

To: USTR  
From: James Love, KEI  
Date: February 7, 2014  
Re: Knowledge Ecology International (KEI) written comments and notice of intent to testify at the Special 301 Public Hearing Monday, February 24, 2014 at the offices USTR, 1724 F Street NW., Washington, DC 20508.

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## Compulsory Licensing of Patents

Pharmaceutical companies, General Electric, and a few other companies have cited compulsory licences issued by foreign governments as a threat to innovation and US economic interests, including as they relate to medical inventions or climate change.

The Pharmaceutical Research and Manufacturers of America (PhRMA) submission to the 2013 Special 301 Report frequently referred to compulsory licensing as undermining IP and domestic industry interests, and compulsory licensing was repeatedly mentioned in the sections on India, Indonesia, and Ecuador as well as the PhRMA concerns about proposed legislation in Thailand, Ukraine, Malaysia, and Costa Rica.<sup>1</sup>

In the Special 301 Report, USTR has taken a nuanced view of this issue. For example, in the 2013 report, USTR says:

“The United States is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow trading partners to address the serious public health problems that they may face. Consistent with this view, the United States respects its trading partners’ rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement, and encourages its trading partners to consider ways to address their public health challenges while maintaining IPR

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<sup>1</sup> PhRMA 2013 filing.  
<http://www.phrma.org/sites/default/files/pdf/PhRMA%20Special%20301%20Submission%202013.pdf>

systems that promote innovation.” (2013 Report, Page 23)

In 2013, USTR did single out three countries involved in compulsory licensing. The first involved China, in connection with patents on technologies involved in the standard setting process. USTR said:

Of serious concern were provisions indicating that China would rely, during the standards development process, either on non-patented technology or on patented technology licensed at a price significantly lower than normal royalties. The draft would also have empowered government authorities to grant a compulsory license if the authorities and patent holders were unable to reach agreement on licensing terms. These provisions and others raised significant concerns from several countries, including in the United States, as reported in depth in previous editions of this Report and in USTR’s 2012 Report on Technical Barriers to Trade (TBT Report). In late 2012, China issued new draft interim rule for public comment. The United States welcomes the deletion from the new draft rule of provisions on below-normal royalties and compulsory licenses. The United States hopes that SAC will also revise other provisions in the draft about which the United States raised concerns. (Page 36-7)

Here we note that the United State shares concerns about patents involving standards. 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.

KEI’s view is that patent policy needs to be more context specific, and the DOJ/PTO statement on standards relevant patents was a welcome step in that direction. To be clear, by cautioning against the grant of injunctions, the DOJ/PTO statement is also a strong endorsement of compulsory licensing of patents, in order to protect the public interest, public health and welfare, and to promote “competitive conditions in the United States economy.

The second mention of compulsory licensing in the 2013 Special 301 report concerned India, and a compulsory license on patents on the cancer drug sorafenib, sold under the trade name Nexavar by Bayer. This is the quote from the 2013 report:

“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. “ (2013 Report, Page 39)

In our view, USTR should have provided a fuller explanation of the circumstances that led to the compulsory license in India. Bayer was charging 3.412 million India Rupees per year for the drug, more than 69 thousand US dollars per year at February 2012 exchange rates, and selling the drug to almost no cancer patients in India. Recently, the CEO of Bayer discussed the case, and focused on the pricing issue:<sup>2</sup>

"In our case, the Indian government said "No, no, your patent is valid, and this is a product for kidney and liver cancer. Your patent is valid we just think you charge too much. And because you charge too much you have to do a mandatory license to a generic company in India that is now going to make this drug and sell it. And on that low price that they will sell it for, you will get 6% royalty." And that was a government decision. So we had a patent but somebody else is allowed to make this product and because there is not enough access to this product for poor Indians. I don't know if you've even been to India, there are a lot of poor Indians obviously, and the hospitals aren't that close by [laughs] to where they live, so we found that this was extremely politically motivated and essentially, I would say, theft. . . ."

"So now, is this going to have a big effect on our business model? No, because 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."

The Bayer CEO's reaction to the Indian compulsory license describes the current reality for the majority of the world's population. Many companies find it acceptable to price products out of reach for the majority of persons living in developing countries.

Hearings in the U.S. Congress and the USTR discussion in its 2013 Special 301 report have focused on another issue in the Nexavar compulsory license -- obligations in Indian patent law for domestic manufacturing. Local working requirements are an important trade issue, but the legal and policy issues are complex, not only in the case of the Nexavar compulsory license, but in general. Note that the United States has raised concerns about local manufacturing provisions in both the Brazil and India patent laws, but has preferred making indignant claims about the illegality of those laws to establishing their actual legality within the system established at the WTO to resolve such disputes.

A pair of 2001 WTO disputes, the first involving a United State objection to a domestic working provision in the Brazilian patent law, and a second involving a Brazilian objection to a domestic manufacturing provision in the United States patent law, were both settled informally.

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<sup>2</sup> See: Transcript of Bayer CEO Marjin Dekkers quote at the December 3, 2013 FT Event, regarding India compulsory license of Nexavar <http://www.keionline.org/node/1924>

- DISPUTE SETTLEMENT: DISPUTE DS199, United States v. Brazil — Measures Affecting Patent Protection
- DISPUTE SETTLEMENT: DISPUTE DS224, Brazil v . United States — US Patents Code

If the USTR wants to claim that the India or Brazil statutes are not compliant with the TRIPS agreement, they have to address the tension between two different treaty provisions. Article 5(A)(2) of the Paris Convention (which is incorporated by reference in Article 2 of the TRIPS), states:

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

while Article 27.1 of the TRIPS provides that:

"patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

Is a compulsory license for a failure to manufacture domestically an illegal restriction of patent rights, under Article 27.1 of TRIPS, or something permitted by the Paris Convention?

The fact that the United States has not used the WTO to resolve its concerns over the India patent law, which was enacted in 2005, and failed to have a transparent precedent set in the earlier Brazil case, gives weight to arguments by trade experts that governments do have the flexibility in the TRIPS to have such requirements.

It is also significant that in 2007, the United States Congress enacted a new compulsory licensing statute for patents on energy storage, which includes local working obligations. 42 USC 17231, the United States Energy Storage Competitiveness Act of 2007 (Pub. L. 110–140, DEC. 19, 2007). This statute is designed to:

“support the ability of the United States to remain globally competitive in energy storage systems for electric drive vehicles, stationary applications, and electricity transmission and distribution.”

If USTR persists in raising questions about the legality in the WTO regime of domestic manufacturing requirements, it is possible that the various US provisions requiring domestic manufacturing of federally subsidized patented inventions will be challenged, in the WTO, or in one of the several FTA agreements negotiated or under negotiation, including those with Investor State Dispute Settlement (ISDS) mechanisms.

## **US use of compulsory licenses**

In addition to the sweeping proposals for compulsory licenses in the case of standards relevant patents, the United States itself is the major user of compulsory licenses in two other areas. These include the extensive non-voluntary uses of patents and copyrights under 28 USC 1498, such as the compulsory licenses benefiting contractors for NASA and the US Department of Defense, and the growing number of compulsory licenses granted by federal judges, when they forgo the granting of injunctions in patent infringement cases, in favor of forward looking royalties as a remedy for infringement, following the standards for injunctive relief set out in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). These include a number of medical inventions, including some that are clearly exported from the United States. USTR also intervened recently to permit Apple Computer to import mobile computing devices and iPads that infringed on Samsung patents.

In recent comments to the WTO TRIPS Council, USTR has used linguistic gymnastics to deny that our USA style nonvoluntary uses of patent inventions are “compulsory licenses.” But denying the obvious does not make the obvious invisible to the world, and perhaps it is time for USTR to develop a new approach -- one that does not rely on lying about such things, and one that is based upon reasonable, realistic and usable standards, with clearer explanations and defenses of those standards for nonvoluntary uses of patents.

## **Do pharmaceutical companies consider compulsory licensing a significant problem?**

One would infer from PhRMA’s repeated negative references that compulsory licenses pose a significant threat to the pharmaceutical industry and have had a major impact on their profits. In order to gauge the industry’s own judgement of the threat of compulsory licenses, KEI examined twelve pharmaceutical companies’ shareholder filings, which outline what a company perceives as significant threats to profits and shareholders’ interests. Towards that end, KEI surveyed the risk factors disclosed by AbbVie, Amgen, AstraZeneca, Bayer, Bristol Myers-Squibb, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Pfizer, and Sanofi.

The documents studied were the 10-K and 20-F statements from 2012 that each company is required to file with the US Securities and Exchange Commission (SEC). The SEC requires that all publicly traded companies disclose certain information on an ongoing basis. The 10-K form is submitted annually and provides an overview of the business and financial condition of the company. The 20-F form is the comparable document required for foreign-based companies that are publicly traded in the US.

The section on risk factors,<sup>3</sup> the disclosure of which is required of every publicly traded company in the US, describes in varying detail the risks and uncertainties that the companies foresees might impact their business, financial condition, operations, and stock prices. The section is intended to provide shareholders with a full account of what each company views as a threat to the functioning of their business and to their overall profits.

In each section on risk factors, we then looked at how much of the section is devoted to a particular topic, which would illustrate the level of consideration that each company affords a certain risk to their business. To account for the sections' discussions of a particular topic we tallied the word count of sections devoted to each topic. If a search term was mentioned once, in a list of topics, with no explicative details, then it was not tallied in the word count and is indicated by a 0 (coded in blue).

Although compulsory licenses are discussed as a threat to the pharmaceutical industries' interests, four of the companies considered do not mention compulsory licenses at all in the section on risk factors (Amgen, Bayer, Eli Lilly, and Johnson & Johnson), two companies had a single mention of compulsory license without context, and six of the seven companies that did discuss compulsory licensing devoted less than 100 words to the topic.

For the 13 large pharmaceutical companies, the median number of words in Section 1A (or 3D) in the SEC annual reports was 8,038. The median number of words discussing compulsory licenses was 42 words -- one half of one percent. (The mean number of words for the Section of risks was 7,932, with an average of 55 words on compulsory licensing -- .7 percent).

Topics that were given far greater consideration included pricing, manufacturing, counterfeit products, competition from biosimilars (of which none have yet to be approved by the FDA), product liability, taxes, patent expirations, competition from new drugs, patent challenges, competition from generics, and global economic conditions. To highlight a particularly stark example, Amgen, with the longest risk factor section surveyed at 17,139 words, did not spend one word mentioning any "concerns" regarding compulsory licences.

## **Patent ownership**

USTR efforts in trade negotiations are often focused on promoting the interests of patent holders. In the 1980s, when trade policy began to focus on patented goods, the United States was more dominant in terms of the global share of patents granted. While the United States is still an important owner of patented inventions, its share of global patenting has declined.

In 1980, the foreign share of of USPTO issued utility patent grants was 39.6 percent. By 1990, the foreign share was 47.6 percent. In 2008, the foreign share was 50.9 percent, and it has been

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<sup>3</sup> On the 10-K, this is section 1.A. and on the 20-F, this is section 3.D.

above 50 percent in every year since.<sup>4</sup>

This significance of foreign owned patents is particularly pronounced at the level of large patent owners.<sup>5</sup> The USPTO published a list of organizations receiving 40 or more patents in 2012. Of the top five patent owning organizations, only one is a US-owned company (the others are Korean and Japanese). Of the top ten patent owning organizations, five are from Japan, three are from the United States, and two are from Korea.<sup>6</sup>

**Ranked List of Organizations with 40 or More Patents, as Distributed by  
the Year of Patent Grant and/or the Year Of Patent Application Filing  
Granted: 01/01/2012 - 12/31/2012. Patents By Year of Grant**

	US	Japan	Korea
<b>Number of patents granted</b>			
top 5 organizations	6457	8938	5043
top 10 organizations	10717	12880	6660
<b>Percent of patents</b>			
top 5 organizations	31.6%	43.7%	24.7%
top 10 organizations	35.4%	42.6%	22.0%
<b>Number of organizations</b>			
top 5 organizations	1	3	1
top 10 organizations	3	5	2

In terms of number of patent filings, one would expect a higher percentage of domestic patents to be filed with the US patent office. In light of the international focus of the USTR and of the Special 301 Report, KEI also considered statistics from patents applications file through the World Intellectual Property Organization (WIPO) Patent Cooperation Treaty (PCT).

The PCT is a treaty with 148 contracting parties, designed to make it easier to seek patent protection by filing a single “international” patent application instead of several separate national or regional patent applications.

In 1982, 45 percent of all PCT patent applications were from the United States. By 2001, the US share was just under 40 percent. By 2009, the US share was less than 30 percent. In 2012, the

<sup>4</sup> U.S. Patent Statistics Chart, Calendar Years 1963 - 2013, USPTO, Patent Technology Monitoring Team (PTMT)

<sup>5</sup> USPTO. 2012. “Ranked List of Organizations with 40 or More Patents Granted During the Period, as Distributed Either or Both by the Year of Patent Grant and by the Year Of Patent Application Filing.” Patenting by Organization: Part B. [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo\\_12.htm#PartB](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_12.htm#PartB)

<sup>6</sup> <http://goo.gl/tUVUUR>

US share was 26.4 percent.

From 1981 to 1996, the US share of PCT patents increased 8 times, and decreased 8 times. From 1997 to 2012, the US share decreased every year.

On a separate note, WIPO reports that:<sup>7</sup>

“In 2012, for the first time, residents of China (560,681) accounted for the largest number of patents filed throughout the world. In addition, SIPO (652,777) accounted for the largest number of applications received by any single IP office – a position it first assumed in 2011.”

In light of the decline of the U.S. share of patent ownership, the perspective of the USTR should likewise shift. Instead of the aggressive approach of placing nations on watch lists for addressing well recognized abuses of patent rights, such as excessive pricing of medical inventions, or opportunistic patents on technology incorporated in standards, the USTR should temper the ways in which it considers its foreign relations. The US is not the largest owner of world patents and should alter its policies to reflect that fact. KEI recommends that the policies adopted by the USTR take into account a more realistic view of the US's share of world patents.

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<sup>7</sup> Global Patent Filings See Fastest Growth in 18 Years. Geneva, December 9, 2013. PR/2013/752.