January 12, 2018

Jyrki Katainen
Vice President
Jobs, Growth, Investment, and Competitiveness
European Commission
Brussels, Belgium

Dear Vice President Katainen:

Our associations write to voice their shared concerns regarding the European intellectual property (IP) incentives review. This exercise risks undermining the innovative industries at the cutting edge of medical innovation and discovery in the EU and more broadly.

Europe is at the forefront of healthcare innovation and IP protection, with 28 percent (60 million) of all European jobs tied directly to IP-intensive industries. According to the U.S. Chamber of Commerce's Global Intellectual Property Index, European nations are among the global leaders in IP protection. Consequently, Europe is a top destination for investment, clinical trials, and diffusion of medical technologies. Unfortunately, the Commission's review of IP incentives risks sending the opposite signal as to the prospects of the European R&D sector and jeopardizing the EU's industrial competitiveness and future growth.

IP incentives are essential for the innovative research and development-based pharmaceutical industry. Europe's IP incentives framework comprises several components that address a complex range of medical needs: patents, Supplementary Protection Certificates (SPC), regulatory data protection and rewards for pediatric and orphan medicinal products. These provide transparency and certainty that facilitate investment decisions, which carry outsized risk in the healthcare innovation space. Any step towards weakening these incentives not only threatens the development and diffusion of medical advancements, but could undermine the European economy.

A major concern regarding the Commission's review is the expected proposal to adopt a manufacturing waiver for SPCs. Proponents of the waiver have claimed that weakening the IP rights environment will create numerous jobs and economic benefits for Europe. Recent studies have debunked these assertions. In fact, an SPC waiver could cost Europe 4,500-7,500 direct jobs in this R&D-intensive industry with an

additional loss of between 19,000 and 32,000 indirect jobs.[1] This could result in a decrease of EUR 215 million to EUR 364 million in R&D investment. Moreover, the evidentiary record shows that an SPC waiver would do little to facilitate the growth of the European generics industry.

This disparity in evidence indicates the need for a more robust impact assessment of the introduction of a manufacturing waiver. It would be unwise to take any action while clear doubts remain about the actual impact of the proposed legislative change, not to mention the risk of spillover in reopening the SPC regulation for full review. We urge you to reject the SPC waiver proposed under the European IP incentives review and to preserve the European IP incentives framework as a whole.

The current IP incentives framework has worked for Europe, generating a healthy market for both innovation and generic competition. As challenges to healthcare— from Alzheimer's to Zika —grow ever more complex, an environment of certainty in Europe promotes, not hinders, investment and research into unmet healthcare needs. Any weakening of the EU's IP incentives framework would undercut pharmaceutical R&D investment by large and small innovators alike, and put European innovators at a disadvantage with competitors based in countries with more competitive IP systems. In fact, small and medium sized businesses develop over one-quarter of all new medicines and up to 61% of innovative orphan medicinal products.

We are ready and willing to work with you and your staff at the Commission, as well as national governments and other European stakeholders, to find a path forward that sustains and advances Europe's IP environment, economic competitiveness, and patient welfare.

CC: Lowri Evans, Director General DG GROW

Amareylis Verhoeven, Head of Unit, DG GROW

Sincerely,

AmCham Bulgaria

AmCham EU

AmCham Germany

AmCham Gibraltar

AmCham Ireland

AmCham Italy

AmCham Netherlands

AmCham Norway

AmCham Slovakia

AmCham Spain

AmCham Sweden

[1] Pugatch, Meir and Torstensson, David P and Laufer, Ma'ayan, *Unintended Consequences: How Introducing a Manufacturing and Export Exemption to Supplementary Protection Certificates Would Weaken Global Standards of IP Protection and Result in Direct Losses to Europe's Research-Based Biopharmaceutical Industry* (October 2, 2017). Available at SSRN: https://ssrn.com/abstract=3051545