



*The Comments of the Biotechnology Industry Organization on the
Discussion Paper on Compulsory Licenses Published by the
Department of Industrial Policy and Promotion within
India's Ministry of Commerce and Industry*

September 29, 2010

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on India's Department of Industrial Policy and Promotion's (DIPP) discussion paper on compulsory licenses published on August 24, 2010.

About BIO

BIO is an industry association that represents approximately 1,200 biotechnology companies, academic institutions, biotechnology centers and related organizations throughout the world, including in India. Most of these companies and organizations are small, emerging companies heavily reliant on private equity to fund their investment in biotech innovation. BIO's members are dedicated to turning cutting-edge science into healthcare, agricultural, and environmental products that benefit the world's population and help sustain our planet. The biotechnology industry is one of the most research-intensive industries in the world. In 2006, biotechnology companies spent more than \$25 billion in R&D. Since its inception, the biotechnology industry has raised more than \$100 billion in private investment. These investments are paying off. There are more than 400 new drug products and vaccines on the market or in development, along with scores of agricultural and environmental biotech products.

The industry is uniquely suited to collaborate and partner with organizations and institutions around the world including in India – and is poised to be a critical player in the quest for innovative technologies in a variety of sectors, including medical, agricultural and industrial areas. As an example, the industry is working in the medical sector to produce the next generation of vaccines and medicines, largely focused on currently unmet medical needs both communicable and non-communicable – such as tuberculosis, malaria, a variety of cancers, Alzheimer’s disease, multiple sclerosis, and diabetes. In the agricultural field, biotechnology innovations are growing the global economy by simultaneously increasing food supplies, reducing pesticide applications, conserving natural resources of land, water and nutrients, and increasing farm income. Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment. And yet, even with all of the advancements in the field, we have only just begun to realize the full potential of this powerful technology.

Biotechnology and India

India is fertile ground for biotechnology research and development with more than 100 R&D focused companies, significant intellectual resources, and the support of the Government of India. The Government of India’s Department of Pharmaceuticals Biopharma Strategy¹ demonstrates the vision and the will of India to become a leading global producer of biopharmaceutical products. This Strategy document recognizes the need for incentivizing innovation in the biotechnology industry by protecting investments and spurring commercialization of government-funded research.

These efforts by India have attracted the attention of the worldwide biotechnology industry, and in particular BIO’s members. On September 21 and 22 of this year, BIO hosted its first-ever partnering conference in Hyderabad, India – called BIO India – which attracted more than 400 biotechnology companies from the United States, Europe and India, and facilitated hundreds of one-on-one partnering meetings between conference attendees. The purpose of this forum was

¹ Leadership in Affordable Therapeutic Products- A BIO PHARMA Strategy for India, Vision 2020, An ABLE-PWC report for Department of Pharmaceutical’s Ministry of Chemicals and Fertilizers, Government of India. July 2010.

to spur collaborations between the biotech industries in India and other countries. Undoubtedly, these partnering meetings and potential collaborations often must have included discussions around the strength of the intellectual property portfolios of promising technologies.

Given the critical role that intellectual property plays in biotech collaborations and investment, we were disappointed to see the recent DIPP's discussion paper on compulsory licensing of biopharmaceuticals, which sends a deeply troubling message to investors and collaborators at a time when the industry and the Government of India are seeking to increase investment, collaboration, and innovation in the biotech sector.

At the outset, it should be noted that BIO recognizes the rights of countries to provide for compulsory licenses in compliance with the World Trade Organization's TRIPS Agreement. Furthermore, BIO understands the desire of India to meet public health objectives. However, we do not believe that the mechanism proposed in the discussion paper, which seems to be aimed primarily at reducing price and boosting domestic manufacture of copies of innovator products, would aid in achieving these goals. Indeed, we believe that the discussion paper sets the stage for the perception of weakened IP rights for innovators, which disincentivizes collaborations and investment in the biotech sector, thereby diminishing the possibility that innovative biotech products will be developed in India or with the participation of Indian partners. Clearly, such an outcome will not result in the availability of innovative biotechnology products for the Indian public, and would be contrary to the goals of the Biopharma Strategy supported by the Government of India.

Patents and the Biotechnology Industry

The key to success of the biotechnology industry – across all of 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 dollars) in research and development with the hope that some of these investments and efforts will yield a commercial product. This model has worked despite the fact that it is lengthy (often taking more than a decade) and that most biotechnology R&D

investments and efforts do not result in a commercial product ever reaching the market. It is only by pushing boundaries of science and taking these risks that breakthrough inventions are discovered and converted into commercially viable products and services.

Given the high R&D risks, the biotechnology business model requires an environment that, as much as possible, eliminates unpredictability in the commercial sector for successfully approved products. One important factor in this environment is the guarantee of patent and data protection. 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 making common-place compulsory licensing and undermining the ability to enforce patent rights will adversely affect the investment and the business environment that is so crucial to supporting innovation in the biotechnology sector.

To illustrate the role of patents in the typical biotechnology venture, consider the following example. A researcher discovers a gene or its expression product that 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 the expression of the gene. Developing such products will require significant investment in the range of tens of millions, and often hundreds of millions of dollars (U.S.), and could take a decade or more to achieve. Patents will be the primary asset used to justify this investment into development of these diagnostic and therapeutic agents. The reliability of the patents as protectors of this investment spurs investment and funding for development of these products and will often be a key factor affecting the decision of a larger company to collaborate with a start-up company or university that owns the patent to do clinical development of products based on the discovery. Of course, the road to development from this point is long and torturous, has a significant likelihood of failure, and is fraught with other commercial setbacks. However, the faith that the discovery will help improve the lives of patients, and the confidence that patent rights will protect products that are successfully developed, propel the transfer of technology and research and development work that follows.

The threat of compulsory licensing to meet a potentially limitless range of public health and pricing goals strikes at the heart of the protection and assurance that is needed to generate investment in this sector. Biotechnology is a global endeavor. Around the world, countries like China, Brazil, Singapore and Malaysia have taken steps toward attracting investment in this unique sector. Ultimately, capital investment will flow to areas where the environment is conducive to innovation. We believe that India has the vision and the human and financial resources to be a leader in the biotechnology space and we are concerned that perceived weakening of IP rights would impede India's rise in this sector.

We strongly urge DIPP to carefully construct its discussion surrounding compulsory licensing so as not to create the perception or reality that patent rights in India are unreliable. Although the discussion paper focuses on compulsory licenses in the biopharmaceutical sector, we believe that the perception or reality could have a detrimental impact in investment in other areas of biotechnology not limited to the health sector, such as climate change technologies. We hope that DIPP carefully considers the views and experiences of those who bring to fruition biotech innovation.

We welcome the opportunity to work with you, and on behalf of BIO's broad and diverse membership, we thank you for the opportunity to present our views for your consideration.

Submitted by,



Lila Feisee
Vice President for
Global Intellectual Property Policy

On Behalf of:
Biotechnology Industry Organization