

ECIPE PRESS RELEASE — NEW POLICY BRIEF

Unintended and Unattended Consequences: The Opportunity Costs of Reducing Exclusivity Rights for Intellectual Property

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Brussels, Belgium, 14th December 2017 - The European Commission is reviewing the use of supplementary protection certificates (SPCs), a patent term extension motivated by the increasing length of market approvals for pharmaceuticals. The initiative is driven by EU Health Ministers thinking that changes in patent exclusivity rights will lower their expenditures on medicines. The generics industry's push for a waiver has been backed by a promise to create additional jobs in the EU, but the evidence behind that promise is doubtful.

Available analyses suffer from a profound lack of appropriate data and disregard the opportunity costs of an SPC export waiver for EU Member States. In this paper, we will highlight that an SPC export waiver could prompt the EU's innovative pharmaceutical companies to 1) reconsider their research and manufacturing activities in some EU Member States and 2) adapt product placement and pricing strategies in several high-income EU Member States to compensate for (the risk of) lower revenues. Given corporate strategies to overcome regulatory fragmentation, and experiences from market launch sequencing in the EU, an SPC export waiver could entail higher drug prices for governments and patients in Germany, the UK, France, the Nordics, and the Benelux.

The effective erosion of exclusivity rights in the EU would also come at the risk of losing innovative capacity and 'high value-added jobs' to other jurisdictions that offer a more attractive mix of IP protection and research and production costs. Moreover, the EU's trade and investment policy has been to get other countries to allow patent term extension to compensate for revenue shortfalls due to longer regulatory approval times. If the EU allows for exports to these third markets when exclusivity rights are still active, it would erode the EU position vis-à-vis countries with weak protection of intellectual property.

Publication details:

Unintended and Unattended Consequences: The Opportunity Costs of Reducing Exclusivity Rights for Intellectual Property, *ECIPE Policy Brief No. 4/2017*

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