JONES DAY

COMMENTARY

JUNE 2018

IN SHORT

The Situation: On May 28 and 29, 2018, the European Commission ("Commission") published two studies aimed at examining the economic and legal impacts of the European Union's regime on Supplementary Protection Certificates ("SPCs") in particular, as well as on pharmaceutical incentives and rewards in general.

The Impact: The publication of these studies occurs in the context of a broad reflection on potential changes to the EU legislation around pharmaceutical incentives and rewards. The evidence and analysis contained in the studies has provided the background for the Proposal for a Regulation concerning the SPC for medicinal products published on May 28, 2018.

Looking Ahead: These recent developments may have significant impact on the pharmaceutical industry, including potentially leading to a reduction of investment in R&D—and consequently innovation—in the European Union.

EU institutions are more than ever set on reevaluating the value of innovation in the pharmaceutical sector against affordability of medicinal products and sustainability of health care systems. Indeed, in a time of concern regarding EU Member States' public debts and public health expenditure, the European institutions have for years undertaken a review of pharmaceutical incentives and rewards.

In October 2015, the Commission Single Market Strategy identified the need to modernize the protection of pharmaceuticals. In June 2016, the European Council invited the Commission to analyze the impact of the pharmaceutical incentives and rewards on innovation, availability, and accessibility of medicinal products. The European Parliament later backed this approach through the adoption in 2017 of a Resolution on EU options for improving access to medicines, in which it called for a framework to "promote, guarantee and reinforce" the competitiveness and use of generic and biosimilars.

The Studies

The Commission, on May 29, 2018, released the long-awaited "Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe," conducted by Copenhagen Economics.

> Importantly, the Study concludes that while the protection for pharmaceutical products in the European Union is among the strongest in the world, the effective protection period of medicinal products decreased from 15 to 13 years between 1996 and 2016.

The Study reviews the pharmaceutical incentives and rewards available in the EU, i.e., the SPC, regulatory data and market protection, market exclusivity for orphan medicinal products, and the six-month extension of the SPC, which is relevant for pediatric medicinal products. It draws a detailed analysis of the incentives' use and overall economic effects on innovation, availability, and accessibility of medicinal products.

Importantly, the Study concludes that while the protection for pharmaceutical products in the European Union is among the strongest in the world, the *effective* protection period of medicinal products decreased from 15 to 13 years between 1996 and 2016. The Study suggests that this trend can be explained by the average product development time in the European Union having increased from 10 to 15 years. According to the Study, this could be the result of both an increase in EU and national regulatory requirements for the placing on the market of medicinal products and of the fact that more risky and complex research and development projects are being undertaken.

The Study also suggests a direct relationship between protection and innovation on one side and a delay on the entry of generics and subsequent downward push on prices. The Study does not go as far as suggesting what is the "right" balance between innovation and generics entry but does suggest that circumventing the trade-off between these two goals would be the best solution.

Generally, doubts remain as to whether the Study has correctly taken into account the value and importance of "secondary" patents such as second medical use patents. The Study concludes that it "would be ideal to secure a sufficient period of protection and reduce uncertainties associated with

developing medicinal products in order to incentivize innovation, while finding other ways of curbing high prices". It is not clear, however, what these "other ways" should be.

Also as part of the incentives review, the Commission released on May 28, 2018, a "Study on the Legal Aspects of Supplementary Protection Certificates in the EU," prepared by the Max Planck Institute for Innovation and Competition. This Study analyzes the functioning of the system of SPCs established by Regulation 1768/92/EEC for medicinal products and Regulation 1610/96/EC for plant protection products. The Study addresses the impact of the Court of Justice of the European Union's case law on the SPC system, the practice of National Patent Offices, and possible models for creating an SPC-manufacturing waiver.

The Legislative Proposal

The evidence and analysis contained in the two described studies has already provided the background for a Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the SPC for medicinal products published by the Commission on May 28, 2018.

The SPC Proposal introduces a "manufacturing exemption for export purposes" to the protection conferred by SPCs. This would allow EU-based companies to manufacture a generic or biosimilar version of an SPC-protected medicinal product during the term of the certificate if this is done exclusively for the purpose of exporting the generic or biosimilar to a non-EU market where protection has expired or never existed.

Not surprisingly, the Proposal has immediately faced important criticisms from the originator industry, notably from the European Federation of Pharmaceutical Industries and Associations. We will shortly publish a separate *Commentary* on the Proposal.

TWO KEY TAKEAWAYS

1. The EU incentives review could potentially lead to further proposals to amend the applicable EU legislation, prompting legal uncertainty for the industry and potentially leading to a reduction of investment in R&D—and consequently innovation—in the European Union.
2. The significant impact of these recent developments on the pharmaceutical industry require careful monitoring of the European institutions' actions regarding the framework for pharmaceutical incentives in the European Union. This is definitely a space industry will continue to watch.


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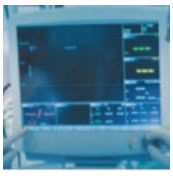

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