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February 6, 2023

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

via <https://www.regulations.gov>

Re: Comments on Joint USPTO–FDA Collaboration Initiatives

Dear Director Vidal:

Intellectual Property Owners Association appreciates opportunity to respond to the request for comments in “Joint USPTO–FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments” (hereinafter “RFC”), published on Nov. 7, 2022. IPO is an international trade association representing a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO’s vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO’s mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO supports the collaboration of the USPTO and FDA to the extent that it can help either agency fulfill its important role. The agencies are encouraged to share information and expertise to improve efficiencies for both. For example, IPO has no objection or concern about the USPTO notifying the FDA of PTAB proceedings on Orange Book patents. In any event, the filing of a PTAB proceeding is a public record. However, the two agencies have distinct obligations and mandates, and neither should waiver from the important functions entrusted to it.

The FDA has a crucial role in public health. According to the FDA mission statement, the agency “is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices” It is also tasked with “helping to speed innovations that make medical products more effective, safer, and more affordable, and by helping the public get the accurate, science-based information they need to use medical products. . . .” Important FDA responsibilities include the review and approval of

innovative drugs, generic drugs, and biosimilars. The agency also has a crucial role in the inspection of facilities and the prevention of mislabeled or misbranded drugs.

The USPTO, in contrast, was established to carry out Article 1, section 8 of the Constitution to “promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” The USPTO serves a crucial role in the American economy. The USPTO’s examination and approval of patents has enabled the growth of many U.S. corporations and empowered small entities and independent inventors. The work of the USPTO has buttressed employment for millions of Americans. The USPTO report on “Intellectual Property and the U.S. Economy, Third Edition,” (March 2022), recognized the importance of the patent system to economic growth in the country.

We believe the most effective way to encourage the proper use of patents in the U.S. economy is to improve the examination function of the USPTO, including by investing in hiring, retaining, and training examiners. An experienced and well-trained patent examination corps will ensure the quality of granted patents. The Patent Trial and Appeal Board, and its role in hearing challenges to granted patents, also helps improve patent quality. In fact, IPO encourages the USPTO to train patent examiners on the growing body of PTAB decisions, and particularly those designated precedential and informative.

Our responses to the questions posed in the RFC are below.

1. What publicly available FDA resources should be included when training USPTO patent examiners on tools they can use to assess the patentability of claimed inventions?

IPO provides no response to this question. See responses to questions 6 and 8.

2. What mechanisms could assist patent examiners in determining whether patent applicants or patent owners have submitted inconsistent statements to the USPTO and the FDA? Please explain whether such mechanisms present confidentiality concerns and, if so, how those concerns could be addressed.

Current USPTO rules of practice provide for an affirmative duty of disclosure on patent applicants (including inventors, attorneys, and others involved with the prosecution of an application) to disclose information that is material to patentability. 37 C.F.R. § 1.56. Decades of judicial decisions inform patent applicants of the risk that a patent will be held unenforceable as a result of inequitable conduct, such as by withholding information material to patentability with the intent to deceive the USPTO. *See, e.g., Therasense, Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). These legal doctrines help ensure that patent applicants disclose relevant information to the USPTO during patent prosecution. This duty generally ceases upon the grant of the patent.

There is a good deal of trade secret information in a New Drug Application (NDA) to the FDA. If someone requests information from an NDA under the Freedom of Information Act (FOIA), the NDA applicant has an opportunity to redact the NDA before providing it to the requestor. One suggestion in the letters exchanged between the USPTO and FDA was that FDA could share drug files with the

USPTO. In the USPTO, patent prosecution is made public 19 months from the filing of the earliest application, unless the application is under a secrecy order. Given this rubric, the confidentiality of an NDA cannot be preserved if it is submitted to the USPTO. Furthermore, the Food Drug and Cosmetic Act and related regulations prohibit the FDA from sharing trade secret information. *See* 21 U.S.C. § 331(j); 21 C.F.R. § 20.85.

“Inconsistent statements” is a reasonable limitation already addressed via other mechanisms. The various existing means to handle inconsistent statements remain effective. There is case law showing consequences when inconsistent statements between the agencies are discovered. Sometimes the consequence has been a holding of unenforceability for inequitable conduct, as in *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345 (Fed. Cir. 2021). *See also, e.g., Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418 (Fed. Cir. 1989). When the source of the inconsistent statements does not have a duty of disclosure to the USPTO, other sanctions are available. The courts can punish deliberate deception that could undermine the patent system. A perception of widespread fraud on the USPTO has existed for decades, but the paucity of examples in the case law suggests this is without basis.

3. What are the opportunities and challenges related to the use of AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, including with respect to how such proceedings may intersect with Hatch-Waxman paragraph IV disputes and the Biologics Price Competition and Innovation Act “patent dance” framework that biosimilar applicants and reference product sponsors use to address any patent infringement concerns?

IPO provides no response to this question.

4. How can the USPTO and the FDA reinforce their collaboration and information exchange in relation to determining whether a patent qualifies for a patent term extension (PTE) and the length of any extension under 35 U.S.C. 156, as described in the Manual of Patent Examining Procedure § 2756? Identify any specific areas for improvement in the effectiveness of the current USPTO–FDA process for adjudicating applications for PTE and in the opportunity for public comment on such applications.

IPO provides no response to this question.

5. The FDA already publishes PTE applications on www.regulations.gov, and the USPTO publishes PTE applications on its Patent Center portal (<https://patentcenter.uspto.gov/>), which replaced the Public Patent Application Information Retrieval (PAIR) system. The USPTO also recently provided centralized access to a listing of PTE applications filed during the last five years at www.uspto.gov/patents/laws/patent-term-extension/patent-termextended-under-35-usc-156. This list includes the patent application number, patent number, link to the electronic file wrapper in Patent Center, PTE application filing date, and trade name identified in the PTE application. The status of each PTE application, including disposition, may be determined by reviewing the electronic file wrapper in Patent Center. What additional information would be useful to include on this web page?

IPO provides no response to this question.

6. What policy considerations or concerns should the USPTO and the FDA explore as they relate to method of use patents and, as applicable, associated FDA use codes, including with respect to generic drug, 505(b)(2), and biosimilar applicants who do not seek approval for (i.e., who seek to carve out from their labeling) information related to a patent-protected method of use (sometimes described as “skinny labeling”)?

The ultimate policy goal concerning method of use patents and skinny labeling is to strike a balance between encouraging innovation and facilitating competition in the pharmaceutical market. In our view, the existing regulations and case law achieve that balance, and little, if any, change is warranted.

The FDA’s role in the Hatch-Waxman and BPCIA framework is—and should remain—principally ministerial. FDA has repeatedly stated that it lacks the expertise, resources, and authority to resolve issues like patent claim scope and that such matters are better left to the courts or the USPTO.¹ Existing regulations appropriately maintain a ministerial role for FDA concerning method of use patents and skinny labels while supplying appropriate tools for generic and brand drug manufacturers to address improper use codes and pretextual skinny labeling.

In support of generic drug manufacturers, the Medicare Modernization Act of 2003 enables the filing of a patent listing dispute request (PLDR) with the FDA, alleging a mismatch between the method of use claimed in a patent and the Orange Book use code description. If the new drug applicant maintains that the Orange Book listing is accurate, the disputed claim scope is appropriately resolved by a district court rather than the FDA.² To the extent that the Orange Book use code is tailored narrowly to the claim scope of a method of use patent (in the first instance or in response to a PLDR), the generic manufacturer can readily gain approval for other uses under the section viii carve-out provision of the Hatch-Waxman Act.³ If the Orange Book use code is overbroad relative to a method of use patent, district court litigation will include a counterclaim by the generic manufacturer seeking an order requiring the brand manufacturer to correct the Orange Book listing.⁴ The availability of a PLDR,

¹ See, e.g., Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50338, 50340 (Oct. 3, 1994); Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36676, 36682 (June 18, 2003); see also, e.g., *Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1672 (2012) (“The FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply. Instead, it simply publishes the codes, patent numbers, and expiration dates in a large volume known as the Orange Book.”); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349–50 (Fed. Cir. 2003) (“The FDA determines whether the NDA holder has submitted information regarding patents that assertedly claim the approved drug or a method of using that drug, and the district court ultimately determines, in the ensuing patent litigation, whether that assertion is correct.”).

² See, e.g., *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012); *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356 (Fed. Cir. 2015); *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (Fed. Cir. 2010).

³ See 21 U.S.C. § 355(j)(2)(A)(viii); 21 U.S.C. § 355(b)(2)(A)(viii).

⁴ 21 U.S.C. § 355(j)(5)(C)(ii)(I).

reinforced by the counterclaim of Orange Book correction, protects generic manufacturers against overreaching Orange Book claims without requiring the FDA to construe patent claim scope.

Conversely, brand manufacturers are well-equipped in district court litigation when an overreaching generic manufacturer pursues a section viii carve-out, or a “skinny label” under the BPCIA, with the intent that off-label distribution will reach the market for the patented method of use. A carve-out on the label does not, in itself, negate intent to induce infringement, and the analysis under 35 U.S.C. § 271(b) proceeds as in other patent contexts. As with claim scope, the issue of induced infringement by a skinny label product is complex. Courts consider numerous factors, such as the defendant’s marketing and promotional activities, the knowledge, prescribing, and dispensing practices of physicians and pharmacists, the prevalence and profitability of the patented use, and the evidence of actual infringement by end users. The FDA is not positioned to conduct such an analysis when assessing the approval of skinny label generic drugs.

In sum, existing regulations and case law appropriately balance the policy considerations at issue, and the roles of the USPTO and FDA should remain essentially unchanged. The system is working appropriately, providing both brand and generic manufacturers with the necessary tools for clarifying (at FDA) and resolving (in district court) disputes related to skinny labeling.

7. What policy considerations or concerns should the USPTO and the FDA explore in relation to the patenting of risk evaluation and mitigation strategies associated with certain FDA-approved products? What other types of patent claims associated with FDA-regulated products raise policy considerations or concerns for the USPTO and the FDA to evaluate?

We submit that the statute governs in all circumstances. A patent should be listed in the Orange Book if it contains a claim reasonably related to an approved drug substance, drug product, or method of use. *See* 21 U.S.C. 355(b)(1). This would generally include: (1) patents associated with an existing REMS (Risk Evaluation and Mitigation Strategy⁵); (2) patents that claim a device constituent part of a combination product; (3) patents that claim a device whose use is referenced in approved drug labeling; and (4) patents associated with digital applications, as long as they relate to a method of using an approved drug and, with respect to which a claim of patent infringement, could reasonably be asserted if a person not licensed by the drug owner engaged in the manufacture, use, or sale of the drug.

Patents that claim how the sponsor has implemented a particular REMS requirement and that meet the statutory requirement of containing a claim reasonably related to an approved drug substance, drug product, or method of use, do not create an additional obstacle for ANDA applicants in developing a single, shared system REMS for that product.

A REMS patent is currently in the spotlight in *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals* in the District of Delaware (1:21-cv-00691). U.S. Pat. 8,731,963 (“the ’963 patent”) relates to Jazz’s

⁵ A Risk Evaluation and Mitigation Strategy is a drug safety program established by the FDA for monitoring medications having serious safety concerns. The goal of REMS programs is to ensure that the benefits provided by the medication outweigh the risks of use.

product Xyrem®. Jazz sued Avadel for patent infringement and Avadel counterclaimed, seeking a declaration ordering Jazz to remove the '963 patent from the Orange Book because it does not claim a method of using the approved drug. The district court ordered Jazz to request delisting, but Jazz appealed, and the Federal Circuit granted a stay of the delisting order pending appeal (No. 23-1186, Dec. 14, 2022). This case illustrates mechanisms for the courts to handle allegations of improper listing. Current law is working as intended and additional measures are unnecessary.

8. Apart from, or in conjunction with, the initiatives set forth in the USPTO Letter, what other steps could the USPTO and the FDA take collaboratively to address concerns about the potential misuse of patents to improperly delay competition or to promote greater availability of generic versions of scarce drugs that are no longer covered by patents?

IPO has concerns about the involvement of the FDA in the review or consideration of a patent application. As discussed above, each of these agencies has its own important remit and subject matter expertise. The USPTO's competency is examining and granting patents. The most effective way to ensure that the USPTO grants patents that satisfy the requirements of patentability is to support its efforts to improve examination quality and ensure that it has the resources necessary to hire, retain, and train examiners in addition to obtaining appropriate technology to enable sufficient those examiners to obtain the relevant prior art.

There are no major patent jurisdictions that currently authorize a drug regulatory agency to review or comment on a pending patent application. Brazil is the only jurisdiction that has asked its drug regulatory agency to review patent applications; this experience suggests some of the problems that arise when a drug regulatory agency evaluates patent applications.

For many years, Brazil involved its drug review and approval agency, ANVISA (equivalent to the FDA), as part of its process of reviewing patent applications covering pharmaceuticals. The stated goal was to increase access to drugs for the Brazilian population. In 2001 an amendment to Brazil's local Patent Statute added Article 229-C, establishing that "the granting of patents for pharmaceutical products and processes shall be subject to the ANVISA's prior approval." The interaction between the agencies became contentious and added years of pendency to the examination of pharmaceutical patent applications in Brazil, by more than 10 years in some cases. For several years the U.S. Trade Representative's annual Special 301 Report cited the requirement that ANVISA participate in the review of patent applications as a reason for including Brazil on its Watch List. Courts stepped in, limiting ANVISA's role during patent examination to matters of public health. Finally, after almost 20 years of experience, the government revoked article 229-C and eliminated ANVISA's role in patent examination in 2021.

IPO acknowledges and fully supports the duty of disclosure during patent prosecution, and the need for patent examiners to have access to information relevant to patentability. IPO also recognizes the legal obligations and importance of being truthful in all representations to government agencies. As a general rule, consistent statements should be made to the USPTO and FDA. However, statements made to the FDA are directed to different concerns than statements directed to the USPTO and must be considered in context and in view of the request by the agency. This fact is oftentimes unappreciated or fails to be considered when reviewing documents submitted to each agency.

Representations to the USPTO are submitted often months if not years before representations are submitted to the FDA as part of regulatory approval. The representations made to the USPTO are made based on the information available to the patent applicant at the time of patent filing and prosecution (often early in the regulatory approval process). In addition, the very different roles of the USPTO and the FDA must be taken into account for any concern about differences in statements to the agencies. Representations made to the USPTO are intended to support patentability, including the requirements of utility, novelty, or non-obviousness, or to demonstrate written description or enablement support. Statements made to the FDA concern the safety and/or efficacy of a drug candidate.

The U.S. Court of Appeals for the Federal Circuit has recognized the difference between statements of utility, which must be made before the USPTO, and statements of efficacy before the FDA. In addition, the USPTO and FDA operate under very different mandates. In the decision *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995), the Federal Circuit instructed the USPTO not to confuse “the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption.” *Brana* concerned new chemical compounds described as useful to treat cancer, and the patent applicant included data to support the stated utility. The examiner rejected the claims on the grounds of lack of utility and the Board of Patent Appeals upheld the rejection. The Federal Circuit reversed, noting that “FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws,” and “were we to require phase II testing in order to approve utility, the associated costs would prevent many companies from obtaining patent protection and promising new inventions. . . .” *Id.* at 1568.

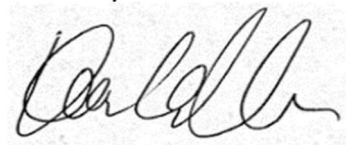
9. What additional input on any of the initiatives listed in the USPTO Letter (1(a)–1(h)), or any other related suggestions for USPTO–FDA collaboration, should the agencies consider?

IPO provides no response to this question.

* * *

Thank you for considering IPO’s comments. As one of the primary organizations representing IP owners, IPO would welcome the opportunity for additional dialogue regarding this important topic.

Sincerely,



Karen Cochran
President