December 4, 2025

Ambassador Jamieson Greer
United States Trade Representative
Office of the United States Trade Representative
600 17th St. NW
Washington, D.C. 20508

Dear Ambassador Greer:

On behalf of the Council for Innovation Promotion (C4IP), a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere, I write in support of your ongoing efforts to negotiate a fair, reciprocal, and balanced trade agreement between the United States and the European Union.

C4IP greatly appreciates your office's charge as captured in the Joint Statement on a United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade to pursue "high-standard commitments related to intellectual property rights protection and enforcement," with the European Union. Intellectual property (IP) rights are a cornerstone of U.S. innovation and manufacturing, underpinning a variety of our most important industries, from energy to technology to medicines. They support 44% of jobs and enable U.S. businesses to compete on the global stage.

Securing fair and reciprocal intellectual property policies in Europe is therefore vital to America's economic and technological strength. In light of that objective, we wish to draw your attention to a set of IP-related issues in Europe that could negatively impact U.S. innovation leadership and the IP rights of U.S. companies and inventors as well as those of Europe. We hope that the Administration will urge the EU to chart a course toward a legal framework that better supports and encourages innovation.

To be sure, EU policymakers have taken several steps to strengthen the intellectual property system and spur innovation.

Earlier this year, the European Commission withdrew a proposed regulation on standard-essential patents, averting the establishment of a centralized patent licensing regime that would have weakened companies' incentives to research and develop new standardized technologies. Europe has also resisted rushing into sweeping regulation of artificial intelligence, opting for a more measured approach to ensure all rights holders are protected by any eventual rules. Indeed, U.S. lawmakers would be wise to emulate this cautious approach by protecting state governments' authority to develop and tweak AI regulations as the technology evolves.

However, other European policy proposals under consideration would take the continent — and the entire West, given American firms' extensive ties and involvement to European markets — in the opposite direction.

Of particular concern is the upcoming final revisions to the General Pharmaceutical Legislation (GPL), with trilogue negotiations between the European Parliament, Council, and Commission potentially concluding this month. This law would make a number of IP-related changes, including (1) reducing regulatory data protection (RDP) for new medicines; (2) conditioning recovery of such lost RDP term on a strict set of requirements, including launching in all 27 EU member states within a short timeframe; and (3) expanding the research-use exemption — often called the *Bolar* exemption — which allows generic manufacturers to perform non-commercial work to prepare regulatory submissions before patent expiry, to activities well beyond those limited bounds. All of these changes threaten to undermine the IP rights that innovators depend on to justify their investment in new medicines and treatments.

First, the GPL proposes to reduce the term of regulatory data protection (RDP) for innovative medicines. RDP is an essential form of protection that, for a limited time, prevents competitors from using an innovator's proprietary clinical trial data to gain marketing approval for their copycat products. This exclusivity period gives innovators an opportunity to recoup their investments, and thus incentivizes firms to conduct and fund future high-risk medical research.

Reducing the RDP term would weaken these incentives, sharply diminishing firms' ability to undertake the kind of ambitious research that is urgently needed in areas such as rare diseases, oncology, and advanced biologics. The result would be slower scientific progress and fewer breakthrough treatments for patients in both the United States and Europe.

Second, the GPL would force innovators to meet localization or launch requirements in order to receive the same length of regulatory data protection they currently receive. These conditions include mandating companies to make their products available in all 27 EU member states within just two years of obtaining marketing authorization. Such a requirement would be unworkable, especially for smaller firms, because companies often lack control over the timing of reimbursement decisions, which vary widely across national systems. Moreover, it would harm innovation, as it would force innovators to divert resources away from scientific research and toward navigating bureaucratic obstacles. Ultimately, these requirements would compound the damage caused by reduced RDP, delaying patient access to therapies and weakening incentives for companies to invest in European markets.

Finally, the GPL would needlessly expand the *Bolar* exemption, which currently permits other companies to use patented inventions for non-commercial activities related to seeking regulatory approval for follow-on products, such as generating data, gathering documentation, or submitting applications. The European Commission's proposal would extend this exemption to commercial activities, including pricing and reimbursement filings.

By shielding a broader range of pre-launch activities from scrutiny, expanding the *Bolar* exemption would make it significantly more difficult for innovators to detect potential infringement before a competing product is ready for market entry. Early detection is essential to enable patent holders to enforce their rights in a timely manner. Diminishing innovators' opportunities to identify potential infringement early would erode patent value, thereby weakening incentives to develop the innovative medicines that form the basis for later generics and biosimilars. In the end, this would harm both manufacturers and patients by weakening the pipeline of new treatments.

All of these changes are ostensibly intended to improve EU competitiveness, but would in practice erode incentives for investment in medical research, create new barriers for U.S. companies operating in European markets, and embolden rivals like China to further disregard U.S. innovators' IP rights. They could also chill investment in other high-tech fields, as investors may view these proposals as the first step in a broader shift toward weakening patent rights across Europe.

In addition to the imminent passage of the GPL and the numerous IP concerns it raises, C4IP is concerned about several other issues pertaining to standard-essential patents (SEPs), which protect widely used technological standards such as Wi-Fi and 5G.

The European Commission had previously proposed a Regulation on Standard Essential Patents that would have created a complex new bureaucracy for reviewing SEPs and setting royalty rates for licenses. By concentrating rate-setting authority in a single administrative body rather than in our current decentralized negotiating system, which has long promoted fair, reasonable, and non-discriminatory licensing terms, the proposal threatened to erode the value of SEPs and discourage U.S. and European companies from investing in next-generation standards.

Fortunately, earlier this year, the Commission withdrew the proposed SEP regulation. C4IP commended that withdrawal as a positive step not only for European competitiveness but also for the many U.S. companies developing technological standards that depend on a fair and predictable global SEP system.

Unfortunately, however, the European Parliament recently voted to sue the Commission over that withdrawal. This litigation has already created renewed uncertainty in high-tech markets, and we are deeply concerned that it could open the door to reviving elements of the withdrawn proposal. Such an outcome would have severe consequences for standards innovators. Allowing a single European agency to dictate SEP royalty rates would devalue patents held by U.S. companies and disrupt Western cooperation in high-tech markets. It would also validate China's ongoing efforts to unilaterally set below-market royalty rates and privilege its own companies over American innovators.

Separately, we are concerned by the European Commission's decision to allow major European automobile manufacturers to jointly negotiate SEP licenses. Allowing SEP implementers to collectively bargain over royalty rates creates significant negotiating disadvantages for patent holders and will inevitably artificially depress licensing rates. As U.S. Deputy Assistant Attorney General Dina Kallay recently noted, this joint-buying arrangement would be considered illegal collusion under U.S. antitrust law. If European regulators continue down this path, SEP innovators in Europe and America will face steep competitive challenges in one of the world's most important export markets.

Taken together, Europe is contemplating a number of IP-related changes that would harm U.S. innovators, consumers, and patients. Europe is one of America's most important trading partners. American companies depend on stable IP frameworks on the continent to sustain global R&D pipelines. Eroding those protections in Europe would make it harder for U.S. firms to introduce new technologies, diminish returns on innovation, and weaken domestic manufacturing and job creation tied to biopharmaceutical and high-tech supply chains.

The United States and Europe have long served as global standard-setters when it comes to intellectual property protections. And at a time when competitors like China are bending the boundaries of international IP protections, it is essential that the West form a united front in strengthening innovation, investment, and the rule of law.

As bilateral negotiations with the EU progress, we urge you to make clear that the policies described above are incompatible with Europe's and America's shared and strategically necessary commitment to a strong and predictable global IP system, as captured in the Joint Statement on a United States-European Union Framework on an Agreement on Reciprocal, Fair, and Balanced Trade. Now, before the agreement is finalized, is the moment when U.S. engagement can have the greatest impact in shaping an outcome that supports long-term innovation and strengthens the competitiveness of American and European firms. Decisive U.S. leadership will send a strong message around the globe that America is prepared to defend the rights of its inventors and will not allow our trade partners — from Europe to China and elsewhere — to ignore or circumvent their agreements to respect U.S. IP rights.

C4IP is grateful for USTR's continued leadership in advancing policies that reward innovation and safeguard U.S. competitiveness. We stand ready to assist in any way we can as you work to strengthen IP protections, ensure a level playing field for American innovators, and reinforce U.S. leadership in the global innovation economy.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)