

Indian Pharmaceutical Alliance

Response to

**Testimony of
Mr Roy F Waldron
Chief Intellectual Property Counsel
Pfizer Inc.**

Before the

**HOUSE COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON TRADE**

Hearing of 13 March 2013

on

U.S.-India Trade Relations: Opportunities and Challenges

13 May 2013

Challenging Investment Climate in India

- a. The ‘global standards’ of intellectual property law are laid down in the TRIPS agreement. India’s patent law conforms to these standards. Yet on page 4 of your Testimony, you state that:

“Despite being a member of the World Trade Organization, and an important global trading partner, India has systematically failed to interpret and apply its intellectual property laws in a manner consistent with recognized global standards.”

India’s Parliament has amended its patent laws, consistent with its obligations under the TRIPS Agreement. Pfizer may have preferred the incorporation of ‘TRIPs-plus’ provisions in India’s patent law for pharmaceutical products, but that were a policy option for India, not a legal obligation. India has made its choice and has charted a course appropriate to its own interests. In doing so, it has been mindful of the serious consequences of TRIPs-plus measures on public health and access to medicines, a concern that has been shared globally. For example, on the eve of India amending its patent laws to conform to the requirements of TRIPS agreement, Dr. Jim Yong Kim - Director, Department of HIV/AIDS, World Health Organisation, wrote to India’s Minister of Health and Family Welfare on 17 December 2004:

“As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to antiretrovirals, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines.”

In fairness, the House Subcommittee ought to have been informed that India had amended its patent law in 2005 to meet its obligations under the TRIPS agreement.

- b. The Testimony further observed that:

“Experience accumulated after India began granting product patents in 2005, shows it has routinely flouted trade rules to bolster the Indian generic industry at the expense of innovators.”

Instead of the generalisation that India has ‘*routinely flouted trade rules...at the expense of innovators*’, it would have been helpful if you were more specific about the ‘trade rules’ that you allege are flouted.

- c. The Testimony alleges that:

“At the same time, Indian pharmaceutical companies have grown their U.S. sales dramatically....This is an issue of basic equity. The Government of India has essentially created a protectionist regime that harms U.S. job creators. The harm is evident in pharmaceuticals where the United States has welcomed Indian generic companies while India is closing its borders to U.S. innovators.”

We agree with you that the ‘*United States has welcomed Indian generic companies*’ and their sales in the U.S. have grown. However, let it also be noted that this has benefited U.S. consumers by ensuring availability of inexpensive generic medicines. Further, several Indian companies have created manufacturing and other jobs in the U.S. It is incorrect to say that ‘*India is closing its borders to U.S. innovators*’. This is not true. Indian patent law does not discriminate between domestic and the foreign companies. It distinguishes only between innovation and discovery of new forms of known substances that do not result in the enhancement of efficacy.

- d. You then call for action:

“Correcting India’s protectionist intellectual property regime will require firm leadership by the United States in international organizations and in India.”

We urge you to reconsider your call. At the very least, the House Subcommittee needs to know that a broad spectrum of international opinion has urged India not to yield to pressures to make its intellectual property laws more stringent than what is required under TRIPS agreement and sees no need for ‘correction’.

It is pertinent to note that when Novartis mounted a challenge to the validity of a crucial provision in India’s patent law aimed at preventing delays to the entry of affordable generic medicines, Congressman Henry Waxman, Chairman, Committee on Oversight and Government Reform, wrote to Daniel Vasella, the Chairman and Chief Executive Officer of Novartis on 13 February 2007:

“India’s robust generics market supplies affordable, essential drugs both to its citizens and to poor nations around the world. Its law contains safeguards designed to preserve a balance between protecting innovation and public health. If India is pressured to make its patent laws more stringent than its obligations under international trade law, this crucial supply could be threatened.”

Congressman Waxman therefore urged Novartis to reconsider their challenge to India’s patent law. We can do no better than echo it in the context of your testimony:

“Because of the profound need for affordable medicines in the developing world, I am writing to urge you to reconsider Novartis’s challenge to public health safeguards in India’s patent law.”

I. Unwarranted Denial of Intellectual Property Rights

India has granted over 160 patents to Pfizer Inc. for products and compositions under the amended Patent Act. Not only Pfizer, several multinational pharmaceutical companies have also been granted a large number of patents. Yet, you have alleged that India has denied intellectual property rights and provided three instances, including one relating to Pfizer. Our response below shows that your assessment is unwarranted in every one of the three instances cited:

a. Sutent

Your Testimony states that:

“In September of last year, India revoked Pfizer’s patent for a cancer medicine, Sutent.....The Indian patent had been in effect for five years prior to its revocation. Its counterparts have never been revoked in any of the 90 countries where it currently enjoys protection, including the United States, Europe, and Japan. The revocation will allow Indian generic companies to manufacture and sell generic copies of Sutent long before the patent is set to expire. This constitutes a fundamental breakdown of an incentive-based IP system.”

Your assertion that the revocation of Pfizer’s patent for Sutent ‘*will allow Indian generic companies to manufacture and sell generic copies long before the patent is set to expire*’ is factually incorrect. It is true that a post-grant opposition to the patent was allowed. It is also true that the patent was revoked on 24 September 2012 on the ground that the invention did not involve an inventive step. However, as you may be fully aware, Pfizer had challenged the revocation in the Delhi High Court and obtained an interim order preventing a generic version of Sutent from entering the market. An appeal against the order of the Delhi High Court was filed in the Supreme Court of India. The Supreme Court of India set aside the revocation of the patent on the ground of violation of natural justice and the matter was remanded back to the Patent Office for fresh determination.

The opposition to the patent was reheard. The patent was again revoked on 11 February 2013. Pfizer filed an appeal against the revocation before the Intellectual Property Appellate Board (IPAB). The IPAB stayed revocation of patent. It noted that the patentee had submitted that “they have a strong case for patentability of the invention” and that the IPAB could not “brush aside the apprehension of the appellant that if stay is not granted, third parties will rush in with their generic drugs and that it will be impossible to set the clock back thereafter”.

As is clear from the above, you have not only misrepresented the facts, but have also misled the House Subcommittee on Trade with your unfounded apprehensions that the ‘*revocation will allow Indian generic companies to manufacture and sell generic copies of Sutent long before the patent is set to expire.*’ It is particularly distressing that you have alleged a ‘*fundamental breakdown of an incentive-based IP system*’ when in fact you have obtained prompt and effective interim relief from the Delhi High Court, the Supreme Court and the IPAB, in a short time by any standard. You have not acknowledged any of this in your testimony.

b. Glivec

Your Testimony states that:

“Glivec™ is another important anticancer therapy for which intellectual property rights have been denied. The patent was denied under section 3(d) of the Indian Patents Act, which contains a discriminatory provision concerning the inventions of the biopharmaceutical industry. The provision requires certain types of inventions to show “enhanced efficacy”, which limits substantially the ability to obtain a patent. Not only is this term unclear, but it goes far beyond the specific requirements of patents under the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement including novelty, inventive step, industrial applicability, and sufficient disclosure for carrying out the invention. Moreover, by discriminating against a particular field of technology, section 3(d) may be inconsistent with provisions of TRIPS, which sets one standard for all patents and does not allow different patent requirements for different industries. Using this prohibition, India has refused a patent to Glivec™ despite patent protection for this product that exists in nearly every other country of the world.”

The first patent for imatinib and its pharmacologically acceptable salts, including imatinib maleate (the generic name for Glivec), has an international priority date of 3 April 1992. At that time, India did not issue patents for medicinal products. When India amended its statute in 2005 to enable issue of patents for medicinal products, it provided for a public health safeguard against ‘evergreening’. Section 3(d) of the Patents Act prohibited the grant of patents to new forms of known substances, unless there was an enhancement in its efficacy.

The second patent for Glivec™ was for a polymorph of imatinib mesylate – the β crystalline form. Novartis could not demonstrate enhanced efficacy for the new β crystalline form and was denied a patent. Novartis unsuccessfully appealed the rejection, first to the Intellectual Property Appellate Board and then to the Supreme Court.

The first patent for imatinib and its salts expires on 4 July 2015 and the second patent for the β crystalline form expires on 23 November 2019 (after considering patent term and paediatric extensions for both patents) in the U.S. The grant of the second patent for Glivec has extended the patent monopoly by over four years in the U.S. Such an extension of patent monopoly is not permissible under Indian law, unless the new β crystalline form demonstrates enhanced efficacy.

While we respect your right to hold an opinion that ‘*section 3(d) may be inconsistent with provisions of TRIPS agreement*’, you cannot be unaware that the opposite view has many proponents, including scholarly opinion in the United States of America¹. The legal view apart, there is widespread support for India’s patent law and its ‘exclusions’. We may point

¹ See for example, Kapczynski A, *Harmonization and its discontents: A case study of TRIPS implementation in India’s pharmaceutical sector*, California Law Review, Vol 97, No 6, December 2009, 1586-87 at p 1598, available online at <http://www.californialawreview.org/assets/pdfs/97-6/2KapczynskiFINAL.pdf> : “Each interpretive tool thus points to the same conclusion: India’s subject matter exclusions and inventive step standard appear to be consistent with the terms of the TRIPS Agreement.”

out one such opinion, by way of an example. On 8 April 2013, *The Boston Globe* commented on the Supreme Court judgement in the Glivec case:

“The ruling by India's supreme court to reject a patent for Gleevec, a powerful cancer drug, is a victory for patients seeking more affordable treatment. India has a woeful history of ignoring patents, but in this case, the court was rightfully skeptical of so-called "evergreening," the practice of tweaking existing drugs to prolong a firm's hold on a patent. There's good evidence this kind of widespread patenting is impeding, not promoting, the search for new, more innovative medications - and driving up costs for American consumers. It's time to reexamine the US patent system, too.....

The United States, on the other hand, has loosened its patent qualifications since the 1980s, and while the number of patents for genuinely new pharmaceutical products has dwindled, the total number approved has more than doubled. Nearly two-thirds of drug patents approved from 1989 to 2000 were for incrementally modified, or evergreened, medicines, according to the National Institutes of Health Care Management.....

Patents can often spur innovation, but granting second and third patents on the same drug may be standing in the way of future cures. For patients who need affordable treatment - inside and outside the US - the wait has been too long.”

c. Pre-grant opposition

Your Testimony states that:

India, however, allows interested parties to “oppose” the grant of the patent after publication, but before the date established for the grant of the patent. Given that the term of patent protection is measured from the date of first filing, these delays erode the effective life of the patent. If not properly policed, these pre-grant oppositions are opportunities for abuse. India also does not provide for adjustment of patent terms to compensate for delays in patent processing.

Your concerns about pre-grant opposition and the absence of patent term extension in India are not well-founded. Pre-grant opposition is provided to enable early refusal of patents that do not satisfy the conditions for patentability. Even if the procedure results in a delay in granting the patent, it does not ‘erode the effective life of the patent’, which remains 20 years from the date of first filing regardless of whether or not there is pre-grant opposition.

The right to sue for infringement of patent arises only on its grant, but the Patents Act in India provides for damages from the date of publication of the patent application in the event of infringement of a granted patent. Thus, there is no warrant for adjustment of patent terms to compensate for delays in patent processing.

In fairness, the House Subcommittee ought to have been informed of this provision in India’s patent law which negates the concerns of Pfizer.

II. Abuse of Compulsory Licensing Provisions

Your assertions relating compulsory licensing in India are misconceived. These are extracted below with our comments:

Compulsory licenses are intended for use in extraordinary situations of extreme urgency or other national emergency to meet the legitimate needs of the public. Often, however, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer technology developed by others without having to pay the substantial costs associated with developing and testing the product. These copiers want to obtain a free ride or use the technology at a much-reduced cost.

It bears mention that the law in India envisages the grant of compulsory license under two provisions:

- Section 84, which has nothing to do with extreme urgency or national emergency, but is intended to ‘meet the legitimate needs of the public as stated by you. These legitimate needs as codified in the Patents Act are when the ‘reasonable requirements of the public’ for the patented invention are not satisfied, or it is not ‘made available to the public at a reasonably affordable price’, or it is ‘not worked in the territory of India’.
- Section 92, which is a special provision for compulsory licensing on notification of a patent (or patents) by Government in circumstances of national emergency, extreme urgency, or public non-commercial use.

Your assertion that compulsory licenses are ‘often’ used by competitors to ‘obtain a free ride’ is wholly misleading. Under law, a compulsory license is issued when it is required for the public good. They are never issued because they benefit an applicant for a compulsory license. The question of ‘competitors’ using the compulsory license to get a ‘free ride’ is wholly irrelevant.

India issued a compulsory license for a cancer medicine patented by an innovative pharmaceutical company last March and the Indian government has sought to justify the compulsory license, in part, on the basis that the product was imported rather than manufactured locally. That industrial policy basis for a compulsory license must be repudiated as it plainly contravenes established international obligations.

The only compulsory license that is issued so far is for Bayer’s NexavarTM. The grant of compulsory license was challenged by Bayer before the IPAB which confirmed the grant on two grounds: the reasonable requirements of the public for NexavarTM were not met and product was not made available at a reasonably affordable price. On the issue of ‘working of the patent’, the IPAB held that it disagreed with the Controller of Patents that that ‘working’ meant manufacture in India and held that the term must be interpreted in the facts and circumstances of each case. In the instant case, the IPAB held that in view of the small quantities imported by Bayer, it ‘had not “worked” the invention on a commercial scale even if “import” alone would satisfy the working condition.’ The IPAB delivered its judgement on 4 March 2013, prior to your written testimony of 13 March 2013.

Moreover, recent media reports indicate that the Government of India has started the process of issuing compulsory licenses for the manufacture of three additional cancer drugs. Unlike the compulsory license issued under Section 84 of the Patent Act against Nexavar™, these compulsory licenses would fall under Section 92 of the Act—the public emergency provision that can be issued directly from the Indian Administration without a notice and comment period to the industry.

We have earlier drawn your attention to Section 92 of the Patens Act, where one of the circumstances for issue of compulsory license could be ‘public non-commercial use’, apart from the ‘public emergency’ provision. The Government of India is only examining the issue. It has not taken any decision yet. Your assessment that the ‘*Government of India has started the process of issuing compulsory licenses*’ overstates the case at this point in time. Patentees are free to represent their case against compulsory licensing under Section 92 to the Government.

We also invite your attention to powers for grant of compulsory license in France, Germany, Ireland, Japan, South Korea, Sweden, UK, etc. Not only the provision exists, several countries have made use of this provision for pharmaceutical products. They include Brazil, Canada, Ecuador, Egypt, Indonesia, Italy, Malaysia, Thailand, the United States of America, etc. You would be aware of President Obama’s Executive Order 13588 to ease drug shortages.

III. *Ignoring Obligations to Prevent Unfair Commercial Use of Data to Grant Generic Marketing Approval*

Your Testimony states that:

Regulatory data protection is required by the TRIPS Agreement and India was required to prevent unfair commercial use of pharmaceutical regulatory data through the grant of generic marketing approval based on the innovator’s data by 1 January 2000. They still have not done so.

We acknowledge that one view of the matter is the one you have expressed; but there is also another legal and public health view of the obligation under TRIPS agreement that is the polar opposite of your view. In fairness, the House Subcommittee should have been apprised of both views.

IV. *Ineffective Patent Enforcement*

Your Testimony states that:

Indian law permits state regulatory authorities to grant marketing approval for generic versions of medicines four years after the product was first marketed. They are not required to verify or consider the remaining term of relevant patents. Because infringers can obtain marketing approval from the government, patent holders are forced to seek redress in India’s court system after approval of the generic – a form of recourse that is not effective in practice.

In India, the law governing drugs, including their approval for marketing, is the Drugs and Cosmetics Act, while the law governing patents is the Patents Act. They are two independent statutes, operating in different spheres and there is neither overlap nor any link between the two. The Drug Regulatory Authority is accountable only for safety, efficacy and quality of drugs, not patent enforcement.

In fairness, the House Subcommittee ought to have been informed that there is no link between regulatory approval and patent status not only in India, but also in many countries around the world. There are several good reasons for the wide prevalence of this practice. For example, if a patent is eventually found invalid, denying marketing authorisation during the term of the patent would cause grave injury to consumers. There is no way to provide them effective relief.

The United States has a very complex Hatch-Waxman arrangement which provides the incentive of 180 day marketing exclusivity to the first challenger of a patent, with the intent of accelerating entry of generic products. This very complex arrangement, including reference to the FDA Orange Book and patent listings, presents major difficulties for any developing country, which has only to look to the US to see how much complex litigation is spawned. This is not something that can simply be transposed to other environments.

In the absence of specifics, we disagree with your generalisation that seeking '*redress in India's court system*' is '*a form of recourse that is not effective in practice.*' Many would find such a sweeping assessment that reflects adversely on the Indian judicial system quite offensive.

Conclusion

We trust that you will consider correcting the factual inaccuracies in your testimony to the House Subcommittee. We also urge you to consider providing the House Subcommittee with a fair assessment of the state of intellectual property protection in India, including the significant number of views that differ from yours. Finally, we urge you to reconsider your 'four recommendations' to the House Subcommittee. As the world leader in pharmaceutical sector, you are uniquely positioned to influence global opinion on issues of incentivizing innovation and promoting access to medicines.

In this context, we would like to invite your attention to Dr. Eric J. Topol's² statement in March 2013:

“As you may know, 11 of the 12 drugs approved by the US Food and Drug Administration (FDA) for cancer over the past year cost over \$100,000 each.”³

We would also like to invite your attention to *The New York Times* on 25 April 2013 which reported on concerns and protest by cancer researchers and doctors against the price of cancer treatments, including Glivec. The article states:

“Prices for cancer drugs have been part of the debate over health care costs for several years – and recently led to a public protest from doctors at a major cancer center in New York. But

² Director of the Scripps Translational Science Institute, California and Editor-in-chief of heart.org

³http://www.medscape.com/viewarticle/780324?nlid=29084_1523&src=wnl_edit_medp_wir&uac=70922PG&spon=17

the decision by so many specialists, from more than 15 countries on five continents, to join the effort is a sign that doctors, who are on the front lines of caring for patients, are now taking a more active role in resisting high prices. In this case, some of the specialists even include researchers with close ties to the pharmaceutical industry.”

This only shows that there are ‘serious medical people’ in the United States who share the concerns India is addressing about the cost of treatment.

Innovative drugs and treatments at these prices are irrelevant to most people in the developing world. The situation is essentially the same for chronic diseases, given the pricing of new drugs in recent years. As few people can afford to buy them, the market for new drugs outside of the developed nations is a small fraction of the total market. Again, we can do no better than echo Congressman Waxman’s communication to Novartis:

“In pursuing the tiny slice of the market with the money to afford its drugs, Novartis may be threatening future access to medicines to the vast majority of Indians who live in poverty – and their counterparts around the world.

Novartis and its colleagues in the pharmaceutical industry should respect countries’ rights to take measures that balance the protection of innovation and promotion of public health. I urge you to reconsider your position in this case.”

As Congressman Waxman also noted, “even if India’s patent laws fall short of the wishes of the pharmaceutical industry; patent holders continue to enjoy stringent protections in the United States and other wealthy nations, where they make the bulk of their profits.”

We venture to suggest that India’s TRIPS-compliant intellectual property regime does not result in a noticeable ‘loss-of-opportunity’ cost to Pfizer, however unsatisfactory you may find it. On the other hand, the cost of coercing poor and less developed nations to implement an intellectual property regime that mirrors that of the USA would need to be accounted for in terms of human lives and suffering.