International Council of Biotechnology Associations

# IP Policy Paper

The ICBA represents the global biotechnology industry, which consists of companies, universities and research institutions researching and developing healthcare, agricultural, industrial, and environmental biotechnology products. The global life sciences industry, fueled by the effective intellectual property (IP) systems, has generated hundreds of medicines, medical diagnostic tests, climate and pest-resistant crops, and environmentally beneficial products, such as renewable fuels and bio-based plastics. The vast majority of biotechnology companies are small and medium sized enterprises that currently do not have products on the market. As such, these companies rely heavily on the strength and scope of their IP to attract investments needed to fund the costly research and development of delivering safe and effective technologies to the people and planet.

## Intellectual Property Enables Biotech Innovation

The agricultural and pharmaceutical biotechnology sectors rely heavily on patents and regulatory data protection to secure investments in risky and costly innovation. The development of a single biotechnology innovation often takes scientists more than a decade to commercialize, and hundreds of millions (and in the healthcare sector more than a billion) of dollars of capital investment, a majority of which comes from private sources. Furthermore, biotechnology product development is also fraught with high risk – the vast majority of biotech research endeavors fail to ever reach the marketplace. Research shows that 9 out of 10 medicines fail to reach market.[1]

Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents and regulatory data protection help provide this assurance. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs reported that potential funders, such as venture capitalists, angel investors, and commercial banks, indicated patents were an important factor in their investment decisions.[2]

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[1] https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#6ec126702d45

[2] Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008. Available at SSRN: http://ssrn.com/abstract=1121224

In addition, while health biotech inventions are entitled to the same patent term as all other inventions – 20 years from the time they are filed – they face 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.

Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and may simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society.

## Practices that Undermine Innovation

Future global biotechnology innovation is threatened by practices that seek to weaken IP rights. They are harmful not only to the biotechnology industry but to the long-term prospects for the economic growth in this sector.[3]

Some problematic practices that undermine biotech innovation include:

a) Compulsory Licenses

Under the guise of "TRIPS" flexibilities, non-government organizations and some international organizations are actively encouraging governments to avoid granting IP rights, force biotechnology companies to transfer technology to local companies, or regularly resort to compulsory licenses (CLs) for biopharmaceutical products.

Some governments have issued or threatened to issue CLs that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. In the case of medicines, the ICBA strongly believes governments should grant CLs only in accordance with international rules and as a last resort in exceptional circumstances. Decisions should be made on public health emergency grounds through fair and transparent processes that involve participation by all stakeholders and consider all the facts and options, including less harmful but effective alternatives to CLs.

[3] Pugatch, Localization Barriers, http://www.pugatch-consilium.com/reports/Localization%20Paper_us_final.pdf

b) Patent Backlogs

Long patent examination and approval backlogs undermine incentives to innovate across sectors and prevent timely patient access to valuable new treatments and cures while also contributing to delay in introduction of new agricultural innovations. Because the term of a patent begins on the date an application is filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines. They create legal uncertainty, for research-based and generic companies alike, and can increase the time and cost associated with bringing a new treatment to market.

c) Restrictive Patentability Criteria

To transform valuable new innovations into products that people can use, innovators must be able to secure patents on all inventions that meet the basic TRIPS requirements of being new, involve an inventive step and are capable of industrial application. National laws, regulations or judicial decisions that prohibit patents on certain types of inventions or impose additional or heightened patentability criteria prevent innovators from building on prior knowledge to develop valuable new and improved technologies.

d) Early Resolution Mechanism for Patent Disputes

A mechanism that allows for effective early resolution of disputes concerning patents of innovative drugs benefits both the innovator and follow-on manufacturers by creating clear rules for resolving costly patent disputes in an efficient manner. It also contributes to improving patent enforcement by ensuring the regulatory agency of a jurisdiction do not inadvertently contribute to the infringement of patent rights.

e) Regulatory Data Protection Failures

Regulatory data protection (RDP) complements patents on innovative medicines and agriculture protection products. By providing temporary protection for the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine or of crop protection products, for marketing approval, RDP provides critical incentives for investment in new treatments and cures.

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Derived from living organisms, biologics are so complex that it is possible for others to produce a version – or "biosimilar" – of a medicine that may not be covered within the scope of the innovator's patent.

f) Limiting the scope of patent term extensions

Supplementary protection certificates (SPCs) and other forms of patent term extensions aim to compensate for the loss of effective patent protection for biopharmaceuticals caused by the lengthy testing and clinical trials required prior to obtaining regulatory marketing approval.

The scope of patent term extensions is being questioned and there are requests for waiving some rights so as to allow stockpiling and export of patent-protected biopharmaceuticals. By undermining the integrity of an important IP right for the healthcare biotechnology sector, this creates caution and distress in the investment community and is as such detrimental to the development of future innovative biopharmaceuticals globally.

g) Linking IP with access

There are efforts within the multilateral health system to undermine the value and scope of IP by pointing to it as a barrier to access to medicines. These work streams simply serve to polarize the issue rather than advance meaningful solutions, because they are not evidence-based and fail to examine the myriad of fundamental challenges that are in fact the cause of limited access – such as poorly functioning healthcare regulatory systems, supply chains and delivery infrastructure and systems.

Biotechnology innovators support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. Patents and regulatory data protection drive and enable the research and development that delivers new treatments and cures. These limited and temporary IP rights are not barriers to access to medicines; to the contrary, they promote access to medicines, particularly when governments and the private sector partner to improve health outcomes.