March 10, 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

Submitted via www.regulations.gov
[Docket No. PTO-P-2022-0037]

Director Vidal,

The Council for Innovation Promotion (C4IP) appreciates the opportunity to respond to your November 7, 2022, Request for Comments (RFC) on Joint USPTO-FDA Collaboration Initiatives. *See* 87 Fed. Reg. 67,019 (Nov. 7, 2022). The RFC seeks public comments on areas for USPTO-FDA Collaboration in response to President Biden's Executive Order in July 2021 on Promoting Competition in the American Economy, 86 Fed. Reg. 36,987 (July 14, 2021), including efforts to provide greater access to medicines for American Families and increase marketplace competition.

Led by former USPTO Directors and federal judges, C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property (IP) rights that drive our nation's innovation, boost economic competitiveness, and improve lives around the world. C4IP serves as a trusted partner to Congress and the Biden administration, as officials seek to develop policies and make operational decisions to ensure a well-functioning IP system that bolsters U.S. innovative competitiveness and investment in new technologies.

C4IP believes in our shared goals of providing greater access to innovative, life-saving, life-improving medicines and socially beneficial innovation. With that in mind, we write to highlight two aspects of the proposed USPTO-FDA collaboration that we believe will impede the achievement of these goals. First, the proposed USPTO-FDA collaboration is advancing in the

absence of any reliable evidence of a problem that needs solving. The IP and innovation communities, therefore, need an evidence-based study and analysis before any additional collaboration commences along the lines suggested by the RFC. Second, the collaboration, as currently proposed, does not sufficiently address the distinct roles and expertise—both technical and legal—of the two agencies. The current proposal will lead to an interagency entanglement that will likely exceed the bounds of permissible agency action and will undermine the patent system by interjecting the voices of numerous federal agencies—none of which have patent-law expertise—into the patent examination and review process.

An Evidence-Based Study is Necessary Before Undertaking Any Collaboration

Our first concern with the proposed USPTO-FDA collaboration is that it is being advanced without competent, reliable evidence demonstrating the need for the contemplated far-reaching actions. Without complete information, the USPTO may be led down a path resting on incomplete and erroneous assumptions.

Evidence is key to making an informed decision. Evidence forms the foundation of any meaningful technical decision, and evidence is necessary for rational agency decision-making, especially so for decisions that need to pass muster under the Administrative Procedure Act. *See, e.g.,* 5 U.S.C. § 556(b). The need for evidence-based agency decision-making is so important that Congress enacted the Foundations for Evidence-Based Policymaking Act of 2018, which created a framework for federal agencies to use comprehensive and integrated approaches to gathering evidence and enhancing the government's ability to perform those evidence-building activities. Pub. L. No. 115-435, 132 Stat. 5529 (Jan. 14, 2019).[1]

In our view, the current dialogue lacks the necessary evidentiary record to support all aspects of the agencies' proposed collaboration. Various parties, such as I-MAK, have made various claims about how patents are supposedly impeding access to medicines. The accuracy and reliability of I-MAK's drug patent numbers, as presented in their attention-grabbing pamphlets

[1] The Foundations for Evidence-Based Policymaking Act requires, for example, that agencies develop evidence-building plans that identify policy questions and the evidence that the agency expects to develop to address them. See generally GAO, Evidence-Based Policymaking, Survey Data Identify Opportunities to Strengthen Capacity Across Federal Agencies, GAO-21-536 (July 2021), https://www.gao.gov/products/gao-21-536.

like "Overpatented, Overpriced" (2018) and "America's Bestselling Drugs of 2019," have been called into question.[2][3] I-MAK, for its part, remains unmoved and continues to repeat its tenuous claims.

We need not rehash all the arguments here, as the comments submitted to date underscore our more salient point: We need reliable evidence and concrete data to understand whether there exist valid bases for taking the extraordinary measures proposed by the RFC. The only way to fill the current evidentiary gap is to conduct proper information gathering and studies.

As it currently stands, many of the RFC's proposed actions seem to be solutions searching for a problem. For instance, the USPTO states that it is seeking to "[e]ngage in greater FDA collaboration in AIA proceedings." 87 Fed. Reg. at 67,021. But is there any evidence that the particular type of patents in AIA proceedings that would be subject to this "greater FDA collaboration" are so different from other patents to require another agency's involvement while other patents do not? In other words, what is the evidence that would justify singling out such patents? Indeed, the USPTO historically has resisted singling out patents or technologies for disparate treatment, and has insisted that the patent system applies equally to all. Plus, is there any evidence that the FDA's participation in AIA patent adjudicatory proceedings would, in fact, be beneficial to AIA proceedings?

Further, precisely what types of patents would the contemplated FDA participation be for? Would it be limited solely to "pharmaceutical" patents, however that is defined, or would it include all patents that are in any FDA-regulated products and services? In other words, as currently written, the USPTO may well be opening the door to the FDA's participation in the patent process for any patents directed to pharmaceuticals, biologicals, medical devices, dietary supplements, food products, and cosmetic products—an extraordinary breadth of technology. And how about other types of patents and other agencies? Will the USPTO next seek "greater collaboration" in AIA proceedings from the Department of Agriculture for agriculture-related patents?[4] Or from the Department of Energy for energy-related patents?

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[2] Ltr. of Adam Mossoff at 2 (Feb. 1, 2023), https://www.regulations.gov/comment/PTO-P-2022-0025-0107; *see id.* at 7 ("These unverified, unexplained, and vast discrepancies between the Orange Book listings and I-MAK's drug patent numbers raise serious questions about the unreliability and veracity of I-MAK claims.").
[3] Ltr. from Sen. Thom Tillis to I-MAK (Jan. 31, 2022), https://ipwatchdog.com/wp-content/uploads/2022/02/1.31.2022-LTR-from-Senator-Tillis-to-IMAK-re-Patent-Data-Sources.pdf.
[4] *See* Ltr. from Vidal to Vilsak & Moffitt (Mar. 7, 2023), https://www.uspto.gov/sites/default/files/documents/uspto-usda-letters03072023.pdf; USPTO, Director's Blog, Increasing Transparency, Boosting Competition, and Supporting Innovation Can Deliver Better Choices for Farmers in the Seed Marketplace (Mar. 7, 2023), https://www.uspto.gov/blog/director/entry/increasing-transparency-boosting-competition-and.

The proposal may lead to numerous other federal agencies—all with no expertise in patent law—becoming involved in the patent examination and adjudication process. We are unaware of any evidence-based reasoning to support such a sweeping approach.

The lack of evidence traces back to the FDA's letter to the USPTO in September 2021. There, FDA expressed concerns about so-called "patent thickets," "product hopping," and "evergreening."[5] But the FDA's letter lacked any specific quantitative data about the extent of those supposed deleterious practices.

In C4IP's view, some forms of agency collaboration can be net-positive, and the USPTO already collaborates with the FDA and other agencies to their mutual benefit. But the type and extent of collaboration must be carefully considered and guided by evidence-based decision-making. Before proceeding with any of the proposed additional collaboration initiatives, therefore, we urge the USPTO to undertake a detailed study to gather the data and rationally assess what, if any, further collaboration initiatives are necessary and appropriate to advance our shared goal of providing greater access to innovative life-saving and life-improving medicines and socially beneficial innovation. The data collected needs to identify the specific problems that have allegedly taken place, and the quantities of such problems. In addition, evidence should be provided that the proposed solutions will in fact solve those problems.

Respecting and Balancing the Different Statutory Roles of USPTO and FDA

Our second concern relates to the problematic entanglement of the distinct roles of the USPTO and the FDA. The RFC seemingly contemplates action and decision-making by FDA that extends far beyond what Congress authorized. The USPTO-FDA coordination—as proposed—will likely lead to improper FDA participation in substantive patent legal decisions. This entanglement is problematic because USPTO and FDA focus on entirely different technical and legal issues and are charged with administering entirely different statutes.

[5] *See* Ltr. from Janet Woodcock, M.D., U.S. Food & Drug Administration, to Andrew Hirshfield, USPTO (Sept. 10, 2021), https://www.fda.gov/media/152086/download; https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf.

As an initial point, targeted collaboration between or among federal agencies can, if appropriately implemented, lead to better decision-making in the Executive Branch. For that reason, Congress can and has authorized various inter-agency collaborations. When Congress authorizes agencies to collaborate, the federal agencies are duly empowered to undertake the shared actions and decision-making that ordinarily are not within the prescribed scope of authority of the individual agencies. They can undertake the necessary training and rulemaking to ensure that agency actions comply with the law.

As of now, however, Congress has not authorized the FDA to participate in any decision-making relating to patent laws. The USPTO alone is charged with reviewing and granting patents. *See, e.g.,* 35 U.S.C. § 2(a) (establishing the USPTO as "responsible for the granting and issuing of patents"); id. § 3 (authorizing the Director to be "responsible for providing policy direction and management supervision for the Office and for the issuance of patents"). The FDA's authorization, in contrast, concerns safety and efficacy issues for food, drugs, dietary supplements, medical devices, cosmetics, and certain other consumer and health products. *See, e.g.,* 21 U.S.C. § 301 et seq. C4IP thus sees no current authorized basis for the FDA to be involved in substantive Patent Office actions, such as AIA proceedings. Moving forward with the contemplated collaboration could invite legal challenges that will distract each agency from its respective mission.

Furthermore, the fundamentally distinct missions of the USPTO and FDA should give pause to the proposed collaboration, especially with respect to including the FDA in the patent review process, whether examination or post-grant proceedings on particular patents. For instance, and as mentioned above, the RFC proposes to "[e]ngage in greater FDA collaboration in AIA proceedings." 87 Fed. Reg. at 67,021. That proposal is an extraordinary, unprecedented, and troubling step that would allow a separate federal agency to inject itself into the PTO's administrative adjudication of patent rights in a particular area of technology.

C4IP sees many reasons to be concerned. Unlike the USPTO's patent examiners or administrative patent judges, FDA employees are not trained on issues of patentable subject matter, claim construction, non-obviousness, enablement, and other patentability criteria. Any FDA participation could inject issues outside the patent statutes.

Issues outside the patent statutes have no place in the patentability analysis. For instance, Senator Warren recently asserted that "[s]ubcutaneous injection for delivery of treatments and medications" is "an obvious use" since "Insulin was discovered in 1921."[6] But that contention is a vast and incorrect oversimplification of drug development, pharmacology, and science in general. Under patent law, a snap judgment of an invention being "obvious" is not the proper standard upon which to assess patentability. *See, e.g., Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966) (establishing the proper legal test for assessing the non-obviousness of an invention). Whether a technical advance—pioneering or otherwise—warrants patent protection depends, in part, on objective evidence of non-obviousness. The proposal articulated in the RFC, to allow for "greater FDA collaboration in AIA proceedings," risks erroneous patentability decisions based on improper legal standards and irrelevant evidence.

FDA standards are not just "different" from USPTO standards; they can be entirely incompatible with patent law. Indeed, as the U.S. Court of Appeals for the Federal Circuit has explained: "Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings." *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994). In other words, an invention—such as a new medical device, drug formulation or new dietary supplement—may meet all the requirements for patentability, but nevertheless, it may not satisfy stricter FDA requirements that would not permit the product to be marketed in the United States. There could be any number of reasons why the FDA would reject an application to market a particular product, yet the product itself is covered by a valid patent claim.

There are more reasons to be concerned about the proposal to engage FDA in AIA and other Patent Office proceedings. First, Congress established AIA proceedings to "provid[e] quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011), 2011 U.S.C.C.A.N. 67, 78. With the RFC's proposed actions, however, adding the FDA to AIA proceedings will only complicate those proceedings, make them more expensive for patent owners, and further decrease the reliability of the U.S. patent system.

[6] https://www.warren.senate.gov/imo/media/doc/2023.02.22%20Letter%20to%20USPTO%20re%20Keytruda%20patent1.pdf.

Second, because of the adversarial nature of AIA proceedings, we see little reason for the FDA or any other federal agency to be involved. Congress intended that post-grant AIA proceedings to be alternatives to district court litigation, and they are fundamentally adversary proceedings between a patent owner and a patent challenger. *See Return Mail, Inc. v. U.S. Postal Serv.*, 139 S. Ct. 1853, 1858 (2019) ("[T]he AIA post-issuance review proceedings are adversarial, adjudicatory proceedings between the 'person' who petitioned for review and the patent owner."). In an adversarial system, the parties are entrusted with bringing forth the evidence and arguments they need, and the government should not put its thumb on the scale. We thus fail to see how the FDA's participation—or the participation of USDA, EPA, FTC, or other agencies—would be a net benefit to the patent system. We note that pharmaceutical patents have been litigated in Article III courts for decades, and yet the FDA never collaborates with the district court judge or the accused infringer in those cases.

Third, the same problems and concerns would apply equally in the context of the examination of patent applications and the reexamination or reissue of issued patents. If the FDA imposes its own views on the examination and reexamination process, patent examiners will receive conflicting messages. With over 8,000 examiners, the Patent Office works diligently to educate and train its examining corps to apply the patent laws in a consistent manner. Involvement by another agency in these proceedings would add unacceptable confusion, uncertainty, and delay.

All this is not to say that the USPTO and the FDA (or other agencies) cannot and should not share any information or not collaborate at all. On the contrary, there are numerous reasonable opportunities for the USPTO and the FDA to work together, and they already do. The FDA could, for example, provide training on how to search and identify certain publicly available information relating to drug applications. Conversely, USPTO public resources may offer education on key elements of the patent examination process that can benefit the FDA and the public.

But if any proposed collaboration extends into the decision-making analyses of the USPTO, then that extends too far and unnecessarily invites the problems noted above. Among other things, the FDA and other agencies should not be permitted to provide any input into or analysis about patentability and whether any pending patent applications or issued patents

satisfy the patent law requirements. And certainly, no FDA input should be in reference to any specific pending patent application or any specific patent office proceeding concerning an issued patent.

We further note that any member of the public may submit potentially relevant information to a patent examiner. *See* 35 U.S.C. § 122(e). The USPTO and the FDA could therefore establish procedures for the FDA to submit public information to the patent examiner, in accordance with the current statute. Importantly, though, such submissions are not invitations for third parties (including other federal agencies) to advance arguments about the merits of the patent application:

> The statutory requirement for a concise description of relevance should not be interpreted as permitting a third party to participate in the prosecution of an application, as 35 U.S.C. 122(c) prohibits the initiation of a protest or other form of pre-issuance opposition for published applications without the consent of the applicant. Therefore, while a concise description of relevance may include claim charts (i.e., mapping various portions of a submitted document to different claim elements), the concise description of relevance is not an invitation to a third party to propose rejections of the claims or set forth arguments relating to an Office action in the application or to an applicant's reply to an Office action in the application.

MPEP § 1134; *see also* 37 C.F.R. § 1.290 ("A third-party submission may not be entered or considered by the Office if any part of the submission is not in compliance with 35 U.S.C. 122(e) and this section.").

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Overall, we submit that it is premature to implement significant new policies and substantial changes to current patent procedures without a thorough study based on reliable data. At a minimum, the contemplated USPTO-FDA collaboration proposals raise significant concerns with their likely impact on the reliability and robustness of the patent system.

Just as problematic is the realistic possibility of USPTO and FDA actions and decision-making that are not authorized by Congress. Without the proper statutory authority, the FDA has no proper role deciding whether patent applications should issue into U.S. patents or whether duly issued U.S. patents should be cancelled.

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. We urge you to remain committed to evidence-based policymaking that supports American innovation.

Thank you again for the opportunity to comment.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)