Biocom California

February 6, 2023

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director
United States Patent and Trademark Office
Department of Commerce
600 Dulany Street
Alexandria, VA 22314

Re: Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments

Submitted electronically.

Dear Director Vidal,

Biocom California appreciates the opportunity to comment on the United States Patent and Trademark Office (USPTO) and Food and Drug Administration (FDA) established docket on Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments[1].

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,700 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates over $375 billion in annual economic activity, supports 435,000 jobs, and increases labor income by $115 billion per year[2].

Our members are at the forefront of innovation and rely on strong patent protections to safeguard their intellectual property (IP), secure investment, and bring their innovations to market. They also require a consistent and predictable regulatory authority to meet the high standards for medical product approval. We have been tracking with great interest the recent joint activities between the USPTO and FDA, as our members are deeply involved with both agencies.

[1] Federal Register. Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments
[2] Biocom California 2022 Economic Impact Report Databook. https://www.biocom.org/eir/

We strongly support the respective missions of both agencies and acknowledge the complementary roles they play in the life science innovation ecosystem. However, because of the different natures of the agencies, we have concerns about the proposed collaboration efforts.

The FDA and USPTO held a public listening session on January 19th and opened a request for comments in relation to their proposed collaboration initiatives. In the federal register notice, FDA and USPTO reference the actions taken by the Administration to bring these two agencies together, including the President's Executive Order and the subsequent correspondence from FDA and USPTO. **Therefore, we respectfully submit the below comments to share our general position on FDA and USPTO collaboration and respond to the specific questions posed by the agencies in the Federal Register.**

General Feedback on FDA and USPTO Collaboration:

Respective Roles of FDA and USPTO

As mentioned above, Biocom California supports the independent missions of both FDA and USPTO. We believe that both agencies provide essential functions for our members in their respective roles. However, the issues and subject matters handled by these two agencies vary significantly.

The FDA's primary role is to evaluate the safety and efficacy of medical products before being approved and made accessible to the public. The FDA also plays an important but ministerial role with patents, taking the information provided by sponsors and making it publicly available for both drugs and biologics in the Orange and Purple Books, respectively. The FDA has stated publicly and in this Federal Register notice that they believe their role in patents is purely ministerial and they have no role in patent validity or adjudication.

The USPTO's role is to award an inventor exclusive rights for a limited time based on utility, novelty, and non-obviousness principles. IP rights are established in Article 1 Section 8 of the Constitution[3], which has created a system that is the foundation for much of our country's economic success. The USPTO was created to manage these rights, expertly issue patents, and adjudicate patent disputes. As part of its mission, the USPTO maintains a technology-neutral patent system based on the standards of utility, novelty, and non-obviousness. Any effort to treat patents related to life sciences differently would violate its mission.

FDA awards exclusivities to provide manufacturers of new products with limited protection from generic or biosimilar competition in the marketplace for a limited time (5 years for new chemical entities, 12 for biologics, and others for orphan drugs, first-to-file generics, etc.). Exclusivities foster innovation by allowing manufacturers to recoup their investment while incentivizing the development of generics and biosimilars once exclusivities expire.

[3] Constitution of the United States. https://www.archives.gov/founding-docs/constitution-transcript

On the other hand, patents are given a 20-year term of protection on the novel, specific patented aspect of a product which is triggered by an application. Patents can also cover many specific aspects of the product as long as each patented piece is novel. The patent constitutes a property right that grants a right of exclusion which allows inventors to control the use of their invention, including transferring, licensing, or selling the patents rights.

The standards used by FDA and USPTO to review applications and the intellectual protections that the two agencies offer are fundamentally different. Therefore, it is important that both agencies make clear to the public that they are not contingent on one another.

It is also important to note the uniqueness of the life science industry. A patent can be filed very early on in the development process to protect the underlying discovery while there may be a significant period of additional development before the product is patented and ready for FDA review. As a result, interactions between the USPTO and FDA may be many years apart and patent ownership may have changed over the course of development. Additionally, our system incentivizes post-approval innovation, which means that patents may be updated throughout the life cycle of the patent as product improvements are researched and developed.

Therefore, we encourage the agencies to be very clear and intentional about the scope of these collaboration activities and whether these activities will apply to certain classes of products, the nature of the sponsor, the setting (pre- or post-approval), how many times patent ownership has changed, or when a sponsor is engaging both agencies within certain time frames.

Importance of Patents in Life Sciences

The life sciences industry is a patent-heavy industry, making protecting the rights of patent owners an utmost priority. It often takes over 10 years and costs an average of $2 billion to bring a product to market, with a less than 10 percent chance of success. Patents provide inventors with a strong backstop against IP theft and can often be the basis for venture capital funding. Patents provide confidence in the technology, positively impact product valuation, and generally create a more conducive environment for business creation and market access. For many small companies, patents are their only asset. These small companies' patents are scrutinized closely before receiving funding and only after careful diligence to evaluate the strength and coverage of their patent portfolio.

We are generally concerned that the weakening of patent rights and the perceived notion that patents impede innovation, without demonstrated evidence, makes the U.S. less competitive both internally and globally. Patents and other intellectual property rights are the cornerstones of life science innovation.

Collaboration Efforts

Biocom California acknowledges that the directive to collaborate stems from the President's Executive Order, which states that "the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law[4]." We believe that the terms "unjustifiably delay" and "beyond that reasonably contemplated by applicable law" set a rather high bar for the agencies to determine if the conduct results in an unjustifiable delay of generic or biosimilar competition beyond reasonably contemplated by the law.

Any effort on behalf of the agencies to make these claims should be clearly and convincingly demonstrated with empirical evidence. Additionally, it is important to note that the applicable laws governing these agencies clearly outline the different natures of the FDA and USPTO.

As these collaboration efforts evolve, we encourage FDA and USPTO to be transparent about communicating to the public any policy changes they are considering. Currently, FDA already has the authority to inspect USPTO records for purposes of enforcing the Food Drug and Cosmetic Act. Similarly, USPTO can request information from FDA relating to questions raised by any drug patent application and have FDA conduct additional research into such questions[5]. Patent examiners are also able to request information directly from applicants, if they deem that information reasonably necessary to the examination of an application. Further, applicants are under a duty to disclose material information[6]. Therefore, any changes to these policies should allow for robust public consideration.

It must be clear what the roles and responsibilities of each agency are in collaboration activities. We strongly urge the agencies to ensure that the information they receive from each other does not affect their jurisdiction and operation. Joint training has already begun with FDA and USPTO and making public the topics being discussed would increase transparency around these efforts.

Finally, in situations where there may be information sharing, we believe that any information shared about sponsors or applicants should also be shared with the sponsor or applicant for the purposes of transparency and to provide an opportunity to remedy any errors regarding transmitted information. FDA and USPTO should have a duty to disclose any shared information, as the data security protocols for each agency are different.

[4] President Biden Executive Order on Promoting Competition. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/
[5] 21 USC Sec. 372.
[6] Rule 56

Federal Register Questions:

1. *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.*

First, the burden of proving that inconsistent statements are prevalent must be substantiated and rest with the parties making the accusation that false statements are being made, not industry or federal agencies. Further, statements made to the USPTO are public, and non-confidential information provided to the FDA is also made available once the review process is completed. Any additional information released could threaten confidential information.

Implementing a process of submission disclosure of "relevant" "inconsistent" FDA statements could also affect companies disproportionally, creating a larger burden on small companies by significantly increasing the cost of prosecuting patent applications. Prosecuting attorneys would likely continually review FDA filings for any possible information that might be later alleged to be inconsistent with the prosecution statements. This will likely lead to over-disclosing FDA filings in order not to be accused of failing to meet the duty of disclosure. Which, as we discuss below, may open up confidential information to third-parties in an innovator's FDA filing. A new disclosure requirement for FDA would result in longer, more frequent, Information Disclosure Statements, putting significant weight not only on the parties involved but also on patent office examiners.

We do not agree that determining whether patent applicants or owners have submitted inconsistent statements to the USPTO and the FDA is within the jurisdiction of the patent examiners. The patent examiner's role is to decide, based on statute, whether or not a claim is patentable[7]. Enabling UPSTO examiners to review FDA filings and communications would create an unnecessary burden on the USPTO and take away from their statutory mandate of reviewing patent applications for patentable subject matter. **Further, there is no substantive proposal in this Federal Register or from the Agencies on how to determine if a statement is inconsistent.** Taking away patent rights based on these statements should be done by courts under equitable principles.

As discussed above, the fundamentally different roles and functions of the USPTO and FDA require the submission of different evidence from drug manufacturers. Statutory standards for patentability and drug approval are vastly different. Even for an Orange or Purple-book listed patent that covers a drug product, the scope of the patent claim may usually be broader than the approved product or use itself. For example, data required to satisfy the utility requirement under 35 U.S.C. 101 or to cross the enablement hurdle of 35 U.S.C. 112 typically are much lower than obtaining a drug approval for human use. Patent law also allows patenting a variety of embodiments of an invention beyond just the best mode, including those that are considered unsuitable for human use. Hence, statements provided to the USPTO for the sake of seeking patent protection proffered by the patent system should be allowed to deviate significantly from those provided to the FDA for seeking market approval, simply because a product or method deemed unsuitable for human treatment still can be correctly characterized as patent-worthy.

[7] 35 USC Sec.101, 112, 102, and 103

There are also major timing differences. Patent examiners only review a patent when it is pending, while most FDA applications are not submitted until after the patents have been granted. As a result, more information could have been gathered between a patent application and an application at the FDA that would possibly make the information submitted inconsistent but not nefarious.

We have concerns over the scope of "statements" made to the FDA, as it appears not only to relate to actual filings made to the FDA, but also to any communication made to the FDA. It is unrealistic for prosecuting attorneys to continually check with an innovator company to determine what has been shared with FDA personnel and the context of such statements. The breadth of the proposed regulatory change could expose prosecutors to allegations of inequitable conduct before the USPTO.

Additionally, focusing on statements made just to the FDA is limiting. Applicants have various other situations where there is a possibility that a company representative might make a statement that could be construed to be inconsistent with the patent applicant's arguments. These instances have nothing to do with patentability, unless they directly violate the duty of disclosure.

We are extremely concerned about confidentiality, particularly if FDA were to unjustifiably share confidential information with USPTO as the two agencies have different data handling procedures for confidential information. USPTO's general position is that information materially related to patentability must be disclosed to the public, whereas FDA is subject to specific statutory restrictions on sharing proprietary information. It would likely be difficult for FDA and USPTO to identify such relevant confidential information, and could result in inadvertent disclosure of that often-commercially-critical confidential information.

Finally, we also have concerns over process and enforceability. It appears that the proposal is to provide the USPTO with what the applicant has stated to the FDA with regard to the patent application claims. Under current law, the USPTO does not have the authority to reject a patent application based on an inconsistent statement. This proposal would necessitate that the USPTO change its rules to provide the authority to examiners to reject patent applications on an inconsistent statement. Such a system would leave to the examiner the question of whether material received by the examiner as a possible "inconsistent statement" might vitiate the assertion of confidentiality made in respect to other portions of an innovator's FDA filing. Statements that are not publicly made to the FDA should not be considered prior art. Courts may render a patent unenforceable for inequitable conduct for making false statements to the USPTO, but we do not believe it falls within the USPTO's jurisdiction.

2. *What are the opportunities and challenges related to the use of America Invents Act (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?*

Biocom California believes that USPTO should bear the burden of resolving patentability-related disputes. If an FDA-related activity is based on patents, of which a patent is the foundation of the issue, USPTO should be the primary agent to resolve the underlying dispute of patentability.

We also note that the USPTO is not traditionally involved in resolving disputes concerning patent infringement, which is traditionally adjudicated by courts and an integral part of Hatch-Waxman and Biologics Price Competition and Innovation Act (BPCIA) litigation. Hatch-Waxman paragraph IV disputes and the BPCIA "patent dance" framework are specially designed to help expeditiously resolve all relevant patent disputes between brand companies and generic or biosimilar competitors with respect to the specific generic or biosimilar product at issue. The disputes under Hatch-Waxman and BPCIA are typically narrowed down to a very narrow set of patent claims after discovery and claim construction, which facilitates speedy resolution of the dispute between the parties. In contrast, AIA proceedings are a general procedure applicable to all technology fields.

A parallel AIA proceeding is often duplicative and adds significant extra costs to the Hatch-Waxman and BPCIA proceeding and can complicate and compromise the speedy resolution of the dispute between the parties when the two proceedings reach different claim constructions or opposite patentability/validity determinations.

As noted above, the **FDA's role is ministerial regarding patents, and they bear no real responsibility to ensure a patent is valid.** We disagree with paragraph 1, section (e) of the USPTO Letter: "the USPTO will work with the FDA on processes and procedures for (1) notifying the FDA of AIA proceeding filings on any Orange Book-listed patents and/or Purple Book-listed patents, and (2) potentially sharing more information between the agencies." The rationale for FDA being given this information is unclear, and it does not appear to have a relation to its role.

3. *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.*

Biocom California believes that current practices at USPTO and FDA regarding PTE have been working well, and both agencies should continue to focus on their respective jurisdictions and expertise. If making the information more available to the public is the desired outcome, such information is already available on the USPTO website. We do not envision scenarios that would require additional collaboration.

4. *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-terms-extended-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?*

FDA's role in PTE is to assist USPTO with determining the length of regulatory review. However, the USPTO is responsible for the extension itself. **We again believe that current practices at USPTO and FDA have been working well. Both agencies should continue to focus on their expertise, and the information online is sufficient.**

5. *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")?*

Neither USPTO nor FDA can add a method of use to a patent that has not already been granted. Similarly, FDA or USPTO cannot add an additional use of the drug to the label that the sponsor did not apply for. To do so would completely reverse the role of these agencies. Regarding method of use patents, only the USPTO is involved in determining if the claims are patentable based on statute.

Therefore, we do not see a rationale as to why the FDA would need to get involved. Generic and biosimilar applicants have achieved significant success with the information that is currently provided by the USPTO and the FDA as separate entities. Similarly, with regard to skinny labels, the USPTO has no jurisdiction over the indications listed on a drug label and lacks relevant experience and expertise in assessing patent infringement that is necessarily associated with any skinny label inquiry. **Biocom California would like clarification from the USPTO/FDA on what they would do with this information from the other Agency.**

As mentioned above, the Agencies must respect their boundaries as outlined in law and regulation. USPTO should not be asking FDA to expand its role in patent adjudication if the law is unclear or silent. There are already effective means for the public to challenge any allegedly improper listing or use code, and the current system has been working well. Therefore, Biocom California does not see a need to change policies.

6. *What policy considerations or concerns should the USPTO and the FDA explore in relation to the patenting of risk evaluation and mitigation strategies (REMS) 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?*

Biocom California again turns to the patent law statutes. If USPTO finds REMS patentable and worthy of issuance of a patent, then indeed, the process should be patented and come with all associated benefits. REMS patent applications should be treated no differently than any other application. The law does not warrant or suggest treating these inventions differently than others, which would be unprecedented. If these applications were treated differently, there would be significantly less ability for companies, especially small companies, to heavily invest in these risk mitigation strategies. The Patent Office cannot delegate any of its administrative duties under the Patent Act to the FDA[8], or have the FDA comment on the patentability of REMS claims. Further, if the policy around REMS changes, the need to address existing REMS patents would present additional difficulties.

7. *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?*

There are several systems already in place to assert the validity of patents, including in courts and at the Patent and Trial Appeal Board (PTAB). FDA and USPTO should attempt to provide detailed information on what they purport is "misuse" and "unjustifiable delay" in order to understand the landscape based on evidence. FDA's role in this discussion is limited because they do not play a role in prosecuting patents or how those patents are enforced.

Concerns about the misuse of patents stem, in part, from accusations that sponsors have been filing several patents on the same product forming a "patent thicket", or that sponsors are frequently updating patents to create "evergreen" exclusivity, or never-ending patent protection for their product.
We believe that these claims must be substantiated by sufficient evidence before policy changes are contemplated.

The sheer number of patents on a product is not an indication of misuse, as our laws do not prescribe a limit on patents, and multiple patents on a product are common with many innovative products and industries. The number of patents on a product is a reflection of the innovation of the product, and a single product may have multiple novel technological aspects and represent an advancement in several fields. Regarding evergreening, industry products are experiencing the same effective exclusivity, meaning time without generic competition on the market (12-13 years), as they have for the last 30 or more years, and the average product is not seeing an infinite extension of their patent regime.

[8] 35 U.S.C §131

Innovators and generic or biosimilar competitors typically resolve their patent disputes through ANDA or BPCIA litigation, a process specifically designed to expeditiously resolve all relevant patent disputes between the parties. The number of patent claims that are eventually adjudicated in an ANDA or BPCIA litigation is typically limited to a very narrow set of representative claims. These representative claims often embody the key inventive aspects of the innovator product that the innovator believes that the generic or biosimilar company would infringe. Upon finding of non-infringement or invalidity of this narrow set of representative claims, the generic or biosimilar company would be able to sell the generic or biosimilar product at issue without the need to challenge and overcome any remaining patents or claims in the so-called "patent thicket". In other words, there is no practical or legitimate reason for a generic or biosimilar company to circumvent the specially designed, fast-tracked ANDA or BPCIA proceeding, but instead insist on challenging and overcoming each and every patent in the so-called "patent thicket" before the PTAB or in courts.

Another claim against innovators is that sponsors have been submitting inconsistent statements to FDA and USPTO regarding patents for their products. However, this too is not supported by sufficient evidence. There have been two cases the USPTO points to in the last 30 years where inconsistent statements have been the issue (*Bruno Independent Living Aids v. Acorn Mobility Services* and *Belcher v. Hospira*). Between 2008 and 2022, there have been 4,696 Hatch-Waxman cases filed in US district courts, and there is no evidence of a recurring problem of inconsistent statements to FDA and USPTO.

We maintain that there is insufficient empirical evidence for these statements to warrant significant policy changes. Biocom California believes that the need for the kind of collaboration desired by critics is unsubstantiated, and the abuse claims need to be scrutinized further by FDA and USPTO.

The question of scarcity of drugs no longer covered by a patent is a larger policy issue that needs to be examined separately for evaluation of the incentives needed to spur the development of these products. Biocom California believes this issue has no relation to this public engagement.

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

1(c) Provide examiners with training, in collaboration with the FDA, on publicly available FDA resources that can be utilized in prior art searches and on the state of the art in the pharmaceutical and biopharma areas and provide resources to the FDA to support its work on matters influenced by patent law and policy.

Biocom California supports more USPTO engagement with industry experts to understand the state of the art in life sciences so that examiners have a better understanding of the state of innovation. We firmly believe that patent examiners should be adept and have the necessary tools to issue "strong" patents. Similarly, we believe that a patent that was issued in error should be challenged as appropriate.

The USPTO should have updated databases that allow it to search the public domain so that examiners do not miss relevant art during prosecution that may render the patent invalid in future litigation. Since information not available to the public is not necessary to determine patentability under the statutes, we do not think the USPTO should receive non-public information from other agencies.

> *1(e) Engage in greater FDA collaboration in AIA proceedings. In addition to improving the robustness and reliability of patents that are granted in the first place, the USPTO will work with the FDA on processes and procedures for (1) notifying the FDA of AIA proceeding filings on any Orange Book-listed patents and/or Purple Book-listed patents, and (2) potentially sharing more information between the agencies. The USPTO will also work with the FDA to assess why there have been so few filings of AIA proceedings on Orange Book-listed patents and biologic patents and why the number of AIA filings for pharmaceutical patents has generally declined.*

Biocom California encourages USPTO to consider that because the Orange and Purple books bring transparency to the patent environment, infringement and proceedings against patents published in the books are not as common. Biocom California lacks an understanding of how the USPTO benefits the FDA by notifying the FDA of AIA proceeding filings on Orange Book-listed patents and/or Purple Book-listed patents en masse. Many AIA filings may not rise to the level of unchecked transmission to FDA based on the quality of the case. **Biocom California believes that providing such raw information would only aid in slowing down the approval of new and innovative drugs by increasing the utilization of attorney time to respond to inquiries raised by the FDA in response to such proceedings.**

> *1(h) Remain open to discussing with the FDA, other agencies, the Administration, and stakeholders the FDA's concerns over practices referred to as "patent thickets," "evergreening," and "product hopping."*

As stated, Biocom California is concerned about the use of these terms. **These practices need to be investigated further to assess whether they have delayed competition, impacted prices, or staggered innovation.** If patents are valid per patent law, they should be treated consistently with other patents, and agencies should not seek rules that only apply to life science products.

Conclusion

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Manager of Federal Advocacy, Rick White, at rwhite@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,

Joe Panetta
President and CEO
Biocom California