January 31, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Director Vidal,

The Council for Innovation Promotion (C4IP) appreciates the opportunity to respond to your October 4, 2022 Request for Comments (RFC) on Initiatives to Ensure the Robustness and Reliability of Patent Rights (87 Fed. Reg. 60130).

The RFC sought "initial public comments on proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition."

Founded and chaired by former directors of the USPTO, C4IP is a bipartisan coalition dedicated to supporting a strong, effective patent system that bolsters U.S. innovation, strengthens our nation's economic competitiveness, and improves lives everywhere.

During the last few months, our coalition has engaged policymakers on a number of fronts and sought to facilitate productive and informed conversations relevant to the intellectual property system. From a discussion of the proposed TRIPS waiver with former U.S. Secretary of Commerce Gary Locke to letters addressing the Patent Eligibility Restoration Act of 2022 (S.4734), the Interagency Patent Coordination and Improvement Act of 2022 (S.4430), and misuse of the Bayh-Dole Act, C4IP has distinguished itself as a non-partisan partner to those considering policies impacting America's intellectual property system.

In this spirit, we hope the candid nature of our response is helpful.

In general, we are concerned with the direction of the questions posted by the RFC, as they imply that our patent system needs an extensive overhaul. It does not.

By their very nature, patents are forward-looking instruments in that they last a number of years. That is why the patent system is so dependent on stability and predictability. Importantly, patent policy and administration should be approached with a steady hand, and changes need to be measured and thoroughly vetted both for their need as well as for their

consequences. Many in the public may read this RFC as signaling that the entire system could soon change in unpredictable ways — negatively affecting both the value of patent rights as well as the interest of new entrants to seek and rely on patent rights.

Consequently, while it is appropriate for the agency to lead public discussions and engage in a productive dialogue on improvements to the system, the current RFC directs the public to question fundamental functions of the patent system. The framing of the questions suggests that the USPTO is pursuing an imbalanced inquiry into our patent system, one that wrongly assumes that major problems exist. Even as the USPTO is pursuing an ambitious goal of quadrupling the number of U.S. inventors, the RFC gives little consideration to the needs of individual innovators, small companies, and startups and may discourage those new entrants from putting in the effort needed to obtain rights.

Our response to the RFC is guided by four themes: Reliance on Accurate Data in Policymaking, Maintaining a Balanced Perspective, A Grounded View of Patent Quality, and The Weight of Unintended Consequences.

Reliance on Accurate Data in Policymaking

We are concerned that inaccurate and misleading data and reports are disproportionately driving public policy discussions related to the patent system.

For example, there is no evidence that drug innovators routinely submit misleading or contradictory statements to the FDA and USPTO — and certainly not for the purpose of obtaining unwarranted patents. This narrative is fueled by faulty and unsubstantiated drug patent numbers released by activist organizations like the Initiative for Medicines, Access & Knowledge (I-MAK). And, in fact, based on such claims from I-MAK, Members of Congress have introduced legislation attempting to address this alleged activity (see, e.g., S.4430, Interagency Patent Coordination and Improvement Act of 2022).

The underlying premise of these activist groups is faulty. There is no evidence that innovators make such submissions in order to improperly obtain multiple patents on the same invention, as opposed to protecting their multiple inventions as appropriate under the laws. Nor is there evidence that the patent system is improperly impeding the launch of less-expensive generics. On the contrary, generic penetration in the United States is among the highest of all OECD countries. Today, about nine in 10 U.S. prescriptions are filled with generic drugs. On average, generics only fill about half of all prescriptions written in OECD countries.

All this while the United States remains the world's most prolific innovator of life-saving pharmaceuticals. Indeed, two-thirds of all new drugs approved over the past decade

originated in U.S. labs, among them numerous medical breakthroughs. The government should be very careful before disturbing this precious balance that has been achieved over the last several decades through carefully-crafted and well-balanced major legislation, including the Hatch-Waxman Act, the Bayh-Dole Act, and the Biologics Price Competition and Innovation Act (BPCIA).

The USPTO should look more closely at I-MAK's claims so that it may engage, inform, and redirect, if possible, legislative and administrative efforts aimed at destabilizing the patent system to the detriment of American innovation. I-MAK's "statistics" have at times been directly contradicted by objective data from official databases, namely the FDA's Orange Book — a public list of approved drugs and their patent information. In a 2019 report, for example, I-MAK asserted that the drugs Eliquis and Xarelto — used to treat blood clots — were covered by 31 and 32 patents, respectively. However, the FDA's Orange Book has listed at most three patents for Eliquis and six patents for Xarelto. I-MAK also claims that the exclusivity periods for drugs covered by so-called "patent thickets" will block competition for decades – yet, generics have already entered the market in frequent cases. Similar data discrepancies abound.

Senator Thom Tillis, in his January 2022 letter to the USPTO, has also requested that the agency itself apply its expertise to review I-MAK's data before citing it or relying on it. Matters of patent law and policy are complex, and misguided policy can lead to dire consequences for innovative industries in a delicately balanced system. There is certainly room to debate the contours of reform, but false information should play no role in the discussions. Policymaking should be guided by thoughtful action and based on accurate data and replicable methodology. And, the USPTO has a critical role to play to proactively lead and inform these complex policy discussions.

At a minimum, patent policy should be guided by balanced data, and relying exclusively on I-MAK presents a one-sided perspective.

Maintaining a Balanced Perspective

Contemporary public dialogue regarding the patent system has been recently motivated by a suspicion of drug patents and a presumption that drug companies are gaming the system. This is then used against the entire patent system and innovators in all industries. We are concerned, in particular, about allegations that pharmaceutical manufacturers file for large numbers of undeserved patents on drugs to inappropriately thwart competition from generics companies. This narrative significantly misunderstands how drug development and the patent system work.

In reality, for the enormous amount of capital spent on research and development, the pharmaceutical industry seeks a modest number of patents in comparison with other

industries — including the high-tech and automotive sectors. When the USPTO does issue a drug patent, as with all other patents, it is because the pharmaceutical innovation is useful, novel, and nonobvious — the congressionally-mandated criteria an invention must meet in order to warrant patent protection.

Those patents can represent real and inventive improvements to a medication that result from years spent researching and navigating the FDA approval process. These improvements often offer substantial benefits for patients, such as greater dosing flexibility and easier adherence to their treatment regimen.

Such improvements to existing technology are a fundamental part of the process of innovation in all sectors of the economy. Virtually every step taken to improve science, manufacturing, or technology is incremental — and follow-on — as inventors build on their own advances and the advances of others. Indeed, the very basis of a patent — requiring public disclosure as a quid pro quo in exchange for protection — is to enable this progression.

Companies in all industries routinely improve existing products and obtain new patents for these improvements. It would be absurd to assert that companies making smartphones are cheating the system by seeking patent protection for improvements in new models of their phones, or that automobile manufacturers are abusing patent laws by patenting improvements to their vehicles.

Put another way, the pharmaceutical industry interacts with the patent system just like every other industry. It ought not to face additional obstacles to obtain patent protection or be singled out for discriminatory policymaking. If this industry is singled out now, which industry will be next?

The USPTO should foster a regulatory environment that rewards innovative improvements that meet the requirements for patent protection as set forth by Congress, without regard for the industry in which those improvements are made. Without this environment, it is likely that major discoveries will not be pursued to the same level. Curtailing follow-on innovation essentially curtails all innovation. By attempting to change the patent system to address perceived issues in just one industry, the USPTO would impact all industries and the American economy at large.

A Grounded View of Patent Quality

Patent quality must always be a major focus for the USPTO — as it has been going back to its founding. In truth, the USPTO has performed and adapted well on patent quality, especially given the constantly evolving nature of technology, court decisions, and laws.

We believe the USPTO has the most robust quality measurement system of any major patent office globally. The USPTO's Office of Patent Quality Assurance employs robust processes to identify statutory compliance errors. The USPTO has also made a dedicated commitment to build, manage, and train its examination corps to avert, identify, and correct errors in the patent application review process.

Of course, patent quality will never be perfect. Each patent application is a complex document that attempts to describe and distinguish a new innovation in the physical world. Those descriptions will never be exactly precise. So, patent examination itself cannot reasonably be expected to work flawlessly or weed out every error — even though the USPTO does a laudable job overall. As a result, it is impractical to expect levels of quality such as those seen in manufactured goods.

Moreover, quality goes both ways — the agency should be as concerned about failing to issue deserving patents, as it is with preventing invalid patents from issuance. Each deserving patent not issued correlates to capital not flowing into the economy, jobs not created, services not launched, and discoveries not reaching consumers and the public.

Of course, patent quality must always remain a priority for the USPTO. But it should not be its only priority. Solely concentrating on quality has the effect of stalling activities aimed at strengthening patent rights overall until the quality of patents is "good enough" — which will never be the case for those who prefer a weak patent system. The perfect should not be the enemy of the good.

The USPTO's focus should span all aspects of the patent system — including but not limited to quality. The agency must not forsake the important work of strengthening the rights of patentees and the enforceability of patents while it works continuously, as it should, to improve patent quality.

The Weight of Unintended Consequences

The value of intellectual property relies, in large measure, on the certainty and predictability of the system itself. This is the challenge the USPTO faces moving forward: From enabling consistent and timely examiner decisions across approximately 9,000 examiners — in light of an ever-growing body of the prior art — to building a reliable body of law that the courts and the public can depend on.

Each major policy change must be led by thorough studies that demonstrate it is needed and that it will have the intended consequences. And each change must be carefully weighed to avoid unintended, disruptive consequences. To that point, the June 8 letter from six

U.S. senators to the USPTO — included in the background of the RFC — caused reasonable apprehension. The letter, without material substantiation, attributed much of the alleged "patent thicket" issue to continuation filing practices.

There is worry within the intellectual property community that biopharma concerns will be used as a wedge issue for returning to some previously proposed and ill-conceived general limitations on continuation practices. Those 2006 proposed rules — on broadly limiting the number of claims that would be examined and continuations that would be allowed — caused significant unrest within the innovative ecosystem and resulted in the USPTO being sued with success.

The USPTO should take extra care when considering changes to continuation filing practices not to repeat the mistakes of recent history. Such changes — even if well-intentioned — could disrupt innovators who rely on continuation filings to claim the rightful scope of their inventions. For example, variations of proposals such as requiring a "second look" have been tried and found unsuccessful in the past.

Again, the framing of the questions in the RFC, in some places, suggests that the Office believes an extensive overhaul is needed to continuation practice or to divisionals or restrictions. We see no evidence that an extensive overhaul is needed. The practice of continuation is not an abuse of the system; rather, it is often necessary to enable fulsome examination and dialogue between examiner and applicant when dealing with a new, complex technology that incorporates multiple inventions.

The RFC also asks about increasing initial patent application filing fees to match the cost of USPTO examination. This is a major potential policy change. It is one that could upend a fundamental aspect of America's patent system, which was designed to be accessible and to democratize invention.

Unlike major patent offices in some other jurisdictions, U.S. policymakers have long ago made a purposeful decision to keep up-front filing fees low in order to encourage more inventors. This is a feature — not a bug — of our patent system, one that allows inventors to obtain protection and attempt success in the marketplace in order to fund their further efforts. And this approach has worked remarkably well, with the United States leading the world over the past two centuries in innovation and technology development. We question the need and the basis for disrupting this long tradition. And the USPTO should ensure that any fundamental changes to the existing fee structure will not undermine current and continuing efforts to expand participation in the innovation ecosystem by those who benefit the most from lower entry fees, including startups, underserved communities, and people of lower incomes.

We at the Council for Innovation Promotion have dedicated our careers to the patent system and understand its far-reaching impacts. We applaud the agency for actively soliciting public input on proposed initiatives. And we urge you to remain committed to evidence-based policymaking that supports American innovation. No major change — along the lines suggested by much of the RFC — should be made without thorough studies and detailed input from all stakeholder groups.

Thank you again for the opportunity to comment. We invite you to consider us a resource as the USPTO weighs these important issues.

Sincerely,

Frank Cullen
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Council for Innovation Promotion (C4IP)