Export Manufacturing Waiver for Supplementary Protection Certificates: a red flag for investment in EU healthcare biotech

PRESS RELEASE

20 February 2019, Brussels: As the Association representing the European biotechnology industry, EuropaBio is fully committed to the development of a legislative environment which facilitates the creation of EU jobs and growth as well as new solutions to healthcare challenges. We therefore note, with utmost concern, the recent agreement by the EU co-legislators on the Supplementary Protection Certificate (SPC) Export Waiver, which was endorsed by the Member States’ Deputy Permanent Representatives today.

EuropaBio Secretary General, Joanna Dupont-Inglis, commented: “The revision of the EU IP framework, to introduce a SPC manufacturing waiver, is a regrettable example of well-meaned but, ultimately, counterproductive policy making, with far-reaching negative impacts on EU competitiveness. It is the small healthcare biotech companies, which are at the cutting edge of creating innovative technologies addressing patient’s unmet needs, that will be hardest hit. These companies, seeking treatments for some of our most devastating and difficult to tackle diseases, take the highest financial risks and rely heavily on investors’ money, often without making any profits for years. They are, therefore, critically dependant on a robust and predictable IP framework.”

EuropaBio supports the overall objective of improving the global competitiveness of EU generic/biosimilar sector, but feels strongly that the agreement on the SPC Export Manufacturing Waiver is at odds with this goal.

In addition, allowing the stockpiling of SPC-protected products, beyond the original export intent, only serves to further undermine confidence in the stability of the EU IP framework at a time our industry is facing increasing global competition. It diminishes the value of investments already committed that had previously been directly incentivised by the SPC framework itself.

Concluding, Dupont-Inglis commented: “What’s needed now is a reinforced incentives framework in order to reassure the global investment community of the EU’s capacity and commitment towards delivering breakthrough care and cures to patients.”

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Additional information: Europabio SPC waiver position paper

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a bio-based and zero-waste economy. EuropaBio represents 75 corporate members and 17 national biotechnology associations and bioregions.

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