The Office of
Hon. Paul R. Michel (ret.)
Alexandria, Virginia

February 6, 2023

Katherine K. Vidal
Director
U.S. Patent and Trademark Office
Alexandria, Virginia 22314

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
Silver Spring, Maryland 20993

Re: Docket No. PTO-P-2022-0037

Dear Director Vidal and Commissioner Califf:

I submit these comments in response to the request by the Food and Drug Administration ("FDA") and the Patent and Trademark Office ("USPTO") for public input on areas for USPTO-FDA collaboration and engagement. *See* 87 Fed. Reg. 67,019 (Nov. 7, 2022) ("the RFC").

I submit these comments on behalf of myself only. The comments are based on my years of experience in patent and administrative law, including as a judge on the U.S. Court of Appeals for the Federal Circuit for over twenty-two years. Since I stepped down from the bench, I have maintained a keen interest in ensuring that the U.S. patent system remains vigorous and robust. Having a patent system that encourages a vibrant U.S. innovation ecosystem is the best means for continuing the innovation that has created some of the most fundamental and significant advances in biotechnology, medicine, and healthcare.

In providing my comments here, I focus on certain specific concerns. Many interested groups, experts, and others have already submitted comments that have detailed other valid concerns. Some have participated in the "Listening Session on Joint USPTO–FDA Collaboration Initiatives" on January 19, 2023. I urge the USPTO and the FDA to consider thoroughly and carefully all those comments. I agree with many points already made by those other commentors, though I do not repeat those points here.

I. The RFC Contemplates Agency Action that is Not Authorized by Congress

A first major concern with the RFC's suggested USPTO-FDA coordination is that it contemplates action and decisionmaking that is beyond the Congressional authorization of the respective agencies. In short, the suggested USPTO-FDA coordination seemingly invites the FDA to participate in substantive legal decisions on patent law. The problem with that suggestion, of course, is that Congress granted to the USTPO sole responsibility for agency-level decisions on patent law.

To begin with, the respective scopes of Congress's authorization of the USPTO and FDA are intentionally non-overlapping and carefully delineated. The USPTO has responsibility for reviewing and granting patents. *E.g.*, 35 U.S.C. § 1. It is not responsible for assessing whether any product covered by a patent is suitable for commercial sale or marketing. *Cf. In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws."); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("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."). It does not have any responsibility or agency expertise on the question of drug accessibility.

In contrast, the FDA's scope of authority concerns safety and efficacy issues for food, drugs, and a range of other products. *See* Food, Drug, and Cosmetic Act ("FDCA"), 52 Stat. 1040, *as amended*, 21 U.S.C. § 301 *et seq.*; *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000); FDA, *What We Do* (Mar. 28, 2018)[1] ("The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."). The FDA does not have any authority or agency expertise in patent law.

If the USPTO and the FDA undertake some of the proposed collaboration initiatives, the result would very likely be agency action that improperly exceeds congressional authorization. For instance, if the FDA were involved in any decisionmaking or substantive analysis concerning the grant or revocation of patents, that would very likely violate several provisions of the Patent Act. *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 as "responsible for providing policy direction and management supervision for the Office and for the issuance of patents").

Section 4 of Title 35 presents a particularly tricky concern about the scope of the proposed collaboration. USPTO officers and employers are generally prohibited from obtaining an interest in a patent while employed at the agency. 35 U.S.C. § 4 ("Officers and employees of the Patent and Trademark Office shall be incapable, during the period of their appointments and for one year thereafter, of applying for a patent and of acquiring, directly or indirectly, except by inheritance or bequest, any patent or any right or interest in any patent, issued or to be issued by the Office."). The plain purpose of this statute is to minimize potentially competing and conflicting interests in USPTO employees who may be making substantive decisions about the patents and applications of other inventors and innovators. That provision does not apply to FDA employees.

Along similar lines, the RFC proposes to "[e]ngage in greater FDA collaboration in AIA proceedings," 87 Fed. Reg. at 67,021, but it is difficult to see how involving the FDA in AIA proceedings[2] is in any way authorized under current law. The proposal to involve the FDA

[1] https://www.fda.gov/about-fda/what-we-do.

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA") established new post-issuance proceedings, such as post-grant review and *inter partes* review. *See also* 35 U.S.C. §§ 311, 321.

in AIA proceedings presents a host of problems. In short, the proposal is akin to asking the FDA to become involved in every district court action involving a patent that covers a product regulated by the FDA. It is a proposal that, in my view, is wholly unprecedented.

First, AIA proceedings were intended to "providing 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. In the decade since their introduction, we have learned that AIA proceedings are subject to abuse and manipulation by parties seeking to avoid liability for infringing patents. We have also learned that AIA proceedings tend to increase the costs to patent owners when they attempt to hold infringers accountable. Under the RFC's proposal, involving the FDA in AIA proceedings will only complicate matters and further increase costs for patent owners.

Second, as explained in more detail below, the FDA is often in possession of troves of highly confidential trade secret information. The information will often include clinical trial data, formulation data, manufacturing data, and the like. Some of it may be relevant to an AIA proceeding, but most of it will not. Beyond the fact that the FDA does not have full authority to share such information, *see infra*, there is little reason to risk an improper disclosure of a drug applicant's confidential trade secret information.

Third, AIA proceedings are adversary proceedings, with a petitioner challenging the patent, and the patent owner defending the patent's validity. As the Supreme Court noted in *Return Mail, Inc. v. U.S. Postal Service*, "the AIA post-issuance review proceedings are adversarial, adjudicatory proceedings between the 'person' who petitioned for review and the patent owner." 139 S. Ct. 1853, 1858 (2019). "There is briefing, a hearing, discovery, and the presentation of evidence, and the losing party has appeal rights." *Id.* There is no reason for the FDA to participate in such an adversarial proceeding.

Indeed, one must ask why the FDA should be encouraged to participate in AIA proceedings but not other litigation concerning pharmaceutical-related patents. Courts have been adjudicating pharmaceutical patents under the Hatch-Waxman Act[3] for close to forty years, as well as for many years prior. In those four decades, the FDA has never collaborated with the adjudicator of patent validity or infringement, *i.e.*, the district court or the jury. But that is what the proposal implies is warranted.

Fourth, involving FDA employees presents similar authorization problems based on the Patent Act's limitations on who can be decisionmakers in AIA proceedings. *See* 35 U.S.C. § 6 (specifying requirements for PTAB administrative patent judges).

This would not be the first time that the USPTO attempted to implement rules that exceeded its authority. About fifteen years ago, the USPTO was enjoined from finalizing agency rules that attempted to limit the number of continuing applications, requests for continued examination, and claims that can be filed. *Tafas v. Dudas*, 511 F. Supp. 2d 652, 671 (E.D. Va. 2007).[4]

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[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[4] The district court's decision was appealed to the Federal Circuit, and, in a mixed decision, the injunction was upheld. 559 F.3d 1345 (Fed. Cir. 2009). The Federal Circuit later vacated the panel decision and granted *en banc* review. Shortly after, David Kappos was appointed Director of the USPTO, one party (GSK) then settled with the USPTO, and the other (Tafas) petitioned the Federal Circuit to maintain the district court decision. On November 9, 2009, the appeals court maintained the permanent injunction, which is still in force.

The point of noting the *Tafas* case is to hope that the agency undertakes a more prudent path forward that would avoid past mistakes. A federal agency is certainly within its right to propose action that is based on a reasonable understanding of the law. But if the proposed action rests on a slenderest of reeds, then any such action will likely spawn multiple lawsuits by parties who might be harmed by the questionable agency action. Given the confidential nature of the FDA-related information and data, as well as other considerations, many companies would be highly motivated to challenge any agency rule that allows the sharing of information and decisionmaking between the USPTO and FDA. The likelihood of such legal challenges would be close to a certainty, and they would unnecessarily drain critical resources of the USPTO and the FDA.

This is not to say that agencies such as that the USPTO and the FDA cannot share certain publicly accessible information in order to facilitate and encourage the best outcomes for advancing innovation. It is important to develop improved methods for patent examiners to identify and review the most pertinent prior art and other relevant information. The USPTO is working on such methods, as noted in Director Vidal's letter of July 6, 2022. The USPTO should be applauded for those efforts to improve the examination process.

In that vein, passive sharing of publicly accessible information between the FDA and the USPTO can be an acceptable form of collaboration under the current law. By passive sharing, I mean the identification of possibly relevant information, without any analysis or decisionmaking relating to the substance of the patent-law issues. After all, any member of the public may submit potentially relevant information to a patent examiner. *See* 35 U.S.C. § 122(e). Thus, the USPTO and the FDA could establish mechanisms to submit such information in accordance with § 122(e).

But if the proposed collaboration is contemplating any sharing of analytical or decisionmaking duties, that is a bridge too far under the law. It also would create practical problems and fairness issues for patent owners and patent applicants. They have the right to know that patent decisions are not being influenced by officers or employees of an entirely separate federal agency. A recent report of the Government Accountability Office highlighted some problematic past practices of the PTAB. "Enhancing collaboration with other agencies," as the RFC proposes, may lead to similar issues about a lack of transparency.

Finally, given the apparent lack of authority for the USPTO and the FDA to exchange all information—such as trade secret information—the agencies should await proper congressional authority before deciding if and how to implement any collaboration mechanisms. Legislation has been proposed, but Congress has not enacted any authorizing legislation. For instance, Senator Durbin (along with colleagues) introduced legislation last year to form an interagency task force between the USTPO and the FDA. *See* S. 4430, 117th Cong. (2021). That bill was not passed, but a similar version was reintroduced in the Senate in January 2023. *See* S. 79, 118th Cong. (2023).[5] The proposed legislation may overcome some of the above-noted authorization problems, but the recent bill's loose and vague language may

[5] *See also* https://www.coons.senate.gov/news/press-releases/senators-coons-durbin-tillis-grassley-introduce-legislation-to-improve-coordination-between-uspto-and-fda; https://www.grassley.senate.gov/news/news-releases/grassley-durbin-tillis-coons-introduce-legislation-to-improve-coordination-between-patent-office-and-fda.

create more problems than it solves, particularly with respect to concerns about the protection of confidential information.

II. Concern About Sharing Confidential and Trade Secret Information

A second major concern with the RFC is that it proposes sharing confidential and trade secret information between the agencies. This proposal is problematic for several reasons.

From an authorization perspective, neither agency appears to have full authority to share a private party's confidential trade secret information with the other agency. For instance, by regulation, the FDA is prohibited from disclosing certain trade secret information. *See, e.g.*, 21 U.S.C. § 331(j); 21 C.F.R. § 20.85. Similarly, the USPTO is required to maintain patent applications as confidential, at least until they are published. 35 U.S.C. § 122(a).

With that baseline in mind, from a practical standpoint, any duly authorized collaboration between the USPTO and the FDA must take every conceivable step to ensure that trade secret and other applicable confidential information are maintained as such. The unauthorized disclosure of trade secret and confidential information would be highly damaging to private companies, particularly emerging biopharma innovators. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). To protect innovators, if the agencies are authorized to share trade secret information, Congress should enact appropriate legislation to make the FDA and the USTPO subject to liability for any unauthorized disclosure.

Even so, at the present time, the administrative record lacks a suitable evidentiary basis to encourage the FDA to be disclosing trade secret and highly confidential information to the USPTO. The perceived benefits of the FDA disclosing trade secret and highly confidential information to the USPTO seem marginal, at best, and appear to be significantly outweighed by the potential harm of improper disclosures.

Moreover, if the USPTO believes it needs additional information from a patent owner or patent applicant, and that information has been submitted to the FDA, the USPTO (through the examiner) can request that information under current law and regulation. Specifically, "the examiner or other Office employee may require the submission . . . of such information as may be reasonably necessary to properly examine or treat the matter." 37 C.F.R. § 1.105. This procedure of requesting specific information from patent applicants has been approved by the Federal Circuit. *See generally Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2009); *see also* 87 Fed. Reg. 45,764, 45,766 (July 29, 2022) (separate USPTO notice confirming that patent examiners can use Rule 1.105 to request from patent applicants "statements made or information submitted to other Government agencies such as the FDA").

To be certain, the FDA and the USPTO can establish, under appropriate congressional authorization, proper means for sharing trade secret and highly confidential information. While the USPTO does have a mechanism for submitting confidential or trade secret information during prosecution,[6] it is not widely used because the expectation is that most information relevant to patent prosecution will be publicly available information. The PTAB does frequently issue protective orders to maintain as confidential certain information of the parties. But again, confidentiality is the exception, not the norm, as USPTO proceedings are

[6] *See* MPEP § 724.02 ("Method of Submitting Trade Secret, Proprietary, and/or Protective Order Materials").

public (once the patent application publishes). Thus, because most USPTO proceedings are public, there is an inherent disconnect with the concept of the FDA being encouraged to share trade secret information with an agency that generally makes decisions based on public information.

III. The RFC Appears Tilted Against Patents and Innovators

My final comment relates to what appears to be the RFC's inherent or implicit bias against patents. The primary focus of the RFC seems geared to take steps that are slanted towards non-innovators. I thoroughly appreciate the need to increase access to medicines for American families, and that access has been advanced through a delicate balance between (a) innovators who devote enormous time and financial resources to developing and discovering new medicines and (b) generic companies who are able to follow the work of the innovators and provide less expensive versions of those medicines after patent protection has ended.

Take, for instance, the RFC's expressed concern about "not unnecessarily delaying getting generic, biosimilar, and more affordable versions of pharmaceuticals into the hands of Americans who need them." 87 Fed. Reg. at 67,020. Putting aside the fact that the USPTO has no authority over, or even agency expertise in, the marketing and pricing of medicines, the expressed concern about "unnecessarily delaying" overlooks the pro-innovation role of patents.

Without patent protection, pharmaceutical companies could not afford to devote billions of dollars in research and development to bring to market the next generation of medicines. The role of patents is to enable those R&D-intensive companies to recover their investments and to generate funding for next-generation R&D. The patents provide the exclusive grant, as envisioned by the Constitution, to encourage and reward innovation. Without patents, the initial investment that makes generic drugs possible simply would not occur.

I therefore respectfully disagree with the focus on the "unnecessarily delaying" concern. Under the balanced Hatch-Waxman system, early generic entry is an exception to the standard patent term. In this sense, it is not a delay but an early entry—but only if the follow-on generic company can show that the innovator's patent rights are not infringed or not valid. Where, however, the patent is valid and infringed, it is not "unnecessarily delaying" generic entry. It is maintaining the balanced *quid pro quo*.

Sincerely,

/Paul R. Michel/

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