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Dear Commissioner

We write as an informal coalition of international civil society organisations interested in innovation policy. We welcome the Commission's Roadmap for the Pharmaceutical Strategy, which comes at a pivotal time for Europe as it looks to recover economically from Covid-19, and deal with other structural challenges such as ageing populations and increasing economic competition from markets outside its borders.

This letter briefly elaborates four areas we believe the Roadmap should focus on in order to retain Europe's competitiveness and ensure health-related innovation meets the future needs of Europe's population:

- Maintain high standards of IP protection to promote economic growth and protect the EU's global competitiveness
- Strengthen the EU's innovation ecosystem by ensuring all publicly-funded research institutions can license and profit from their research
- Reform the patent system to strengthen R&D incentives for the diseases of ageing and other unmet needs
- Ensure GDPR does not present a barrier to data-driven drug development in the EU.

1. **To retain the EU's global competitiveness and promote post-Covid economic recovery, the Roadmap must maintain the EU's high standards of IP protection.**

The Roadmap comes when European countries are urgently looking to re-start growth as a result of Covid-19. Part of the answer is for Europe to focus on high-value knowledge-based industries. These offer major growth opportunities: in the EU, for instance, patent-intensive sectors constitute 17% of all employment and 15% of total GDP. The Roadmap should build on existing EU strengths, in particular its world-leading biopharmaceutical industry.

Biopharmaceutical R&D is high risk and capital-intensive, so protection of intellectual property rights (IPRs) is key. Strong European IPRs are especially important in the context of growing global competition from emerging markets, many of which are strengthening their own regimes for the protection IPRs (notably China).

EU member states already preside over strong systems for the protection of patent rights, which the Roadmap must preserve and strengthen. The Roadmap must avoid the temptation to weaken IPRs as a means of containing spending in drugs given that other cost drivers are at the root of healthcare inflation.<sup>lii</sup> Instead it should recognise IPRs are a strong determinant of innovation and access. Evidence shows stronger IP protections are associated with speedier in-country launches of new drugs; and conversely, weak IP rights cause new drug launch delays of many years.<sup>iii, iv, v, vi</sup>

## **2. To strengthen Europe's innovation ecosystem, the Roadmap should allow all publicly-funded EU to license and profit from their intellectual property.**

The EU is home to several major biopharmaceutical companies but has struggled to create life science innovation clusters to match those in the US and increasingly elsewhere. These clusters drive collaboration between governments, academia, venture capital, small biotech companies and large biopharmaceutical companies, and generate significant economic value, employment and innovation.

In the United States a clear approach to the intellectual property created by universities has been central to the development of its strong innovation ecosystem. In particular, the 1980 Bayh-Dole Act gave universities and non-profit research centres rights to the intellectual property they develop from federally funded research, thereby boosting commercialisation activity at these institutions and bringing more valuable innovations to the marketplace. Over 200 new drugs and vaccines have been developed through public-private partnerships facilitated in part by the Bayh-Dole Act.<sup>vii</sup> Between 1996 to 2017, university patent licensing contributed \$865bn to US GDP and supported up to 5.8m jobs.<sup>viii</sup> Bayh-Dole has also driven the growth of dozens of life science innovation clusters, most notably Boston and San Francisco.

EU firms by contrast generally struggle to translate public funding of academic research into patents and innovations that drive economic growth. This is a result of a fragmented and uncoordinated approach to the commercialisation of biopharmaceutical inventions originating from publicly-funded universities.

Although many EU member states (notably Germany, Finland, Italy and Norway) have technology transfer legislation supporting university commercialisation of publicly-funded research, there is a non-transparent and non-uniform system for determining who owns university inventions. Each country has different rules affording different levels of freedom – and in many cases no rights at all for universities over their intellectual assets.<sup>ix</sup> This lack of harmonisation creates uncertainty for potential investors. The Roadmap should therefore consider introducing similar legislation to the Bayh-Dole act to boost Europe's innovation ecosystem.

## **3. Align innovation to unmet health needs by strengthening the patent system**

Europe has an ageing population yet there is a lack of treatments for many of the associated diseases, including neurological and degenerative diseases, and drugs for early stage cancer. Unfortunately, the patent system discriminates against commercial R&D into such diseases.

Due to their complexity, R&D for these diseases typically take much longer than for infectious diseases, frequently eating up most of the 20-year patent term before any commercial sales can take place.<sup>x</sup> As a consequence, many companies have abandoned disease areas that require long-term trials because the patent system does not allow sufficient time to recoup research costs.<sup>xi</sup>

The EU's system of Supplementary Protection Certificates (SPCs) grants up to five years patent term extension to compensate for delays in regulatory approval process (and additional six months for paediatric drugs), but this is often not enough time to allow a sufficient period of market exclusivity for the most challenging diseases. The dilution of the SPC manufacturing waiver in 2019 further reduced intellectual property incentives to invest in society's most pressing needs.

The Roadmap must revisit the duration of patent terms in order to ensure that R&D for the most pressing health concerns is sufficiently incentivised. At a minimum, the Roadmap should preserve the SPC system, including for orphan and paediatric drugs. It should consider recalibrating it for diseases that have particularly long R&D timelines.

#### **4. Strengthen data driven drug R&D by reforming GDPR**

Data-driven drug development will accelerate access to more effective and affordable treatments. Increasingly sophisticated data and data-driven analytical tools such as Artificial Intelligence can be deployed in many areas of the R&D lifecycle, from automatically screening chemical compounds to optimizing clinical trials. Facilitating data-driven drug development is crucial to the future competitiveness of the EU life science sector.

The potential of data-driven drug development is limited by EU rules around the sharing of data, specifically the GDPR which prevents sharing of EU-sourced data except with the handful of small non-EU jurisdictions that have near-identical legislation.

Biopharmaceutical R&D increasingly involves international collaboration and data sharing across borders, often outside the EU. GDPR limits the ability of EU-located biopharmaceutical companies to participate in these international collaborations. Further, it reduces the size of data sets, and introduces inefficiencies by preventing data processing from taking place outside the EU.<sup>xi</sup>

The Roadmap should therefore investigate reforms to the GDPR to prevent any disadvantage to EU companies in this vital area.

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We look forward to your feedback and to the opportunity to discuss these proposals with you further.

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<sup>i</sup> EC (2012), Long-term care: need, use and expenditure in the EU-27, available at [http://ec.europa.eu/economy\\_finance/publications/economic\\_paper/2012/pdf/cep469\\_en.pdf](http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/cep469_en.pdf)

<sup>ii</sup> OECD Health Statistics, 2017

<sup>iii</sup> Lanjouw, Jean (2005). "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry". Available at SSRN: <http://ssrn.com/abstract=984259>

<sup>iv</sup> Borrell, Joan-Ramon (2005). "Patents and the faster introduction of new drugs in developing countries". *Applied Economics Letters*, 12 (2), 379–382.

<sup>v</sup> Kyle, Margaret & Qian, Yi (2014). "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS". NBER Working Paper No. w20799. Available at SSRN: <https://ssrn.com/abstract=2543650>

<sup>vi</sup> Cockburn, Iain M., Jean O. Lanjouw, & Mark Schankerman (2016). "Patents and the Global Diffusion of New Drugs." *American Economic Review*, 106(1): 136-64.

<sup>vii</sup> Alliance of University Technology Managers, "Driving the Innovation Economy" Factsheet, available at [https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM\\_FY2018\\_Infographic.pdf](https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf)

<sup>viii</sup> Ibid

<sup>ix</sup> Bagley, Constance E. and Tvarnec, Christina D., Promoting 'Academic Entrepreneurship' in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient (September 12, 2015). *Duke Journal of Comparative & International Law*

<sup>x</sup> Leitzan, Erika, The Drug Innovation Paradox (April 7, 2017). University of Missouri School of Law Legal Studies Research Paper No. 2017-12.

<sup>xi</sup> Budish, Eric, Benjamin N. Roin, and Heidi Williams, (2015) "Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials," *American Economic Review*, 105(7): 2044-85

<sup>xii</sup> Stevens, P & Cory, N (2020) "Building a global framework for digital health services in an era of Covid-19," Information Technology and Innovation Foundation: Washington DC

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