



The Honorable Prabha Sridevan
Chair, National IPR Think Tank
Department of Industrial Policy & Promotion
Ministry of Commerce & Industry
Udyog Bhavan
New Delhi 110-001
India

Dear Justice Sridevan,

At the outset we thank you for giving us the opportunity to provide our comments in respect of India's proposed National IPR Policy released on December 24, 2014, heretofore referred to as the "Draft Policy" or the "Draft".

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centres, and related organizations worldwide. BIO's members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. In India, BIO's members have partnered with Indian companies, built research facilities and are collaborating with its research institutions. India itself, boasts over 350 biotechnology companies employing over 20,000 scientists and contributing over US\$5 billion to the Indian economy. As an example of our commitment to India, last year, BIO along with the Association of Biotechnology Led Enterprises (ABLE) released a white paper entitled "Accelerating Growth: Forging India's Bioeconomy" where we assessed the emerging Indian biotechnology industry from various angles including taxation, infrastructure regulation, intellectual property and technology transfer. The white paper can be accessed via <https://www.bio.org/articles/accelerating-growth-forging-indias-bioeconomy>

General Comments

BIO commends the Government of India for recognizing the critical role that intellectual property plays in innovation and for initiating a review of its policies regarding intellectual property. The biotechnology industry has unique concerns in that it is extremely risky and capital intensive. The industry relies heavily on intellectual property (IP) protection to translate a promising research idea to an utilizable product or technology. The development of a single biotechnology product (specifically a biopharmaceutical) often takes more than a decade, and can require as much as US\$2 billion of capital investment, including the cost of failures.¹ Indeed, while pharmaceutical inventions are entitled to the same patent term as all other inventions – 20 years from the time they are filed – they have the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between 8 to 10 years of the patent life.

Accordingly, we commend the Think Tank for the current draft Policy and we hope to provide such comments as to improve the policy and provide insight into the unique concerns of the biotech sector.

On its face, the Draft Policy primarily defends the *status quo* in regards to intellectual property rights (IPR) in India and the past positions of the Indian Government. However, given the significant economic initiatives of Prime Minister Modi, we would

¹ http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study, November 18, 2014.



hope that India would take this opportunity to candidly review its existing rules and policies in IP.

We think the current Draft could be significantly improved if it would address the role of IPR in innovation, why IPR is necessary to India's economic development, and the current state of innovation and creativity in India. The Draft assumes that IP needs to be protected because of global norms, e.g. World Trade Organization membership, but doesn't demonstrate an intrinsic understanding of why the IP system was created or how the general public benefits from a strong IP system. Indeed, the current draft does not discuss why a policy is even needed. BIO believes that such a discussion can usefully inform the policies, rules and regulations governing intellectual property rights..

Below, please find BIO's more specific comments on the Draft Policy.

Specific Comments

1. Page 2: *Piracy and counterfeiting discourage creativity and innovation apart from having a deleterious effect on the economy and consumers, and the same shall be sternly dealt with.*

BIO COMMENTS: The issue of piracy of IP-protected products has been effectively dealt with in certain areas like film and music but still needs to be strengthened across other areas. In the life sciences sector, counterfeits can prove to be fatal to human lives. In such a sector, very stringent laws as well as meaningful and consistent enforcement of such laws are required to be in place.

2. Page 3: *The IP regime in India has adequate safeguards in the form of judicial review and appellate provisions. The Indian judiciary is a strong and independent pillar of the government and has made immense contribution in enforcing IP rights. Judgments of Indian courts relating to IP disputes have clearly expressed the intent and purpose of our laws.*

BIO COMMENTS: Whereas, judicial remedies do exist, the adjudication process is long and there should be provision for exemplary penalties in order to impart an effective deterrence for repeated acts of infringements.

3. Para 1.2.4: *Promoting the idea of high quality and cost-effective innovation as a particularly Indian competence leading to competitive advantage.*

BIO COMMENTS: This is indeed a valuable initiative. However, the incentives to create such an environment do not currently exist. The IPR policy should outline the incentives needed to create an environment where Indian scientists and engineers are encouraged to develop cost-effective innovations. For example, Indian laws and regulations, including but not limited to patent laws, should provide incentives for incremental innovations that Indian Industry is not only capable of introducing but also can use to achieve the goals of greater cost-effectiveness.

4. Para 1.2.5: *Involving eminent personalities as 'ambassadors' to spread awareness of India's IP.*

BIO COMMENTS: The awareness should not be limited to India's IP but more importantly, should also extend to awareness on importance of innovation and creativity for India's progress as well as the importance of respect for IP in India



5. **Para 1.2.9:** *Studying best practices in other countries to design and launch public outreach programs.*

BIO COMMENTS: Apart from the best IP Practices in other countries, it is equally important to include global IP success stories in public outreach programmes in order to inculcate the value of innovation.

6. **Para 1.3.3:** *Collaborating with MNCs and large corporate entities to jointly develop IPR programs for their employees and encourage them to adapt the same and propagate them to the public.*

BIO COMMENTS: The collaboration with corporate entities must also include exchange of thoughts on success stories as well as challenges faced by such entities with regard to IPR in order to maintain a mutually beneficial information channel between the Government and the corporate entities.

7. **Para 1.4.4:** *Instituting prizes and awards to encourage IP creation activity in specific sectors.*

BIO COMMENTS: Whereas prizes & awards may help, the actual encouragement for IP creation come through the example of rights holders in India benefiting economically from adequate protection under India's IP laws.

8. **Para 2.3:** *Focus on improving IP output of national research laboratories, universities, technology institutions and other researchers by encouraging and facilitating the protection of intellectual property created by them.*

BIO COMMENTS: The positive agenda in this paragraph should be extended to its logical conclusion by commercializing the IP created by such institutions. Here, encouragement of public-private collaborations involving industry would be immensely beneficial.

9. **Para 2.4:** *Include IP creation as a key performance metric for publicly-funded R&D entities as well as technology institutions, and gradually extend such evaluation from Tier-1 to Tier-2 institutions*

BIO COMMENTS: Commercialization of IP should also be included as a performance metric apart from creation and protection of IP. Additionally, these institutions should be adequately staffed with qualified IP professionals who are appropriately incentivized to seek out and commercialize inventions developed by employees.

10. **Para 2.8:** *Stimulate large corporations, both Indian and foreign, that have R&D operations, to create, protect and utilize IP in India.*

BIO COMMENTS: R&D operations represent a risky and expensive proposition for firms, whether small or large. For all practical purposes, such stimulation can only come from adequate protection and stringent enforcement of IP. Again, positive examples of Indian corporations having benefitted from IP creation will serve to encourage others to make similar investments.

11. **Para 2.10:** *Facilitate creation and protection of 'small inventions' through a new law on utility models.*

BIO COMMENTS: Inventions howsoever 'small' as they may seem, as long as they fulfil the criteria of novel, non-obvious and industrial applicability must be eligible to be



patented under the mainstream Patent Law, i.e., Patents Act, 1970. In fact, in the present stage of research & development in India particularly in the Life Sciences sector, India is most capable of such innovations and the same must be incentivized through adequate protections under the Patent Law. Unfortunately, provisions like Section 3(d) debar protection to such inventions.

12. Para 2.12: *Provide statutory incentives, like tax benefits linked to IP creation, for the entire value chain from IP creation to commercialization.*

BIO COMMENTS: IP creation, particularly in biotechnology, is a global process and the entire value chain in most cases is of a global nature. Therefore, all incentives, tax or otherwise, cannot be restricted to indigenously-produced IP alone. Such a situation would make this positive initiative redundant.

13. Para 2.15: *Encourage innovations in the agriculture sector through application of IP for higher sustainable agricultural production.*

BIO COMMENTS: Like the agriculture sector, the biotechnology sector is equally important considering the significant potential of India's agri-biotech industry. The existing Patent Law in respect of bio-pharma and biotech sector is overly onerous and thus stifles innovation in the sector. This anomaly needs to be addressed in earnest.

14. Para 2.17: *Create a sui generis system for protection of traditional knowledge which will safeguard misappropriation of traditional knowledge as well as promote further research and development in products and services based on traditional knowledge.*

BIO COMMENTS: Whereas protection of traditional knowledge is undoubtedly important, it is equally important that genuine innovations, specifically in the pharma-biotech & agri-biotech must not be overly restricted on extrapolative interpretation of traditional knowledge norms. For example, while we acknowledge the policy against patenting of naturally occurring cells, we believe that the use of such cells in a pharmaceutical composition should not be restricted from patenting, in order to support and promote innovation in medical treatments. In our view, such subject matter should be assessed under the standards of novelty, inventive and industrial applicability on a case-by-case basis, as indicated under the Indian Patents Act.

Further, the Draft Policy must address some of the challenges posed by the Biological Diversity Act, 2002 (BDA) which inhibit innovation and deter investments in agricultural advancements. Lack of certainty, predictability and transparency in scope of the BDA decision-making process, as well as the discriminatory nature of the measure which preferences Indian companies, are inconsistent with India's commitments in the various related multilateral agreements including the Convention on Biological Diversity and the Nagoya Protocol and the International Treaty on Plant Genetic Resources, among others.

15. Para 3.1: *Review existing IP laws, where necessary, to update and improve them or to remove anomalies and inconsistencies, if any.*

BIO COMMENTS: The current draft just suggests that laws and regulations need to be updated occasionally to keep up with the times, but no policy directions or policy rationale given. No specifics for different areas of IP and what changes are needed in those specific areas have been suggested. While reviewing the existing Patent Law, it is important to remove inconsistencies between the Patent Law and the Regulatory Laws



specifically in respect of the life sciences sector. Overtly restrictive provisions that undermine legitimate issuance of patents especially in the pharma-biotech sector must be removed. Further, since innovation & IP are more often than not global in nature, Indian laws should be in consonance with the international benchmarks.

16. Para 3.6.1: *Identify important areas of study and research for future policy development, such as: Interplay between IP laws and between IP laws and other laws to remove ambiguities and inconsistencies, if any.*

BIO COMMENTS: In this aspect, it is important to remove inconsistencies between the Patent Law and the Regulatory Laws specifically in respect of the life sciences sector. An example of this inconsistency is the lack of patent linkage within the country's drug regulatory system.

17. Para 3.6.3: *Protection of undisclosed information not extending to data exclusivity.*

BIO COMMENTS: Without the element of non-reliance, the entire aspect of protection of undisclosed information in the pharmaceutical and agri-biotech sector is commercially meaningless. Physical protection of regulatory dossier is redundant in case the same is relied upon by the regulator thereby giving unfair commercial gains to third parties.

18. Para 3.6.5: *Exceptions and limitations.*

BIO COMMENTS: Exceptions to IP rights such as compulsory licensing severely restricts legitimate entitlements of an innovator and undermines its efforts & resources. Such exceptions must be used as a last resort as these exceptions severely discourage innovation and investment.

19. Para 4.10.9: *Provide continuous training to staff of the IP Office to update them of developments in procedures (especially search and examination), substantive laws and technologies, with the Rajiv Gandhi National Institute of Intellectual Property Management, Nagpur (RGNIIIPM).*

BIO COMMENTS: Training to staff of IP offices should be wider in scope rather than one particular institute. The IP Office staff must be exposed to the IP offices of other jurisdictions to inculcate international best practices. Furthermore, in support of comments 8 and 9, similar training should also be extended to technology transfer officers of Indian academic and government research institutions.

20. Para 4.10.10: *Remove disparities among different branches of the trademark registries and patent offices and adopt standardized procedures in examination/grant of applications including maintenance of rights.*

BIO COMMENTS: Proper processes should be put in place to minimize subjective enquiries into patentability provisions by different patent offices that lead to unpredictable application of patentability standards at different patent offices.

21. Para 5.4: *Promote public sector initiatives for IP commercialization*

BIO COMMENTS: Public Sector initiatives for commercialization could be facilitated by promoting public-private collaborative research and development as well as licensing arrangements for public sector IP with the industry to achieve optimum commercialization that could benefit both the private as well as the public sector.



22. Page 20: *IP rights are essentially private rights. The primary obligation of protecting IP rights is on the IP owners who can seek both civil and criminal remedies for enforcement of their rights. Along with effective enforcement of IP rights, it is equally important to balance the rights of the public to prevent misuse or excess of IP rights.*

BIO COMMENTS: On one hand, the current text expresses firm belief that IPR are private rights and that enforcement is the responsibility of the private owner without acknowledging the role of the state in enforcing those rights. On the other hand, the text speaks vaguely about “misuse or excess of IP rights” without elaboration. It must also be emphasized that the state machineries and their respective working should not allow infringement of such private rights. A case in this point is that in life sciences sector, lack of coordination between the patent office and the regulatory authorities make it easy for third parties to infringe patents.

23. Para 6.3.1: *Facilitate IP dispute resolution through different measures including: Recommending designation of a specialized patent bench in the High Courts of Bombay, Calcutta, Delhi and Madras for speedy disposal of patent cases and providing infrastructural support such as video conferencing.*

BIO COMMENTS: Since patents involve technical issues, it is highly recommended that a panel of technical experts are attached to these specialized Benches for assisting the Judges on technical issues involved in patent disputes.

India needs innovation to not only ensure that it remains competitive on the world stage but also to deliver to its population the benefits of innovation. Therefore, it is important to formulate and articulate a clear and comprehensive NIP where IP is seen as a tool for incentivizing research and innovation, not an end in itself.

BIO firmly believes that a strong innovation friendly eco-system can encourage, stimulate and sustain creation of IP in the field of Biotechnology. Such an environment, in turn, will encourage foreign direct investment, technology transfer, local R&D leading to improved availability of newer and better products. A stable business environment is a crucial foundation for innovation.

Yours Sincerely,

A handwritten signature in blue ink, appearing to be "Lila Feisee".

Lila Feisee

Vice President, International Affairs