April 23, 2025

Mr. Stéphane Sejourne
Executive Vice President
of the European Commission
Prosperity and Industrial Strategy

Mr. Olivér Várhelyi
European Commissioner
Health and Animal Welfare

Ms. Henna Virkkunen
Executive Vice President
of the European Commission
Technology Sovereignty,
Security and Democracy

Ms. Ekaterina Zaharieva
European Commissioner
Startups, Research and Innovation

Mr. Maroš Šefčovič
European Commissioner
Trade and Economic Security,
Interinstitutional Relations
and Transparency

Honorable Members of the European
Commission
Berlaymont
Rue de la Loi 200
1049 Bruxelles

To the attention of the European Commission:

On behalf of the Council for Innovation Promotion (C4IP), we write to express our profound concerns regarding some of the proposed revisions to the General Pharmaceutical Legislation (GPL) and "Patent Package." We are a group of former U.S. federal judges and U.S. Patent and Trademark Office leaders with expertise in trade, technology, and innovation policy. We believe this proposed shift in the European Union's approach to intellectual property will have severe consequences for the entire Western world.

Strong and predictable intellectual property protections incentivize investment, research, and technological advancement. Weakening these protections will have far-reaching ramifications — creating regulatory instability and deterring the necessary high-risk investments that drive progress in biotechnology, artificial intelligence, and other cutting-edge fields.

The EU's actions will reverberate far beyond its borders. Historically, the EU, along with the United States, has served as a bellwether for global IP policy; if either jurisdiction weakens its protections, other countries are likely to follow suit. This domino effect would further erode the global innovation landscape at a time when China continues to willfully devalue European and American intellectual property to serve its national interests.

Specifically, we are concerned with the Commission's proposal to reduce regulatory data protection periods in the General Pharmaceutical Legislation. Regulatory data protection serves as a vital exclusivity window, safeguarding innovators' proprietary clinical trial data from premature competitor access. Strong regulatory data protection provisions are imperative for incentivizing investment in high-risk research areas such as rare diseases and next-generation biologics. Reducing these protections would make Europe a less attractive market for drug development, ultimately delaying or curtailing entirely patient access to life-saving treatments.

Furthermore, the General Pharmaceutical Legislation revisions, as proposed by the commission, impose an unrealistic and counterproductive requirement that companies launch their products in every EU member state within two years as a condition for maintaining the current period of exclusivity for regulatory data. This mandate disregards the complexities of market access, including differences in reimbursement processes and regulatory timelines across the EU member states. Rather than accelerating patient access, this provision would create additional burdens for biopharmaceutical innovators, stifling progress rather than facilitating it.

Among several concerning aspects of the recent proposals is the creation of a centralized and expanded framework for compulsory licensing. Under the proposed regulation, the European Commission may unilaterally issue a Union-wide compulsory license during any "Union-level crisis or emergency" — a term that is troublingly not defined, presenting the possibility that its vagueness may be manipulated to the detriment of innovator rights-holders. Safeguards to prevent such abuse are called for under the TRIPS Agreement but appear to be lacking in this proposal. First, TRIPS requires that each country decide on a compulsory license independently, consistent with its national laws, but the proposal overrides this country-by-country process, instead only requiring (at most) consultation with Member States as part of an advisory body in advance of a Commission decision. Second, in addition to disallowing groups of states to collectively issue a compulsory license, TRIPS requires

that any compulsory license be subject to independent review under Art. 31(i). But such review is not available here under the normal processes set forth under Arts. 6-9. In sum, by allowing forced licensing based on declarations of an undefined "crisis," eliminating the TRIPS requirement of country-level review, and omitting independent checks, the proposal significantly lowers the bar for overriding patent rights — and places the EU at odds with its international IP obligations.

Some aspects of the Supplementary Protection Certificates (SPCs) proposal would further undermine incentives for innovation. SPCs function as a critical mechanism to compensate for a portion of the patent life lost during lengthy development and regulatory approval processes, allowing innovators to recoup their investments. Creating a unitary EU-wide SPC is a welcome development. But by allowing third parties to challenge SPCs before approval, the proposed reforms introduce unnecessary legal and financial uncertainty.

While several of the General Pharmaceutical Legislation and the Patent Package proposals are directed at pharmaceutical innovation, combined, these changes would have far-reaching consequences for research-intensive industries in all areas of technology. Notably, the compulsory licensing proposal applies to all utility patents. Collectively, the proposals send troublingly mixed messages, suggesting that IP rights are contingent on shifting and unpredictable regulatory developments and other unforeseeable contingencies. To promote a robust innovation ecosystem, the Commission should reconsider these proposals to ensure that they more clearly provide innovators secure rights for predictable periods of time.

Beyond Europe, the Commission's Patent Package and General Pharmaceutical Legislation could — and likely would — trigger a harmful domino effect. The European Union has long been a global standard-bearer for IP protections. The precedent set by weakening these safeguards would legitimize and accelerate global efforts — particularly by China — to erode innovators' rights. The Commission's own report, authored by former President of the European Central Bank Mario Draghi, underscored that strengthening — not weakening — IP protections is essential for maintaining Europe's economic competitiveness and technological leadership.

This warning is not theoretical. China recently issued proposed regulatory data protection measures that, like the EU Commission's, would tie the length of protection to how quickly a company launches its product in the local market. China has also aggressively sought to reshape global IP rules to its advantage, as evidenced by the 2023 Chongqing court

decision, which attempts to unilaterally set global licensing rates for non-Chinese patents. China's interventionist approach strategically weaponizes IP regulations against foreign rights holders, threatening Western advancements in 5G, artificial intelligence, quantum computing, and biotechnology. The European Commission must not enact policies that validate such predatory tactics.

In line with this, we welcome the Commission's recent decision to withdraw the Patent Package's Standard Essential Patents (SEP) regulation, which would have granted the EU Intellectual Property Office the authority to create a regulatory body within an agency without any current expertise in patents with the unprecedented ability to set royalty rates for patents covering highly technical and valuable standards.

The Commission's decision to course-correct on SEPs underscores the necessity of maintaining a balanced, innovation-friendly regulatory approach. This decision marks an important step in recognizing that regulatory overreach in IP policy is counterproductive. We are encouraged that the Commission acknowledged these concerns raised by European and other innovation-driven interests.

C4IP was at the forefront of efforts to highlight the risks flowing from the EU SEP regulations through in-depth analyses, direct engagement with policymakers, and public discourse. Our co-chairs and former USPTO directors Andrei Iancu and David Kappos submitted formal comments to the European Commission alongside other former U.S. government officials. We also engaged with the EU Parliament and previously corresponded with then-U.S. Secretary of Commerce Gina Raimondo ahead of a summit on transatlantic economic cooperation.

Our current letter is in keeping with these prior engagements, likewise aiming to encourage a reassessment of the recent IP proposals so that any enacted reforms will ultimately strengthen — rather than diminish — the EU's foundational laws for innovation. Looking ahead, the focus must be on fostering incentives for high-risk innovation rather than imposing barriers that stifle technological progress. Competitiveness in biopharmaceuticals, advanced manufacturing, and emerging technologies depends on a stable, predictable regulatory environment that does not stifle innovation through regulatory overreach.

Accordingly, we urge the Commission to reconsider the aspects of the proposed revisions to the General Pharmaceutical Legislation and the Patent Package discussed herein. Thank

you for your careful consideration of these concerns, and we stand ready to provide further insights and expertise as you deliberate on these critical policy issues.

Sincerely,

Andrei Iancu
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Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2018-2021)

David J. Kappos
Co-Chair, Council for Innovation Promotion (C4IP)
Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2009-2013)

Cc:

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