

Mrs Elzbieta Bienkowska
Commissioner for Internal Market, Industry
Entrepreneurship and SMEs

Rue de la Loi 200
1049 Brussels
Belgium

Brussels, 9 March 2018

Dear Mrs Bienkowska,

On behalf of BIO.BE I am contacting you regarding an issue that will have a significant impact on Belgian and European industries in general. BIO.BE is the Belgian federation of companies active in life sciences and biotechnologies. With nearly 90 life sciences members amongst the 750 affiliated to essenscia, BIO.BE promotes the excellence of its members to deliver innovative products, services and technologies for a better life today and in the future.

We are concerned about the ongoing discussions within the European Commission regarding the revision of the European framework of incentives for intellectual property ('IP incentives'). Most notably, we are worried about the considerations to soften the protection granted by the so-called Supplementary Protection Certificates ('SPCs'). These certificates compensate a part of the period of patent protection that is lost due to lengthy clinical trials and authorisation procedures that newly developed medicines need to pass before their market launch. Since these evaluations are conducted already during the 20 year term of patent protection, only 8-12 years of protection effectively remain.

It is now being considered to reduce the SPC patent extension by introducing a so-called manufacturing waiver. This measure would allow manufacturers of generics and biosimilars to manufacture products despite the ongoing SPC protection.

IP incentives are crucial for our industry to attract investments into research & development ('R&D') of new medicines, since they guarantee R&D to be economically profitable. The protection granted by the SPCs is therefore enormously important for sustainable research and development of innovative medicines. Our members have developed their long-term strategies on the basis of the existing, solid IP framework. Investments in the innovative pharmaceutical industry are high-risk and long-term; sustainability of these investments can only be achieved by a high level of certainty in the returns and the ability to continue the investments in the future.

Belgium and all other European Member States are highly dependent on the innovative force of pharmaceutical R&D. Introducing measures that would weaken the existing IP incentives would diminish the reliability of the entire intellectual property framework, causing drastic drops in investments into R&D of new and innovative medicines. Without these investments our members and all other research based pharmaceutical and biotechnology companies would not be able to continue carrying out expensive but necessary research and development. Not only would this threaten the economic viability of businesses but further cause a standstill in medical progress.

Research based pharmaceutical and biotechnology companies in Belgium and throughout all European Member States have reached a high level of competitiveness. European businesses are "world leaders" in pharmaceuticals

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and healthcare biotech.¹ Biotechnology is thus a key sector for Europe in the 21st century. The European Commission should not take any measures that pose a threat towards the competitiveness and role of European businesses in this sector.

On behalf of our members I ask you, dear Mrs Bienkowska, that you take the aforementioned arguments thoroughly into account and that you refrain from any measure that would put the innovative Belgian and European pharmaceutical sectors at risk. I implore you not to weaken the intellectual property framework which is a cornerstone of the global success and competitiveness of our Belgian members and of European businesses as a whole.

I of course stand at your disposal shall you have any questions or require any further information.

Thank you very much for your consideration.

[Redacted]
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Frederic Druck
Secretary General

This letter was sent to the following personalities:

Vice-President Jyrki Katainen
Commissioner Elżbieta Bieńkowska
Commissioner Marianne Thyssen

MEP [Redacted]
MEP [Redacted]
MEP [Redacted]
MEP [Redacted]
MEP [Redacted]

¹ COM(2017) 707 - A balanced IP enforcement system responding to today's societal challenges