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The Comments of the Biotechnology Industry Organization on India's Draft National IPR Strategy as Prepared by the Sectoral Innovation council in IPR

November 8, 2012

The Biotechnology Industry Organization (BIO) is grateful for the opportunity to provide comments on India's *Draft National IPR Strategy,* hereafter referred to as "Draft Strategy". Moreover we applaud the Government of India (GOI) for taking on the difficult but important task of improving India's intellectual property (IP) system to spur innovation. It is in the interest of BIO and its many members to pass along the experiences and wisdom gained through three decades of experience in bringing new biotechnology products to market. India is at the cusp of this new and promising industry and it is in this spirit that these comments are provided to the Government of India .

About BIO and the Biotechnology Industry

BIO is a trade association representing more than 1,100 companies, academic centers and research institutions involved in the research and development of innovative biotechnology products and services. Ninety percent of our members are small- and medium-sized enterprises (SMEs) working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment. Simply put, this global industry would not exist without a stable, predictable and transparent intellectual property system that enables researchers and their sponsors to manage the risks of biotechnology innovation.

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Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of more than one million direct jobs, and millions of related jobs in countries throughout the world. Today, there are more than 200 biologic medicines and vaccines that benefit millions of patients worldwide. More than 600 new biologic medicines are in development, including treatments for cancer, diabetes, cardiovascular disease, HIV/AIDS, Alzheimer's disease, and numerous rare conditions. These products are helping more than 325 million people worldwide. Another 400 biotechnology medicines are in the pipeline. Biotechnology tests enhance our ability to better tailor patient care through greater precision in diagnosis, in many cases in a less invasive manner. Today, there are more than 1,200 molecular diagnostic tests being used in clinics around the world.

Biotechnology also holds great hope for feeding the world by increasing crop yields, preserving and improving soils, enhancing the control of pests, weeds and harmful diseases and producing more healthful food with enhanced vitamin and nutrient levels. Agricultural biotechnology has helped produce dramatic increases in yields of cotton, soybeans and corn – all staple crops that feed and clothe millions. These agricultural innovations are increasing food supplies, conserving natural resources of land water and nutrients, increasing farm income, and growing the economy worldwide.

Within the field of industrial biotechnology, companies are leading the way in creating both conventional and next generation advanced biofuels, which can be produced from forest residues, algae, municipal solid waste, or other renewable sources of biomass, without compromising the environment. In addition, industrial biotechnology helps make manufacturing processes cleaner and more efficient; creates new materials, food ingredients and other products; unlocks cleaner sources of energy; and reduces industrial waste. For example,

biotechnology enzymes are used in such wide-ranging products as cheese, detergents, environmentally-friendly plastics and renewable fuels like cellulosic ethanol.

Developing a biotechnology product is a lengthy and expensive Endeavour. In the health sector, on average, it takes US$1.2 billion over a period of more than a decade to bring a new biopharmaceutical to market; for agricultural biotechnology it takes hundreds of millions of dollars and over a decade to develop a new product. Biotechnology companies—whether in the United States or in India—choose to make this investment when there is a reasonable expectation of a return on investment, although there is never a guarantee of success. However, if the product is successful, inventors want to ensure that they reap the benefits in recognition of the tremendous risks they had taken. That is why Intellectual Property is so important. To raise the significant capital required for research and development, companies must first be able to assure investors that their patent portfolios are not at risk from competitors. No company--whether an SME or a multinational company-- can afford to take such risks if its investment in ultimately successful products cannot be protected after it struggled through the arduous product development process. And thus, no company will, in the long term, view significant R&D investment in a country where patents can be easily swept aside, whether through a post-grant opposition or a compulsory license. This is particularly the case when other countries in the region provide stronger, more stable intellectual property protection.

India's Biotechnology Sector

The government of India has recognized the tremendous potential of biotechnology and has invested billions in biotechnology research. Many of India's premier institutions are developing biotechnology incubators to facilitate

the development, manufacture and commercialization of research arising from this investment.

Today, India's biotechnology sector is a burgeoning one, with more than 325 companies, some having revenues in the billions of dollars. According to the 2012 *BioSpectrum*-ABLE (Association of Biotechnology Led Enterprises) *Biotech Industry Survey*, the industry grew by 24% in the last ten years, surging to $4 billion.[1] Analysts opine that given the right environment this growth can surge to 30%. If that happens, the industry will be a $100 billion giant by the year 2025.[2]

Indeed, after the U.S., Brazil and Argentina, respectively, India is the fourth largest nation in terms of hectares cultivated with biotech crops with 10.6 million hectares (22.6 million acres) of biotech cotton grown in 2011. There has been an increase in the number of farmers cultivating cotton in 2002-2003 from five million to eight million in 2011-2012. Notably, the number of cotton farmers who have adopted Bt cotton has increased from 50,000 in 2002-2003 to seven million in 2011-2012, representing about 88 percent of the cotton growing farmers.

The Indian bioindustrial sector registered an eight percent growth in its revenues with total sales of $142 million. This increase in enzymes consumption is attributed to the rise in demand from the food, pharmaceutical, detergent and energy sectors. India both imports and exports enzymes for different purposes. The domestic consumption of enzymes for 2011-2012 stood at about $110 million, while the exports brought $32 million in revenues during the same

[1] http://www.ableindia.in/pdf/10th_survey.pdf, 2012 BioSpectrumSurvey October 2012
[2] Ibid

period. The enzymes sector in India has been growing at about 8-10 percent a year over the last 10 years and is expected to see a similar growth percentage in 2012-2013.

India is on the cusp of biotechnology innovation, but as the Government has correctly recognized, it is not enough to invest in biotechnology research. India must improve the enabling environment necessary for biotechnology to flourish, a centerpiece of which is protection of intellectual property rights (IPR) .

The Biotechnology Business Model—Small and Medium Sized Enterprises

The key to success of the biotechnology industry – across of all its sectors – is a business model that is based on taking significant risks to develop products based on innovation. Specifically, the biotechnology business model is based on making significant investments (often hundreds of millions of U.S. dollars) in early stage research and development with the hope that some of these investments and efforts will yield a commercial product. On average, it takes more than 10 years to develop a biotechnology medicine or a plant improved through agricultural biotechnology from its inception to regulatory approval and finally to market launch. As mentioned above, 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. This model has worked despite the fact that the development process is long and that most biotechnology R&D investments and efforts do not result in a commercial product reaching the market primarily due to the strength of the patent system. It is only by pushing scientific boundaries and taking risks that breakthrough inventions are discovered and converted into commercially viable products and services.

The life sciences industry in India, as with anywhere in the world is fueled by the strength of and predictability of the patent system. Thus, biotechnology innovation requires IPR 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 biotechnology innovations, consistent patent term, flexible licensing practices, and effective patent enforcement. Downstream protection is just as important, because 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.

The biotechnology business model requires an environment that, as much as possible, eliminates unpredictability in the commercial sector. One important factor in this environment is the guarantee of patent exclusivity. Specifically, by ensuring that the products or services that may eventually be marketed can be protected from unauthorized copying and use, companies can justify taking risks and making significant R&D investments. Introducing unpredictability by changing the availability of patent rights, or the conditions in which patent rights can be asserted, or threats of compulsory licensing will adversely affect the business environment that is so crucial to supporting innovation in the biotechnology sector. Such unpredictability will undoubtedly hinder India's efforts to nurture small- and medium-sized enterprises within its borders.

Patents in the life sciences sector protect the type of products and processes that are integral to small- and medium- sized companies doing business in the biotechnology sector. By enabling these companies to prevent the unauthorized

use of the patented technology, companies can justify pursuing their research and development efforts. Indeed, it is the guarantee of securing and using rights in the future that companies rely upon to justify making investments in R&D today.

To illustrate the role of patents in the typical start-up biotechnology venture, consider the following example of biotechnology innovation in the health sector. A researcher, typically in a university laboratory, discovers a gene which is expressed only by a particular type of cancer cell. This discovery can result in a variety of distinct research and development initiatives – ranging from diagnostic tools for detecting the presence of the gene or its expression product in test samples taken from patients, to therapeutic agents that selectively kill cells that express the gene or inhibit its expression. As soon as practical after the discovery of the gene and its practical value, patent applications must be filed. Filing the application early ensures that the researcher or its sponsor (a university or startup biotechnology company) can secure rights in the inventions that derive from the discovery, and permits the researcher to publish the results. The patents based on this early application will be used to justify the investment of millions of dollars into development of these diagnostic and therapeutic agents. Translating this initial discovery into a tangible product can take more than a decade of research and development and the investment of hundreds of millions of dollars. The exclusivity provided by patents issued from this early application of this technology provide investors with a more tangible right in the technology, and will be a key factor affecting funding of the business venture. A larger company will also consider the strength of patent rights when deciding whether to conduct clinical development of products discovered by any startup company or university that owns the patent. Such endeavor involves a significant likelihood of failure, and is fraught with other possible commercial setbacks. Further scientific advancements lead to additional innovation, which

may be pursued in multiple aspects by different parties. The confidence that patent rights will protect products that are developed, propel the transfer of technology and collaboration on the research and development work that follows.

Given the importance of patent protection for biotechnology product development and commercialization, a streamlined process for patenting, and the appropriate scope and patentable subject matter protections are of great importance. In particular, in India, where both the public and private sectors have invested heavily in biotechnology, resulting 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. Nevertheless, both Indian and foreign companies which have filed patents in India have experienced problems throughout the examination process as well as post patent grant.

BIO's Overall View of the Draft Strategy

BIO supports the overall goal of the Draft Strategy to raise awareness of the importance of, and respect for IPR and to encourage IP creation in both private and public institutions. BIO specifically supports the Government's goals to set up "facilitation centers" so that institutions can identify patentable matter and file for IP protection. Successful efforts in this area have been made in several other countries including in the U.S. where such centers are part of "incubators" co-located with research institutions and economic development centers. In this regard, we recommend a review of the recent Battelle report[3] which provides a detailed look and several examples of ways such "centers" can assist start-up

[3] Battelle/BIO State BIO SCIENCE Industry Development 2012. http://www.bio.org/sites/default/files/v3battelle-bio_2012_industry_development.pdf

companies to do research in wet-labs, patent inventions, find partners, investors and the like.

BIO also supports the Government's proposal to create favorable tax treatment for R&D expenditures. Small companies generally register net operating losses in their first years. Moreover, they continue these losses, even several years after companies commercialize products. This is because of the significant upfront cost of investment that must be recouped in order to make a company profitable, and sustainable.[4] Accordingly, tax relief in this area can provide significant incentive. However, in order for this incentive to work, it must be linked to other improvements including in the IP regime.

BIO further supports initiatives to better leverage academia and public research laboratories to create and commercialize research through training researchers and generating overall awareness of the importance of IP creation and licensing. In this regard, BIO supports the Draft Strategy's proposal to include "technology transfer or technology licensing" offices in research institutions and universities as a component of the scientific role of a research institution. As the Government pursues legislation in this area, it should consider the importance of flexibility for entities to license in a manner that best enables dissemination of technologies for commercialization. In this regard, BIO suggests that the Government of India collaborate with organizations such as the Association for University Technology Managers (AUTM)[5] in the U.S. as well as BIO through its various events. These organizations have robust training programs, which focus on the framework and efficient mechanisms for technology transfer/licensing to spur commercialization. In addition, these organizations provide opportunities for collaboration between Western and Indian institutions.

[4] http://www.biotech-now.org/business-and-investments/inside-bio-ia
[5] http://www.autm.net/Mission_and_Goals/8908.htm

BIO also supports the Draft Strategy's goal of strengthening enforcement of IP. We applaud the Government for focusing in part on the protection of new plant varieties and acknowledge that the Draft Strategy clearly states that protection of plant varieties is essential to encourage the development of new plant varieties and to protect existing plant varieties, and that such protection will facilitate the growth of seed industries and ensure the availability of quality seeds and planting material for the Indian farmers. Although in 2001 India introduced a legislation known as the Protection of Plant Varieties and Farmers Rights Act and a certain degree of protection is granted on plant varieties, India is not a member of UPOV and on certain aspects the Indian legislation on plant varieties deviates significantly from the principles set forth in UPOV. In particular, the extensive farmer's privilege and far-reaching grounds for a compulsory license erode the strength and scope of protection. In addition, the wide-ranging information that must be provided to the relevant Indian authorities at the time of filing, the compulsory deposit of parental lines to a public gene bank, the possible claims for benefit sharing by farmers/communities and the compensation for alleged disappointing performance of the protected variety render the current Indian system less strong and less attractive than the Plant Variety Protection laws in UPOV countries. This will have a negative impact on the development of new varieties by Indian seed companies and international seed companies in and for India. It furthermore deprives the Indian farmers from innovative varieties.

It furthermore appears that the bulk of the enforcement section focuses on copyright and trademarks and does not address enforcement of patents. We urge the Government to consider the challenges posed by infringers of patents in India as well. The concerns pertaining to infringement and enforcement of patents will be addressed in more detail below. Moreover, as the Government looks at enforcement of protections on Geographical Indications (GIs), it is

critical that it consults with stakeholders to ensure that protection of these GIs do not interfere with, or undermine existing protections.

BIO notes the Government's support of patent protection as a means to encourage innovation. BIO urges recognition that what is called "incremental innovation" is simply innovation in its purest form since all human activity relating to invention and technological development is by its nature incremental. For reasons described above, the need for a sufficient term of patent protection to enable biotechnology companies to recoup their investment, is necessary for innovation in the biotech sector. Reduced patent terms such as those presented by the Draft Strategy at page 20 are not likely to be useful for the biotechnology sector, though the proposal may appeal to other less capital intensive industry sectors. In the biotech space, the importance of innovation cannot be understated. We urge amendments to section 3(d) of the Patents Act to remove onerous and non-conventional limitations on patenting which result in reduced incentives for innovation in India (addressed in more detail below).

BIO suggests that the Government include IP regimes that protect against unfair commercial use of undisclosed test data or other data as discussed below. Biotechnology companies invest significant sums in the development and fine-tuning of manufacturing and test data. A recent study demonstrates[6] that approximately 90% of the development cost of a biopharmaceutical product is due to the development of the complete regulatory data package necessary to obtain regulatory approval. TRIPS Article 39.3 provides a framework, and several countries have in place, laws for protection of the data generated in order to enable innovators to recoup this significant investment. This topic is further addressed below.

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[6] http://www.manhattan-institute.org/html/fda_05.htm

Finally, BIO supports the goals set forth in the Draft strategy on page 11, to strengthen IP protections, promote respect for IP, and facilitate commercialization of IP and the creation of new IP regimes to address the specific needs of the country and existing gaps, by the introduction of utility model type of patent protection. However, BIO cautions against using such mechanisms in ways that would merely to weaken the patent system.

BIO's Specific Areas of Interest with Respect to the Indian Patent Regime and the Draft Strategy

As the Draft Strategy indicates, for several years after acceding to the WTO, India made great strides in spurring innovation through improving its patent system. However, in recent years, India's early efforts have been undermined by certain judicial, legislative and administrative actions, which are listed below.

- With respect to the IP Regime, BIO commends the Government for having implemented several process-related changes in the various Indian Patent Office branches and for proposing several other modernization activities (pages 15-17). However, it should be noted that there still remains inconsistency in practice, which arises from the existence of regional patent offices in India. There have been instances where patentees have reported opposite results when filing in separate regional patent offices. In this regard, BIO suggests that the development of guidelines coupled with training on patentability criteria would help alleviate some of the disparities that patentees face on a regular basis.

- Furthermore, BIO has heard from members that delays in processing applications coupled with the drawn out opposition procedures is a significant problem for patentees. This is exacerbated by the fact that the timelines and processes for opposition procedures are not well-defined.

Patentees often wait many years for a patent application to enter into the examination process only to have the claims opposed in a pre-grant proceeding.

Under Indian patent law any person can mount a pre-grant challenge on a specific ground without *res judicata* which means that even if the pre-grant opposition is decided in favor of the patentee, the same grounds can once again be presented by another challenger. While the Patent Office combines certain pre-grant oppositions before examination, once examination has commenced, this method is abandoned. Accordingly, patentees often find themselves with serial pre-grant oppositions. This is further exacerbated by another provision in Indian patent law which allows for post-grant opposition on fairly broad grounds which can be mounted by a "person of interest". The definition of a "person of interest" is currently ambiguous due to a recent judicial decision which includes a non-governmental organization as a party to a challenge. Moreover, there is no rule which prevents a person who has mounted a pre-grant from mounting a post-grant challenge. Accordingly, patentees often find themselves in challenge after challenge, from the moment they file a patent application at the IPO. Further exacerbating the problem, Indian Patent law does not allow for extension of patent term for administrative and regulatory delays caused by the inefficiencies in the process, which contributes to a loss of value for legitimate biotech patents. While ideally, the broad nature of post-grant challenges is sufficient to weed out any sub-quality patents, we believe that the unlimited pre-grant opposition should be abolished or at minimum severely curtailed to better reflect international practice. Moreover, we are concerned with recent decisions of the Patent Office to revoke patents that cover the compounds of certain pharmaceutical products (e.g., the cancer drug Sutent and

hepatitis-C drug Pegasys). Although the grounds of such revocation will be the subject of much discussion and litigation, these decisions in India are the exception among the many countries that have granted these patents. The unpredictability caused by such an action will inevitably undermine the Government's goal of collaboration, commercialization and IP creation.

Patentees filing in India not only experience unnecessary delays and burdens due to the pre-and post-grant challenge procedures, but once they have managed to overcome these obstacles and are granted a patent, they are subject to a compulsory license. The Patent Office announced on December 24, 2009, that all patentees must submit a yearly "statement of working" that proves that the patentee is exploiting its invention in India. If the patentee does not comply, the government may issue a compulsory license. The regulation allows the patent office to cancel a patent if it has not been continuously worked on for a period of more than two years after falling under certain specified conditions. This provision may result in the loss of intellectual property rights when a biotechnology company cannot work on the drug due to extraneous conditions (such as an FDA "clinical hold"). As indicated above, the biotechnology industry requires long-term development and investment, which results in biotechnology products typically taking longer than three years from patent grant to make it to market. U.S. law recognizes this challenge by allowing patent term restoration to compensate for the loss of patent life caused by product development and delays in regulatory approval.

- The inconsistency in application of pre- and post-grant opposition procedures, taken with the broad exceptions for use of patented

technology by the Indian Government or third parties, provides extensive authority for the grant of compulsory licenses, including licenses justified only on the basis that the products falling under the patent are not substantially manufactured in India. This came to fruition earlier this year, when the Patent Office granted a compulsory license to Natco Pharma for Bayer's cancer drug Nexavar. We understand that this issue is currently on appeal, but the foundational problems indicated above continue to exist and should be addressed by the IPO.

- India's Patents Act requires 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. 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. Oftentimes patentees have obtained samples or materials from universities or in partnership with universities or depositories. Identifying the source of these materials is may be impossible as many may have been obtained decades prior. At the USPTO roundtable interested parties were informed that for the purpose of the IPO, identification of the source is sufficient. However, the law requires both the source and origin to be disclosed. 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.

- Indian patent law prohibits or limits the ability of biotechnology companies to patent certain broad classes of fundamental innovations.

Prohibited from patenting are transgenic plants and animals which are innovations in the agricultural sector; and limited in their patenting are formulations, dosage forms, or chemical variations of an earlier patented product in the pharmaceutical sector. With respect to the latter three innovations, India imposes higher standards in these areas than are applied in other major countries. Patents on all of the above inventions provide incentive to biotechnology companies for investigating their discoveries and improving their own products. With respect to improvements, often times during the course of development, unique and novel properties of the same product are discovered. Other times, formulations that reduce the administered dose of a product are discovered. Patents on such improvements do not prevent generics from copying the original product once the patent has expired. Indeed such improvements provide greater choice for patients.

- The Indian Patents Act includes Section 3(d), which explicitly excludes from patentability new forms of a known substance that does not result in "enhancement of the known efficacy of that substance." This requirement excludes from patentability many significant pharmaceutical inventions such as, e.g., new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits that may not result in "enhanced efficacy" *per se*. Even if not removed, new forms of a substance that have benefits to the patient with clear support for its therapeutic improvement should be central to the concept of "improved efficacy" yet are noticeably absent in consideration for granting a patent. In addition, this provision appears to be inconsistent with India's obligations under Article 27 of the TRIPS Agreement, which requires that patents be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step and are capable of

industrial application." Section 3(d) also creates an additional hurdle to patentability that is applied only to certain chemical products, and therefore appears to violate the non-discrimination clause with respect to field of technology set forth in TRIPS Article 27. We eagerly await a decision from the Supreme Court regarding this issue in the Novartis AG v. Ministry of Industry and Commerce case which may have a bearing on the interpretation of this provision.

- Finally, while TRIPS Article 27.3 allows member states to exclude method of treatment claims, pursuing that course may not be in India's best interests. India excludes method of treatment claims, which prevents U.S. biotechnology companies with needed treatment methods from entering the Indian market to provide life saving products. Furthermore, other patent offices that prohibit method claims (such as the European Patent Office and the State Intellectual Property Office (SIPO) in China) permit alternative formulations of method claims, such as for the "use of compound X in preparation of a medicament for treating disease Y" or "compound X for use in treating disease Y." The lack of flexibility in India's patent law prevents biotechnology companies from seeking protection and bringing their products to India.

While some or all of the above issues may be within the purview of the authors of the Draft Strategy to address, there are other concerns described below which fall outside of the IPO's purview. However, it is important for the IPO to understand the challenges being experienced by the biotechnology sector as they go through their research and development process. Below are some areas of concern.

Courts

Indian law recently recognized patent protection for pharmaceutical compounds. The standards for claim interpretation, trial, and enforcement of injunctions are still under development. Generally, the courts lack uniform standards for issuing injunctions and have not given deference to the determinations of the Patent Office. The courts have often not enforced injunctions to protect patents issued to foreign applicants. Indian courts also often decline to uphold patents that have been granted with the same or similar claims in jurisdictions with higher patentability requirements. The courts have also declined to consider granted patents when deciding whether to approve marketing applications by generics if a patent is being tested in the courts or in opposition.

Recent case law developments have drawn concern from our member companies in the areas of obviousness, novelty and rejection of new methods for using known compounds. For example, the interpretation of the obviousness standard for dosage forms and other similar inventions has drawn concern.[7] The second issue involves the interpretation of the novelty and obviousness standards in the context of an enantiomer product.[8] The final issue is the rejection of any applications for new methods of use for known compounds.[9]

Biotechnology companies would find it helpful if the Government of India partnered with other patent-friendly nations to conduct training for Indian court officials to help handle the various issues involved in patent cases, which are often difficult and require specialized training. Such training would be beneficial to the Indian court system to help them make consistent decisions and create

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[7] including Aventis Pharmaceuticals, 1021/CHENP/2006 (2009), and Novartis AG, 728/CHENP/2006 (2009).
[8] Astra Aktiebolag, 1255/DEL1995 (2009)
[9] GlycoScience Labs 1752/CHE/2006 (2009)

uniform standards for enforcement. Consolidating patent cases into a few specialized patent courts might also help these issues as it would allow judges to gain expertise in a very new and complex area of law.

Drug Regulatory Body

BIO also supports the Draft Strategy's goal of strengthening enforcement of IP. We applaud the Government for focusing in part on the protection of new plant varieties and acknowledge that the Draft Strategy clearly states that protection of plant varieties is essential to encourage the development of new plant varieties and to protect existing plant varieties, and that such protection will facilitate the growth of seed industries and ensure the availability of quality seeds and planting material for the Indian farmers. . Although in 2001 India introduced a legislation known as the Protection of Plant Varieties and Farmers Rights Act and a certain degree of protection is granted on plant varieties, India is not a member of UPOV and on certain aspects the Indian legislation on plant varieties deviates significantly from the principles set forth in UPOV. In particular, the extensive farmer's privilege and far-reaching grounds for a compulsory license erode the strength and scope of protection. In addition, the wide-ranging information that must be provided to the relevant Indian authorities at the time of filing, the compulsory deposit of parental lines to a public gene bank, the possible claims for benefit sharing by farmers/communities and the compensation for alleged disappointing performance of the protected variety render the current Indian system less strong and less attractive than the Plant Variety Protection laws in UPOV countries. This will have a negative impact on the development of new varieties by Indian seed companies and international seed companies in and for India. It furthermore deprives the Indian farmers from innovative varieties.

It furthermore appears that the bulk of this section focuses on copyright and trademarks and does not address enforcement of patents. We urge the Government to consider the challenges posed by infringers of patents in India as well. The concerns pertaining to infringement and enforcement of patents will be addressed in more detail below. Moreover, as the Government looks at enforcement of protections on Geographical Indications (GIs), it is critical that it consults with stakeholders to ensure that protection of these GIs do not interfere with, or undermine existing protections.

Although the Draft Strategy recognizes that trade secrets are an important form of intellectual property and that a predictable and recognizable trade secret regime will improve investor confidence, India has not yet implemented any meaningful protection for the data that must be generated to prove that pharmaceutical, agricultural chemical products and plant biotech products are safe and effective, neither through effective laws for the protection of trade secrets nor for the protection of regulatory data As mentioned above, the downstream protections of data exclusivity are at least as important as upstream or patent protection for biotechnology inventions. In the biopharmaceutical sector, this is in large part due to the fact that a significant portion of the spending on the drug development process takes place during the testing and clinical trial phase when companies generate the necessary data for regulatory approval. Due to the lack of effective protection of trade secrets, disclosure of trade secrets can lead to a significant loss of potential revenue, thereby discouraging the research and development of innovative products. In addition to this, under Article 39.3 of the TRIPS Agreement, protection must be extended against unfair commercial use of such data by makers of generic copies of innovator products (i.e., products that must be shown for the first time to be safe and effective, or to not cause significant risk to the environment).

BIO views the 2007 Reddy Report[10] and its recognition that the present legal provisions in India do not adequately meet the spirit of TRIPS Article 39.3 as a positive development. Further, BIO views positively the suggestion in that report that India should adopt a fixed data protection term and suggests an adjustment of Indian law to international standards i.e. at least 10 years as that provided for crop protection products; at least five years for pharmaceutical products; or more for biologics as in other countries. This term of fixed data protection should prevent relevant regulatory officials from relying upon data submitted by the originator when approving second and subsequent applications for the same product. Nonetheless, it appears that meaningful protection for this data will not be implemented in the near term. In addition, even the suggested post-transition period protection suggested in the Reddy Report is subject to numerous, and apparently wide-ranging, proposed "safeguards," a number of which would appear to undermine the proposed protection almost entirely. Effective market exclusivity for regulated pharmaceutical, agricultural chemical products and plant biotechnology products would contribute significantly to providing adequate and effective protection of intellectual property rights in India for BIO's members.

Conclusion

Once again, BIO is grateful for the opportunity to provide comments on the Draft National IP Strategy, and commends the Government of India for taking on the laudable goal of strengthening the Indian IP system in an effort foster

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[10] SATWANT REDDY AND GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY THE GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF THE TRIPS AGREEMENT (May 31, 2007). E.g., see safeguard (xi), which states that "[i]n cases where repeating the clinical trials for a drug is not considered essential, the Regulatory Authority may allow marketing approval to subsequent applicants of a drug similar to an earlier approved drug by placing reliance on the first applicant's undisclosed data."

economic growth, innovation and IP creation. We believe that the biotechnology sector in India has significant contributions to make to this effort, and stands ready to work with the Government to meet its overarching goals.

For additional information about BIO, the biotechnology industry in India and any issues raised in this paper, please don't hesitate to contact me at lfeisee@bio.org.

Respectfully submitted by,

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