International Council of Biotechnology Associations

10 January 2018

Elżbieta Bieńkowska
Commissioner for Internal Market, Industry, Entrepreneurship and SMEs
European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
1049 Brussels
BELGIUM

Dear Commissioner Bieńkowska,

The International Council of Biotechnology Associations (ICBA) welcomes this opportunity to comment on proposals being considered in the ongoing Incentives Review process to recalibrate rights currently provided by Supplementary Protection Certificates (SPCs). The ICBA is a coalition of non-profit, national biotechnology trade associations from 25 countries each with membership comprised primarily of small and medium-sized innovative biotechnology enterprises. The ICBA's main objective is to improve understanding of public policies that support the growth of the innovative biotechnology industries.

The ICBA urges the European Commission to reject proposals to curtail SPC rights by permitting during a SPC term European generic and biosimilar companies to manufacture products for export (manufacturing waiver) and to stockpile products during the SPC term (stockpiling waiver). The ICBA and its members trust that the Commission will carefully consider this and other submissions by research-intensive industries and choose not to damage the viability of European small and medium sized biotechnology enterprises by weakening the SPC component of the European Union's intellectual property rights-based regime.

Innovation that translates into the development of novel, safer and more effective medicines is the heart of the biopharmaceutical industry's mission. Advanced biopharmaceutical products promise to revolutionize medicine and deliver cures for various cancers and other diseases that today have few or ineffective therapeutic options. These innovations are characterized by a very complex, expensive development path and technologically complex manufacturing challenges. Emerging transformative health technologies include gene therapy, cell therapy and engineered tissue products.[1] Biologics, therapeutic products made with recombinant technology, are now increasingly available and are improving patient outcomes.

Over the last decades, innovators and biopharmaceutical businesses in the EU have been

[1] See, "Biotechnology in Europe" 2014 at 13; published jointly by Europa-Bio and EY, accessed at: http://www.ey.com/Publication/vwLUAssets/EY-biotechnology-in-europe-cover/$FILE/EY-biotechnology-in-europe.pdf.

among the leaders in this promising sector that is yielding exponential growth of treatments and therapies aimed at improving and saving lives across Europe and elsewhere.
The EU's comprehensive framework of rights-based incentives for the biotechnology industry is a foundational component of an enabling environment essential to sustaining the long-term, high-risk investments needed to realize the promise of health-related biotechnology innovation. Those rights provide certainty, essential to sustaining and growing investment by EU Member States, venture capitalists and larger companies. For the EU to remain a global leader in this branch of innovation, it is important to maintain, not erode that comprehensive framework of rights.

SPC rights compensate innovators for lost standard patent term that results from costly and lengthy development and regulatory approval timelines. As stated in the SPC Regulation, "[m]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research."[2]

SPCs currently provide right-holders the exclusive right to manufacture their approved products, including for purposes of exportation. Being the sole producer and exporter of an IP protected product from the EU market is one of the significant commercial activities through which patent owners derive economic value from their inventions. This exclusive right helps to promote investment in the research, development and production of new medicines in Europe for domestic consumption and for sale abroad.[3] The innovation-enhancing incentives of SPCs would be significantly eroded if the EU export market for high-value innovative therapeutic products were to be systematically distorted in favour of IP-infringing copycat products.

The proposed SPC manufacturing waiver is premised on contentions that it would "create thousands of high-tech jobs in the EU and many new companies." Belief that benefits will flow from eroding SPC rights is based on an academic study by Vicente and Simões, published in the *Journal of Generic Medicines* in 2014.[4] In the article, the writers argue that adopting a manufacturing waiver provision would result in substantial economic gains in the EU.[5]

The magnitude of those estimated benefits and the likelihood they will materialize has been rebutted in publications that the Commission should consider.[6] In addition, the benefits, if any, are likely to be temporary and disproportionately affect the innovative biotechnology sector, as they will result in part from exploitation of a transient technological advantage

[2] Council (EC) Regulation No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products; *see also* Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (no longer in force).

[3] European Union R&D Scoreboard, *The 2016 EU Industrial R&D Investment Scoreboard*, EUROPEAN COMMISSION (2016), httpe://iri.jrc.ec.europa.edu/.

[4] Vicente, V. and Simoes, S. (2014). "Manufacturing and export provisions: Impact on the competitiveness of European pharmaceutical manufacturers and on the creation of jobs in Europe", Journal of Generic Medicines, Vol. 11, Issue 1–2, 21 pp.35–47.

[5] Id. at 35.

[6] Sussell, J. A. et al. (2017). "Reconsidering the economic impact of the EU manufacturing and export provisions", Journal of Generic Medicines, Vol. 13, Issue 2, pp. 73–89.

enjoyed by European biosimilar producers. That advantage might for a short time allow EU biosimilar makers to capture market share from EU biologics innovators during the SPC term. But as the required technological capabilities spread globally to manufacturers in lower-cost regions the advantage held by EU biosimilar manufacturers will erode.

Structural changes to the EU's rights-based regime should not be made to exploit a potential short-term advantage at the risk of longer-term economic gains. Apart from the questionable and time-limited benefits postulated to flow from adopting the proposed manufacturing waiver, the Commission should weigh the costs in possible job loss and economic harm in the EU to the innovative biopharmaceutical sector that are predicted to result from this change. According to a recent study, implementation of an EU-wide SPC manufacturing exemption could potentially result in annual losses ranging between USD 1.34 billion to USD 2.27 billion to the European innovative biopharmaceutical industry. These losses translate to estimated direct job loss of between 4,500-7,700 (with an additional 19,000-32,000 indirect job losses) and a decrease of between EUR 215 million to EUR 364 million in R&D investment.[7]

The current EU intellectual property rights-based incentives framework, including SPCs, has fostered a robust ecosystem of innovation and generic competition within Europe. It protects and encourages the substantial investments made by the EU and others in this transformative technology. Adopting the proposal for a manufacturing waiver during the SPC term would undermine the rights-based framework that has and is making new healthcare solutions available. The EU should not alter its IP framework to facilitate exploitation of short-term technological advantage. It should instead continue to help build an innovative biotechnology future and enjoy the benefits of that policy direction.

Sincerely,

Andrew Casey
Chair, International Council of Biotechnology Associations (ICBA)
President & CEO, BIOTECanada

On behalf of ICBA members:

Africabio – Republic of South Africa

ASSOBIOTEC - Republic of Italy

[7] Pugatch, "Unintended Consequences" 2017 at 3, accessed at: http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf.

Association of Biotech-Led Enterprises (ABLE) – Republic of India

Association of German Biotechnology Companies (DIB) – Federal Republic of Germany

AusBiotech – Australia

Belgian Association for Bioindustries (BIO.be) – Kingdom of Belgium

BIO Taiwan – Taiwan

BIODeutschland – Federal Republic of Germany

BioIndustry Association (BIA) – United Kingdom of Great Britain and Northern Ireland

BIOTECanada – Canada

Biotechnology Innovation Organization (BIO) – United States of America

Costa Rican Biotechnology and Medical Device Business Association (CRbiomed) – Republic of Costa Rica

Czech Bio – Czech Republic

EuropaBio - Europe

Finnish BioIndustries (FIB) – Republic of Finland

HollandBIO – Kingdom of the Netherlands

Hungarian Biotechnology Association - Hungary

Japan Bioindustry Association (JBA) - Japan

Korea Biotechnology Industry Organization – Republic of Korea

NZBIO – New Zealand

PeruBiotec – Republic of Peru

Portugal's Biotechnology Industry Organization (P-BIO) – Portuguese Republic

Spanish Bioindustry Association (ASEBIO) – Kingdom of Spain

Swiss Biotech Association (SBA) – Swiss Confederation

The Greek Initiative on Bioeconomy – Hellenic Republic

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