innolux's infringements of patents owned by Mondis. The patents involved plug-and-play video display technology, relating to television and computer monitors. The court ordered in favor of Mondis and the jury awarded \$15 million in damages to be paid by Innolux. The court then later adjudicated a further \$1,971,810 in 2011 supplemental sales and \$73,725 in prejudgment interest to be awarded. The court decided on an ongoing royalty rate of 1.50% for computer monitors and 0.75% for televisions, as a percentage of total product revenue, for the remaining life of the infringed patents.⁴²

⁴¹ Activevideo Networks, Inc. v. Verizon Communications, Inc., Verizon Services Corp., Verizon Virginia Inc., and Verizon South, Inc., Nos. 2011-1538, 2012-1129, 2012-1201 (US Court of Appeals, Fed. Cir., August 24, 2012)

⁴² Mondis Technology Ltd. v. Chimei-Innolux Corp., et al., Civil Action No. 2:11-CV-378-JRG (US District Court, E.D. Texas, April 20, 2012)