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VIA ELECTRONIC MAIL
CONFIRMATION BY COURIER

May 23, 2013

D G Shah, Esq
Indian Pharmaceutical Alliance
c/o Vision Consulting Group
201 Darvesh Chambers
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Khar, Mumbai 400 052
INDIA

Re: Response to Letter Dated May 13, 2013

Dear Mr. Shah:

I have received your May 13 letter and attachments, and would like to take this opportunity to respond to what you have set forth. I realize that the IPA represents many of the local Indian generic companies that have benefited from the recent anti-patent decisions undertaken by the Indian government. These recent decisions underscore a pattern of deteriorating IP protection in India that undermines the innovative pharmaceutical sector's ability to compete fairly, and creates a business environment that is unpredictable and threatens patients' access to innovative medicines. It is understandable that your companies may object to our shedding light on the situation and the surrounding inconvenient facts, but my view is that it is important to understand the evidence. I reject the notion that there are factual errors in my testimony and will take each of your points in turn.

On the notion that the business environment in India has deteriorated – and as a counterpoint to your assertion that India is receiving as much foreign direct investment as ever – I stand by the most recent reports that indicate that FDI into India declined in 2012 over 2011 by 16% (http://www.livemint.com/Money/RjQHyvDbIgVA2SwIp2wUGO/Foreign-direct-investment-to-India-slows.html). This trend is indicative of a system less welcoming for capital flow. The emphasis of my testimony to the U.S. House Ways and Means Trade Subcommittee is that the further escalation of anti-patent activities in the last 12 months by the Indian government will

create a further disincentive to investment in India – a logical position to take given the consequences of a national policy of disenfranchisement of intellectual property rights. What happened prior to recent events, in 2010 and earlier, is irrelevant as the events I testified about have all taken place within the last 12-18 months.

Regarding India's rating on the Global IP Center's IP protection scale, the fact that India is a lower middle income country is irrelevant to the determination of its rating with respect to rule of law issues. India as one of the world's most populous and fast-growing countries on earth most definitely should be measured in such a survey – the failure to do so would leave a gaping hole in the landscape, particularly when considering pharmaceuticals, where India is one of the largest manufacturing countries for medicines on the planet. As with the issue of declining FDI in India, information tending to show a less attractive environment from a financial and legal policy perspective will always be relevant in a world of constrained resources, particularly on the decision-making on the flow of capital and where best to bestow trade benefits.

Your enclosure listing Pfizer patent applications and granted patents is noted. A fundamental mistake that is often made by non-practitioners of patent law is to misunderstand the value and role of a patent. A patent is a legal right that is worth less than the paper it is printed on if there is no succor and redress for the rights holder from the sovereign where it is granted. If there is no meaningful enforcement of patents and the patents are revoked or licensed to others for the mere asking, there are simply no discernible rights left to the patentholder in India. The parlous environment for patent rights in India has set the ground to render each and every one of those cited Pfizer patents without effect or meaning in the Indian legal environment. Your citation to our portfolio illustrates the magnitude of the problem not just for Pfizer but for our industry as a whole.

You state that I should have informed the Trade Subcommittee that India had amended its law in 2005 to meet its obligation under WTO-TRIPs (Agreement on Trade-Related Aspects of Intellectual Property). Unfortunately, the 2005 amendments failed to reach TRIPs standards. The Indian Parliament ostensibly amended its law to withdraw the prohibition on the patenting of medicines under its 1970 law, but at the same time adopted exclusions from patentability under Section 3(d) that effectively nullified the contributions of the whole of the discipline of pharmaceutical sciences (as distinct from medicinal chemistry and biological sciences). A pharmaceutically active entity (chemical or biologic) is next to worthless unless there is a means by which that active ingredient can be accessed by the human body and reach the site where treatment is made effective. The Glivec product is one example of a product that had enhanced bioavailability over the prior art. Anyone in the pharmaceutical sciences will tell you that developing forms of compounds that have increased bioavailability is the holy grail for pharmacists. A patient can ingest all the active ingredient he/she can, but if it is not in the correct and bioavailable form you will not be treating the patient's disease. A drug that is more bioavailable is by any definition a more therapeutically effective drug.

To dismiss as "evergreening" the absolutely critical area of pharmaceutical sciences (and you inexplicably quote law journals and newspaper editorials in your defense and not one scientist) is blithely to dismiss the valuable work that millions of pharmacists and pharmaceutical scientists do every day to meet the needs of patients. Their innovation spells the difference between life and death for patients around the world. To discriminate against some of the most

important scientific subject matter within the pharmaceutical sector is a violation of Article 27 of TRIPs. The fact that India has a thriving business in manufacturing medicines for export is irrelevant to whether its laws should discriminate against legitimately patentable subject matter. In fact your argument and accompanying quote makes the point: India's chief reason and rationale for not complying with the full extent of its TRIPs obligations is related to preserving its domestic industry's export markets.

The visionary purpose of the TRIPs Agreement was to expand free trade, improve capacity building and technology transfer among WTO member states so that we have a world with lower costs of goods, lower economic costs of entry and greater competition. India's effort to curtail market entry by non-Indian companies and to protect the *status quo* is contrary to that vision. The statement regarding India's flouting of the trade rules refers specifically to the recent moves to restrict non-Indian companies from doing business in India by stripping pharmaceutical competitors of the very advantages that make them competitive. Innovation in the pharmaceutical sector is critical and the industry's competitive advantage is its inventiveness and innovative capacity that should be encouraged, supported and protected whether it takes place in London, Cairo or Hyderabad. Intellectual property protection is key as the value the sector brings is encapsulated in the ideas and science it develops at great expense. When I say that India is closing its borders to US innovators in pharmaceuticals, there is no more effective way of doing that than the corrosive decisions that the Indian government has undertaken against pharmaceutical patents.

You urge that India's protectionist regime should somehow be immune from its obligation under TRIPs because of the opinions of some political personalities and others. Unfortunately, the rule of law and treaty obligations cannot be abrogated in this case simply on the basis that others feel that certain Indian companies should continue their oligopoly on generic medicines abroad. This is the antithesis of free trade – the notion that India is an exception to world norms on trade because it has an industry that some feel should be protected against the rules that all the others must abide by.

You note some of the procedural history for the Indian Sutent patent case in your remarks. You correctly state that the patent was revoked twice and that such revocation would allow Indian generic companies to manufacture and sell generic copies of Sutent before the patent is set to expire. During a period of 3 weeks when there was no injunction in place, Natco flooded the Indian market with copies of its sunitinib product from March 23 to April 16. Relief was temporarily granted by the Delhi High Court on April 16 but this was too late. My description of this case was neither inaccurate nor misleading.

You maintain that I should have informed the House Subcommittee about the Indian patent regime's provisions that allow for collection of damages notwithstanding the legion of pre- and post-grant oppositions, any number of revocation proceedings and three or more grounds of compulsory licenses (depending on the subtitles in the law). I have reasonable concerns about a regime that provides ample thickets of procedures for taking away patents and that has to date has not upheld a single patent in a compulsory license, enforcement or revocation proceeding will be granting damages awards.

You urge that merely because there are provisions in the Indian patent law (Sections 84 and 92) for compulsory licensing, that *ispo facto* these provisions are fair and not abusive in the

context of international norms. You do not dispute my assertion that the local working requirement is an abusive and improper provision under TRIPs under the Indian Patent Office view, that is, if this is meant to require local manufacture (an interpretation which the IPAB did not completely disavow). You cite the grounds of reasonably meeting requirements of the public and reasonably affordable price as adequate to justify the Nexavar compulsory license – but the standards here are so vague and malleable such that any non-Indian company will find itself on the other side of the argument every time. Even in the cases where non-Indian companies have drug access programs and nearly all patients receive complete or partial subsidies, there is always citation to some price point sourced from a non-Indian market to prove that the local price is lower and/or market needs are not being met. The provisions can be and have been so easily manipulated and abused such as to deprive a patentee of rights that for all intents force that company from competing in the Indian market.

It is disingenuous to cite France, Germany, Ireland, Japan, South Korea, Sweden and the UK as examples to justify a policy of compulsory licensing. There is no dispute that compulsory licenses provisions exist in a number of countries for the specific purpose of treating unusual situations of extreme urgency and emergencies. Routine use of compulsory licenses for procurement and industrial policy purposes is abusive of patent rights and make bad policy. The United States has not used compulsory licenses to procure drugs and any assertion of that it has done so is not to be and will not be taken seriously by the Trade Subcommittee. President Obama's Executive Order 13588 to ease drug shortages was not a compulsory license – it was designed to entice a generic company to manufacture a drug that had been off-patent for many years that other generic companies for economic and other reasons did not produce. To spare you the effort of making the argument that it has happened 120 or so times, the rest of the drug shortage list maintained by the FDA all consist of off-patent medicines.

Your citation to my testimony on India's persistent violation of Article 39.3 of TRIPs makes no explicit counterargument except to say that there are differing views and they are not reflected in my testimony. The literal terms of Article 39.3 are clear and India is in violation for not protecting proprietary data submitted for pharmaceutical drug approval against unfair commercial use. I stand by that assertion.

I also stand by my statements regarding ineffective patent enforcement in India. We remain concerned over the circuitous and lengthy legal route that multinational companies are being compelled to take to address their patent challenges. Even your present Minister of Law and Justice has acknowledged the tremendous years-long backlog of cases and delayed justice in the Indian judicial system. It is a statement of fact – no offense to the judiciary intended – that justice delayed is justice denied wherever it occurs.

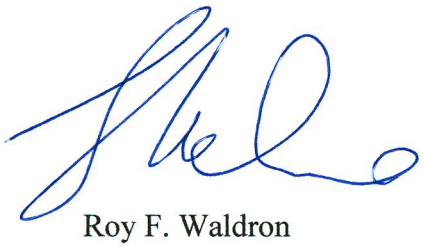
In conclusion, what you have pointed out as factual inaccuracies in my testimony are nothing of the sort. I provided what I viewed as a fair assessment of the legal and factual situation in India, a market that has in recent months treated our industry most unfairly. I stand by my recommendations to the Trade Subcommittee which by and large is able to distinguish the difference between compliance with international obligations/norms and industrial policy motivations. We are not the only industry that has become victim to a growing environment of Indian protectionism. Your final appeal to suggest that "coercing" India to adopt standards under TRIPs is somewhat unethical is misleading – India is a voluntary signatory to the TRIPs agreement, and it receives abundant benefits under the US Generalized System of Preferences.

My testimony before the House Subcommittee was to point out the trade obligations that India is currently eschewing and how much and how badly this behavior is affecting our industry.

You point out at the beginning of your letter that several members of the IPA are "also engaged in research and development of new drugs" and "therefore have a stake in promoting a balanced system of incentivizing and protecting intellectual property rights in India." It is therefore in our shared interest to ensure that the Indian system attains the necessary balance — so that intellectual property protections can continue to facilitate medical progress by providing critically needed incentives for both foreign and domestic companies to develop medicines that address unmet medical needs. I believe that enabling a fair operating environment is essential for the industry as a whole—whether domestic or foreign — to continue developing and making innovative medicines available to address life's most challenging diseases.

Pfizer is deeply committed to ensuring broad access to our medicines. We have always put the needs of patients first when we embark in research and development of new or better life-saving medicines. I have no doubt that we will continue to develop strategies where both access and innovation needs are suitably addressed. That said, one should remember that access to medicines is not determined by the pharmaceutical industry alone. A more holistic and sustainable approach is needed to ensure that patients have access to our medicines and Pfizer is committed to contributing towards a stronger healthcare infrastructure as a key part of this long-term solution. We have and always will welcome a deeper dialogue with key stakeholders to better understand how we and the pharmaceutical industry can partner with government to enhance medicine access and become a key healthcare solutions partner.

Sincerely yours,



Roy F. Waldron