

February 5, 2019

OPEN LETTER TO THE EUROPEAN INSTITUTIONS

I am writing in my capacity as the President of EFPIA, the European Federation of Pharmaceutical Industries and Associations, and as Chairman of the Executive Board and CEO of Merck. I would like to express my deepest concern with the ongoing debate on the proposal to amend the Supplementary Protection Certificate (SPC) Regulation to introduce an SPC manufacturing waiver.

The compromise provisions proposed by the European Parliament diverge significantly from the limited scope of the initial proposal by the European Commission and undermine the strong and reliable intellectual property (IP) rights in Europe. These rights are key elements in sustaining Europe's investment climate and in attracting top performing high-technology sectors.

Innovation is essential for the biopharmaceutical industry. We need robust and predictable IP rights to advance the development of new treatments. Since the 1990s, the innovative pharmaceutical industry has brought over 1,100 new medicines to patients, clearly improving their lives.

Alongside that pursuit for new medicines, we contribute to a healthier economy in Europe that can compete on a global scale. In 2017 our industry invested EUR 35 billion in research and development in Europe. The companies of our sector employ 750,000 people in Europe and generate three to four times more employment indirectly. These investments are principally made possible by the strong and unique IP framework in Europe, of which the SPC is a key component.

Our industry is extremely concerned that the proposal for the SPC manufacturing waiver will put patient access to medical innovation, highly skilled jobs and investment at risk.

The call for introduction of generic and biosimilar stockpiling in Europe two years before SPC expiry, as voted by the European Parliament, has not been subject to any impact assessment. Moreover, the proposed application date sets a dangerous precedent for retroactive application, impairing vested rights acquired as a result of significant investments by our companies.

International competition to attract life science investment is growing significantly and there is a great deal at stake for Europe. A strong IP system remains crucial for companies deciding where to make their research and development investments.



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For our sector it is essential that Europe's world-class protection of intellectual property rights be guaranteed in future. We are deeply concerned that IP rights in Europe are being weakened, while the EU demands exactly the opposite from its trading partners.

Thank you in advance for your kind consideration.

Yours sincerely,



Dr. Stefan Oschmann

President of EFPIA

Chairman of the Board and CEO Merck



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