



Comments of the Biotechnology Industry Organization (BIO)

To the Office of the Controller General
Patents, Designs and Trade Marks,
Government of India

Regarding the Draft Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material

28 November 2012



The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments in response to the government of India's "Draft Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material" hereafter called "Draft Guidelines".

About BIO and the Biotechnology Industry

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, 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 India's research institutions. India itself, boasts over 350 biotechnology companies employing over 20,000 scientists and contributing over US\$ 2 billion to the Indian economy.

The life sciences industry in India, as with anywhere in the world is fueled by the strength of and predictability of the patent system. This is because biotechnology research and development is risky, resource and time intensive. On average, it takes more than 10 years to develop a biotech medicine or a plant improved through agricultural biotechnology from its inception to regulatory approval and finally to market launch. The average, fully capitalized cost of developing a new medicine has been estimated at \$1.2 billion and a new biotechnology derived plant product at \$133 million. Most biotechnology innovation begins in the laboratory where a particular gene of interest is identified. This gene may have some correlation with a specific disorder or disease or perhaps a new plant trait or enzyme. Further research and development of these promising discoveries can take years, even decades, and hundreds of millions of U.S. dollars to achieve. Biotechnology innovators generally patent these promising discoveries to a) generate interest from investors to further research on these discoveries; and/or b) license them to potential partners or developers. In these situations patents are used as instruments to assure investors that their investment is secure and has the potential to be recouped and can be transferable. Weak patent rights, or an absence of patent rights, will severely hinder the development and commercialization and hence the availability of promising biotechnology discoveries.

In short, biotechnology innovation requires predictable and effective IP protection throughout the research, development and commercialization process,



including upstream (early stage) and downstream (product) IP protection. Such upstream protections generally include broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement. Downstream protection is just as important as a significant portion of the development time and money goes towards generating the regulatory data package that is required by various regulatory authorities. Therefore, downstream protection for biotech products must include sufficient protection against competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

Given the importance of patent protection for biotechnology product development and commercialization, a streamlined process for patenting, and the appropriate scope and subject matter protections are of great importance. Therefore, changes to the law or guidance which affect the patentability of biotechnology inventions are extremely important to our members. In particular, in India, where both the public and private sectors have invested heavily in biotechnology, which research has resulted in numerous promising discoveries in biofuels, healthcare and in agriculture, a patent framework that facilitates the translation of these discoveries to products will be of great value.

BIO and the CBD

At the outset, it is important to note that BIO supports the overall goals of the Convention on Biological Diversity (CBD) which forms the basis for the Draft Guideline's approach to addressing Traditional Knowledge and Genetic Resources. Moreover, BIO strongly opposes any wrongful removal of genetic resources from their rightful owners without permission and supports sharing the benefits of such resources upon mutually agreed terms with their rightful owners.

BIO believes that a practical and workable Access and Benefit Sharing (ABS) system will benefit both the owner and the user of genetic resources and help countries to utilize their resources to develop their economies. A system that engenders innovation through a robust legal framework will not only attract outside investment, but also foster local entrepreneurial activity. Conversely, burdensome and unnecessary requirements and bureaucracy will diminish the likelihood that companies will invest in the research and development of genetic resources.

In this regard, BIO is a proponent of the utilization of model guidelines, model Material Transfer Agreements and contractual agreements for ABS after a country has implemented the CBD through national legislation. This would address perceptions of misappropriation while preserving certainty in the patent system. BIO's *Guidelines for Members Engaged in Bioprospecting*,



(<http://www.bio.org/ip/international/200507memo.asp> and <http://www.bio.org/ip/international/200507guide.asp>,) which are consistent with the CBD, make BIO's position on these points clear and provide guidance to its members on these issues. BIO has also developed a model Material Transfer Agreement, model MTA, which is available at www.bio.org.

Finally, it should be noted that BIO has been an active participant in the World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property, Traditional Knowledge, Genetic Resources and Folklore, (WIPO-IGC) since its inception.

Draft Guidelines

Given the importance of protections for basic biotechnology inventions to the survival of the biotechnology sector in India, BIO has reviewed the Guidelines and has identified specific questions, and areas for improvement.

Screening for Traditional Knowledge (TK)

The Draft Guidelines indicate that Indian law has provisions for the protection of TK and biological resources pre-patent, during patenting and post-patent. The Guidelines further direct examiners and controllers to ensure screening of patent applications pertaining to TK. The purpose of a separate screening process for TK is not clear given that the India Patent Law already provides a process for analyzing the patentability of claims. Such a screening process has the potential to create/add to, the patent application processing backlogs which will be burdensome to applicant. Moreover, BIO is concerned that a special procedure for assessing "TK" given the ambiguity associated with what can be considered TK can create significant delays in patent examination. BIO is concerned that this may not be a mere process of classifying inventions, but rather could lead to determinations about the nature of the invention that may have a substantive impact on patent examination without a fair and effective system for enforcing the rights and adjudicating disputes. For example, it is unclear whether a determination that an invention is or is not based on TK would have any effect on whether currently publicly available information declared to be "TK" would be considered to withdrawn from the public domain. In addition, such a determination may lead to an unintended result that TK rights are in conflict with or would be perceived to be superior in effect or operation than those provided under patents, copyrights, trademarks, trade secrets, plant variety protection or other intellectual property protection systems to other products. BIO urges that all applications should be treated on a case-by-case basis, as



indicated under the Indian Patents Act, for novelty, inventive step, sufficiency of description, etc.

Guiding Principle 1- Assessing Novelty

Guiding principle 1 stipulates that if a subject matter relates to extracts/alkaloids and/or isolation of active ingredients of plants which are inherently present in plants, such claims cannot be considered novel when the use of the plants is known as part of TK. Such an assessment of novelty is at odds with other major patent offices including the European Patent Office (EPO), US Patent and Trademark Office (USPTO) and Japan Patent Office (JPO). In each of these jurisdictions, lack of novelty requires that the claimed substance have the exact chemical structure as that previously existing in the prior art. Moreover, in most jurisdictions, the isolation of an active/functional component from its natural environment is patent-eligible and is (or can be) novel and non-obvious. As an example, the isolation of the anti-malarial drug quinine from the bark of the cinchona tree, which was known to Amazonians to treat fever, could give rise to a patent covering *isolated* quinine, because the identification of the *specific* active ingredient and the process to isolate it is considered novel and non-obvious. Such a patent would not prevent the continued use of the cinchona tree bark to treat fever.

Guiding Principles 2-6- Assessing inventive step

These five guiding principles reflect a stronger presumption of obviousness than what exists in most jurisdictions. In particular, the guiding principles seem to disregard the possibility that the art may not provide a reasonable expectation of success. In most jurisdictions, the motivation to combine two products is not indicative that a person of ordinary skill in the art will have a reasonable expectation of achieving the desired result. The assessment of inventive step is fact- dependent and should be assessed on a case by case basis. A one-size fits all approach set through general guidance has the potential to prevent patents on innovative biotechnology products, thereby stifling innovation in this sector. BIO members file patent applications in most Patent Cooperation Treaty (PCT) countries in the hopes of launching key products in those markets. Such divergent protections between key markets would create problems for biotechnology companies and may affect business decisions with respect to those products. In addition, such a strict approach to patentability is likely to discourage research and development activities in the area of biotechnology in India.



Section 17- Source and Geographical Origin

India's Patents Act and the Draft Guidance require applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. These special disclosure requirements impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty. While the Guidance requires that an objection be raised to conform with the requirements, under the Indian law, the failure to identify the geographical source of a biological material **and** its origin may be a basis for opposition or revocation proceedings. However, the necessary relationship to the patented invention is not clear and their impact is inherently retroactive in effect. For example, companies often have obtained samples or materials from universities or in partnership with universities or depositories. Identifying the source of these materials may be impossible as many may have been obtained decades prior to eventual use and filing of a patent application. These requirements pose unacceptable risks for patent applicants and undermine the incentives of the patent system to promote research and innovation in the biotechnology sector.

Moreover, such requirements do not further the objectives of the CBD, which we understand to be the intended objective. Instead, an effective ABS regulatory system, based on mutually agreed terms between the provider and user of genetic resources, which may include terms relating to future intellectual property rights based on use of such resources, is the best mechanism to ensure furtherance of the ABS objectives of the CBD. This approach should apply for all uses of genetic resources, whether those uses are subject to intellectual property rights or not.

BIO appreciates the opportunity to provide these comments for your consideration and is available to discuss these issues in greater detail at your convenience. To facilitate this discussion, we invite members of the IPO to participate in a roundtable discussion with industry at BIO's International Convention in Chicago, USA in April of 2013.

Please contact Lila Feisee, Vice President for International Affairs at lfeisee@bio.org or +1 202 962 9502 with any questions or comments.