



Comments on National IPR Policy

Submitted by

INDIAN PHARMACEUTICAL ALLIANCE

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1. My name is Dilip G Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am submitting these comments on the draft National IPR Policy (Draft Policy) on behalf of the IPA.
2. The IPA's membership consists of twenty pharmaceutical companies which collectively account for close to 85% 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 for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.
3. While the IPA represents a segment of the pharmaceutical industry in India, it is deeply conscious of its larger responsibilities and has always endeavoured to provide inputs relevant to policy making in the national interest, including in the area of Intellectual Property Rights.
4. First and foremost, we wish to place on record our appreciation of the effort put in by the IPR Think Tank. We believe that the Draft Policy addresses several important issues and deserves the most serious consideration.
5. We commend the IPR Think Tank for its thoughtful articulation of the overarching intention of the Draft Policy, the reiteration that India is fully compliant with its international obligations and the framework for future negotiation in international forums:
 - "The Policy intends to harness the full benefits of creation and innovation in the larger interest of society and citizens."
 - "India is fully conscious of its international obligations and has always abided by them. At the same time, it has protected the national interest and balanced the rights of IP owners with their obligations to society."
 - "In future negotiations in international forums and with other countries, India shall continue to give precedence to its national development priorities whilst adhering to its international commitments and avoiding TRIPS plus provisions. The policy space and flexibilities available under the international instruments will continue to be used judiciously to keep IP laws updated."

We urge that that the above be incorporated into the National IPR Policy.

6. Our comments below are from a pharmaceutical industry perspective and are mainly restricted to patent-related issues. For the sake of brevity, we are commenting only on the issues of concern.
7. Objective 2: Creation of IP. The Draft Policy recommends the grant of 'petty patents' or 'utility models' for inventions that do not satisfy the criteria for patentability but are 'novel, utilitarian and inventive in their own spheres', primarily to enable protection of inventions among "the MSMEs and in the unorganized/informal sectors". New legislation is proposed for this purpose. The Draft Policy has not spelt out the subject matter that will be covered in the new legislation for utility models. We submit that the DIPP had published a Discussion Paper in May 2011 on Utility Models and had invited public comment. The IPA had made a

submission at that time, which is annexed (Annex-1). We reiterate the submissions made therein. Briefly:

- The justification for the grant of utility models cannot be extended to pharmaceuticals.
- The enactment of a utility model would undo Section 3(d). It will have the potential to delay affordable generics and adversely affect public health by granting patents without scrutiny or by doing away the requirement of inventiveness.
- Utility protection is not available for pharmaceuticals in many countries of the world. The introduction of utility protection in India has the potential to deny Indian exporters such markets as manufacture in India would not be possible in the face of a utility patent though similar protection may not be available in foreign markets.
- Scholars have sounded several cautions in introducing utility models in view of the potential for abuse and have specifically urged consideration of exclusion of some types of invention as dictated by public policy such as chemicals, pharmaceuticals, biological material or substances and processes to manufacture them.
- China, Japan, Korea, Mexico, Taiwan and many other countries appear to limit the subject matter in their utility models and pharmaceuticals are not covered.

Should a utility model be decided upon, other than for chemicals, pharmaceuticals, biological material or substances and processes to manufacture them, a separate legislation should be enacted for this purpose as recommended in the Draft Policy.

8. Objective 3: Legal and Legislative Framework. We note that the Draft Policy:

- Categorically states that “[t]he existing laws were either enacted or revised after the TRIPS Agreement and are fully compliant with it. These laws along with various judicial pronouncements provide a stable and effective legal framework for protection and promotion of IP. India will continue to utilize the legislative space and flexibilities available in international treaties and the TRIPS Agreement while considering amending or enacting new laws.”

We urge the incorporation of the above into the National IPR Policy.

- Recommends “objective and analytical studies” and inputs “from all stakeholders” before making statutory changes.

We urge that the above be modified as under: (*modifications are in italics*)

- “For this purpose, objective and analytical studies will be garnered and inputs will be invited from all stakeholders to keep the laws updated in consonance with

national needs and priorities. *Such studies shall include the assessment of welfare costs if pharmaceutical products are likely to be impacted.*¹

- “3.1 Review existing IP laws, where necessary, to update and improve them or to remove anomalies and inconsistencies, if any”.

The deletion of this clause is recommended, as it is always open to Government to propose legislation and Parliament to enact laws. As such, this clause is superfluous. On the other hand, its retention may provide an opening to argue that the National IPR Policy itself has drawn attention to possible anomalies and inconsistencies and pressure may be mounted to introduce TRIPS-plus provisions under the guise of remedying them. Such attempts are not improbable, as has been demonstrated recently by renewed attempts to introduce ‘patent-linkage’ (ie linking drug regulatory approval to patent status) despite its earlier rejection in a judicial proceeding.²

- “3.3 Engage actively in the negotiation of international *multilateral* treaties and agreements in consultation with stakeholders; examine accession to some multi-lateral treaties which are in India’s interest; and, become signatory to those treaties which India has de facto implemented to enable it to participate in their decision making process; *however, it should be noted that TRIPS-plus provisions in bilateral and regional free trade agreements ought not to be acceded to as they hinder timely access to generic medicines and adversely impact public health;*”³

¹An example of assessment of welfare costs is Shubham Chaudhuri, Pinelopi K. Goldberg, and PanleJia; Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India, *American Economic Review*, 96(5): 1477-1514, December 2006.

²See *Bayer Corporation v Union of India* LPA 443/2009, Delhi High Court, 9 February 2010; the SLP filed by Bayer was dismissed by the Supreme Court in December 2010

³In 2006, the Commission on Intellectual Property Rights, Innovation and Public Health warned that “[b]ilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.” (World Health Organization: Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, April 2006, p 148, available at <http://www.who.int/intellectualproperty/documents/thereport/CIPRH23032006.pdf>).

In 2009 the Report to the Human Rights Council of the UN General Assembly by the Special Rapporteur has devoted a whole chapter to the effect of FTAs on and has categorically called on developing countries to not incorporate TRIPS-plus provisions in their national laws and on developed countries not to encourage developing countries to enter into FTAs with TRIPS-plus provisions. See p 21 onwards, Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development, 31 March 2009, available at http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf.

See also World Health Organization, World Intellectual Property Organization and World Trade Organization: Promoting Access to Medical Technologies and Innovation, Geneva, 2013, p 42 available at http://www.who.int/phi/promoting_access_medical_innovation/en/ “In its 2012 report on the attainment of the MDGs, the United Nations noted that TRIPS flexibilities facilitating local manufacturing and importation of essential medicines appeared to be more broadly incorporated in national laws, but that the use of these flexibilities may be hampered by bilateral and regional free trade agreements (FTAs). See also the section on FTAs, p 84 onwards: “Thus, reasons of principle and practicality lead to a ratcheting-up” effect on IP standards, in that they can lock in higher levels of protection, with potential effects on innovation and access to medical technologies.”

- Clause 3.6 recommends identification of areas for study and research to aid policy development in the future. It also provides an illustrative list of such areas, which appear to mainly relate to IP laws and their interplay with other laws. We apprehend that the focus on laws, though illustrative, may direct attention mainly to the legal framework for 'data exclusivity' which is settled. Hence, the illustrative list be deleted. Instead we suggest that the IPR Policy should prescribe the need of continuing studies that better serve policy development. Illustratively, the studies and research could focus on *outcomes* of the IPR Policy by developing suitable measures and determining how far the stated objectives of the IPR Policy have been met, what has worked and what has not. In addition, objective and analytical studies could also be undertaken to keep laws updated in consonance with national needs and priorities, with inputs from all stakeholders, as stated earlier.
9. Objective 4: IP Administration and Management. The Draft Policy has recognized the imperative of “continuous education and training and regular audit” of IP officers and their work. Augmentation of manpower for speedy liquidation of the backlog of work is one of the recommended steps (4.2) as well as “periodic audits of processes being adopted in IP administration for efficient grant and management of IP rights” (4.10.6). We recommend the inclusion of a specific clause for the audit of granted patents, which will serve as a powerful tool for improving the quality of examination, particularly as it will balance the tendency to grant patents after cursory examination if the emphasis in administration is on productivity. In this context, we draw attention to the discussion paper put out by DIPP in 2011 on the organisational structure of the Office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications. The response of the IPA to this paper is attached (Annex-2) which includes a section on the need and benefit of audit of granted patents.
10. Objective 6: Enforcement and Adjudication. The Draft Policy has addressed a number of important issues to increase the effectiveness of enforcement of IP rights and the adjudication of disputes. Among them are the recommendation of designating “a specialized patent bench in the High Courts of Bombay, Calcutta, Delhi and Madras for speedy disposal of patent cases” (6.3.1) and “[w]orking closely with judicial academies to conduct regular IP workshops/colloquia for judges”.

We wish to point out that:

- The establishment of specialized patent benches in the High Courts has the advantages of consistent and speedier decisions. Unlike in the US, where there is a specialized Court
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of Appeals for the Federal Circuit, which is the only appellate-level court with the jurisdiction to hear patent case appeals, the proposed specialized patent bench, subject to the usual system of rostering, will not be isolated and will very much be part of the High Court and the evolution of the general law. This is important as the narrow focus of specialized courts sometimes have unintended consequences.⁴

- The Draft Policy does not specify who should be working closely with the judicial academies to conduct regular workshops for the judges. Familiarizing judges with patent law is indeed important, and in the absence of sufficient precedent as in the case of India, particularly for pharmaceutical patents, there is a tendency to look to other jurisdictions. But in organizing these workshops one should avoid focusing on the US as it has a long history of patent litigation, without adequately emphasizing the differences between the statutory scheme in the US and India. The principles evolved in other jurisdictions such as Canada are rarely mentioned. It may be appropriate to clearly consider the content of the training to achieve its objectives. It may be of some relevance to note that the Federal Judicial Center of the US sponsors monographs for the benefit of the judiciary and one was published in 1988 on Patent Law and Practice. It is now in its seventh edition and has been cited in several decisions, including the Supreme Court of the United States.⁵ Such a monograph, based on Indian law, will be equally useful for judges and litigating counsel and promote consistency.

11. Coordination, implementation, benchmarking, monitoring and evaluation of the IP policy.

The Draft policy envisages the establishment or designation of a high level “nodal agency in the Government responsible for bringing cohesion and coordination among various Ministries/Departments in the way they deal with IP matters under their charge.” Our understanding is that the DIPP is presently charged with this responsibility. The need is for providing an institutional framework for the DIPP to draw upon expert resources in developing IP policy in the national interest. These resources are scarce and are often available outside the Government system. Further, the range of IP issues relevant for policy making is diverse, and no single body will have the requisite expertise across the range of IP, or the time to deliberate on the many issues that are arising. It is for consideration whether a system of advisory committees for each IP right, consisting of Government officers from the relevant ministries, external academic and industry experts, the legal profession and so on could be constituted to serve the purpose envisaged in the Draft Policy. Serving on such a committee for each IP right would also not be so onerous as to make the committee dysfunctional.

⁴See for example, Adam B. Jaffe and Josh Lerner: Innovation and its Discontents, Princeton University Press, 2004, pp 9-10 ““In 1982, the U.S. Congress decided to address this problem, which was perceived to be undermining the effectiveness of patent protection and thereby threatening U.S. technological and economic strength. It established a centralized appellate court for patent cases, the Court of Appeals for the Federal Circuit (CAFC). The change was presented in the congressional hearings as a benign one, bringing consistency to the chaotic world of patent litigation, and predictability to the enforcement of valid patent rights. But it was clear from the beginning that advocates of stronger patent protection hoped that the new court would come down squarely on the side of patent holders.

And this is precisely what happened. Over the next decade, in case after case, the court significantly broadened and strengthened the rights of patent holders”.

⁵ Herbert F. Schwartz and Robert J. Goldman, Patent Law and Practice, Seventh Edition, Bloomberg BNA, 2011