Pre-Hearing Statement of the

INDIAN PHARMACEUTICAL ALLIANCE

before the

U.S. INTERNATIONAL TRADE COMMISSION
INVESTIGATION No. 332-543

TRADE, INVESTMENT, AND INDUSTRIAL POLICIES IN INDIA:
EFFECTS ON THE U.S. ECONOMY

Washington D.C.
13 February 2014

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Introduction:

1. Good morning. My name is Dilip Shah. I am the Secretary General of the Indian Pharmaceutical Alliance (IPA) and am testifying on its behalf. The IPA is grateful for having been given this opportunity.

2. The IPA's membership consists of nineteen pharmaceutical companies collectively account for close to 80% of the expenditure on pharmaceutical research and development in the private sector in India. We therefore have a vital interest in the protection of our innovations, not only in developing cost-effective and useful improvements in existing medicines, but also in discoveries of new medicines.

3. The United States of America is the knowledge leader of the world and its pharmaceutical industry is no less. It is therefore a matter of considerable disquiet that the pharmaceutical industry in the USA is concerned by the impact of India's patent regime on its investment in innovation, employment and the economy.

4. I will briefly traverse these concerns, though I would request your indulgence for a little more than the allotted time. I will briefly touch upon the facts and perspectives that may assist this investigation in this testimony and will provide a more comprehensive assessment in our Written Statement.

Patentability and the Exception in Section 3(d) of the Patents Act:

5. Since 2005 when India fully implemented the TRIPS Agreement, over 1500 patents have been granted to the top nine global pharmaceutical companies alone, for products and compositions, apart from patents for manufacturing processes. When the innovator pharmaceutical industry talks of 'denial' of patents, it is not talking of patents for medicinal products in general, but really of second or third patents for the same product. We also need to examine whether such denial is 'unjustified'.

6. Typically, these follow-on patents are for new forms of the product and invariably prolong patent monopoly for it. These are the patents that are prohibited by Section 3(d) of the India's Patents Act. However, such inventions when they enhance efficacy, are granted patents. There is a long list of granted patents.

7. The effect of this provision is evident from the familiar example of Gleevec, a Novartis product for cancer. The generic name of the medicine is imatinib mesylate. The first patent application for imatinib and all its salts was made internationally in 1992, prior to the TRIPS Agreement.

8. A second patent application for a new crystalline form of imatinib was made internationally in 1997. This was filed in India in 1998. But it failed to demonstrate any increased efficacy of the new form over the previously known substance.

9. The implication for patent life of the product is evident from the US itself:

    - The 20-year term of the patent for imatinib and all its salts ended in 2013.

    - In the meanwhile, the USPTO granted a second patent for the new crystalline form. The 20-year term of the second patent ends in 2018, thereby extending the patent monopoly of Gleevec by five years. This does not include patent term and pediatric extensions.

10. The innovator pharmaceutical companies justify second and subsequent patents for the same product and the consequent extension of patent monopoly by the need to recover the huge investments in R&D. They also say that the unjustified denial of such patents in India will seriously erode the value of their investment in innovation.

11. Others contest this view. For example, 119 experts in chronic myeloid leukemia, a condition for which Gleevec is indicated, from over fifteen countries, including the US and Western Europe published an article in *Blood*, a US medical journal, in April 2013.

12. The authors say that:

    - The initial pricing of Gleevec in 2001 was US$ 30,000 per patient per year. It was considered high at that time. Gleevec was expected to notch up sales of about US$ 900 million a year, which would have recouped the cost of development within two years.

    - Gleevec became a blockbuster and usage exceeded expectations. The price was also increased over the years, to US$ 92,000 per patient per year. The revenue from Gleevec were about US$ 4.7 billion in 2012.

    - The authors say that this pricing 'resulted in numerous appeals by patients and advocates to lower the price of imatinib.'

13. The Gleevec example is not intended to suggest that the US alone should incentivize innovation with patent monopolies, or that such incentive in the US alone is enough. India should also provide patent protection for inventions and it does so for 20 years. The Gleevec example also illustrates the impact of extending patent monopolies beyond 20 years and the reasoning behind the enactment of Section 3(d) to pre-empt such extensions.

Compulsory Licensing:

14. Innovator pharmaceutical companies have expressed concern about the grant of compulsory licenses by India for reasons other than public health emergencies. This is not a provision that is unique to India. Many countries provide for grant of compulsory licenses in the 'public interest', a term that is universally acknowledged to have a wider ambit than public health emergencies. At least eight of the twelve Western European countries have provisions in their laws for grant of compulsory licenses in the public interest. So do many Asian and Latin American countries.

15. India has arguably a more restrictive provision. Compulsory licenses under Section 84 can be granted on any of three grounds: if the reasonable requirements of the public for the patented article are not met, or the patented article is not available at a reasonably affordable price or if the patent is not worked on a commercial scale in the territory of India.

16. The provision in Indian law is therefore neither unusual nor a cause of concern. But we should also examine its implementation. As far as we are aware, only two applications for compulsory licenses have been made since 2005. The first was for Bayer's Nexavar, which has resulted in the grant of a compulsory license. The second was for Bristol-Myers Squibb's Sprycel, which was rejected.

17. The application for a compulsory license for Nexavar was the first in India, though there has been a provision for its grant at least from 1950. It was granted by the Controller of Patents in March 2012 on all the three grounds that I have enumerated earlier, including that Bayer failed to work the patent in India as it imported the drug.

18. Bayer appealed against the grant to the Intellectual Property Appellate Board (IPAB). The IPAB confirmed the grant of the compulsory license, but disagreed with the interpretation of the Controller on the working of the patent. The IPAB upheld the grant of the compulsory license as Bayer – quote - "had not worked the invention on a commercial scale even if "import" alone would satisfy the working condition" – unquote.

19. I do not refer to Bayer's case to justify the grant of a compulsory license. But I do want to make the point that it is the result of a careful assessment of the facts and is subject to multiple rounds of judicial review. Compulsory licenses are not granted in India for the mere asking. And when they are granted, as the IPAB has categorically said, it is not to favor any applicant but to implement the law to meet the reasonable requirements of the public at a reasonably affordable price.

20. So the key question is: How does one determine 'reasonableness'? The law is still evolving. Bayer has appealed the decision before the High Court of Bombay and the appeal is pending consideration. In the meanwhile, the decision of the Controller of Patents and the IPAB indicates what in their view is **not** reasonable, namely, Bayer making Nexavar available at US$ 74,000 per patient per year for a few hundred patients.

Other Concerns:

21. The innovator pharmaceutical industry has some other concerns that need to be examined. I intend to provide a more comprehensive overview of the context and facts relating to these other concerns in the Written Statement, given the constraints of time.

22. Very briefly however, some of these concerns are procedural, as for example, the 'unnecessarily burdensome patent application requirements'. This provision is applicable to all applicants, Indian and foreign. All that it requires is a statement from the applicant giving particulars of applications made for the same or similar subject matter in jurisdictions outside India and updates on them till the grant or rejection of the patent in India. This will help Indian Patent Office to sensitize itself with the thinking of other jurisdictions.

23. Another such concern is with the provision for pre-grant oppositions to patent applications. Pre-grant oppositions help 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 affect the life of the patent. Nor does it cause substantive injury to a patentee, as 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.

24. Yet another concern is that it is possible in India for a generic to seek marketing approval when a patent is in force, unlike in the US where this can be done only after 30 months, should the innovator sue for infringement within the stipulated time. I may point out that most countries, including those in the European Union do not have such a provision. There are several good reasons for not following the US model. For example, if a patent is eventually found invalid, the delays occasioned by holding up marketing authorisation during the term of the patent would cause grave injury to consumers and there is no way to compensate them.

Impact on the US Investment in Innovation, Employment and Economy:

25. My objective in this testimony is not to downplay the concerns of the innovator pharmaceutical industry or to justify India's IP policy. It is to advocate a data-based approach that would reasonably set out the extent of impact of India's IP policies on the revenues of innovator pharmaceutical companies and at the same time demonstrate sensitivity to India's concerns. The findings of this investigation will further this objective.

26. I believe the respect in India for the knowledge leadership of the US is high and this constitutes a firm basis to believe in the potential of an evidence-based dialogue for mutual benefit, as opposed to other options.

Thank you for the opportunity to be heard, and for your attention.