AIPLA
American Intellectual Property Law Association

February 6, 2023
Via Federal Rulemaking Portal at https://www.regulations.gov

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

RE: Joint USPTO-FDA Collaboration Initiatives – Request for Comments

Dear Director Vidal:

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to reply to the notice of November 7, 2022, from the United States Patent and Trademark Office ("USPTO") requesting comments on joint USPTO-FDA collaboration initiatives[1] (the "Notice").

AIPLA is a national bar association of approximately 7,000 members that include professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property.

Our members represent both owners and users of intellectual property ("IP").

Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

General Comments

AIPLA thanks the Director for this opportunity to submit written comments in response to the questions presented in the Notice. AIPLA would also like to express its appreciation for the opportunity to speak at the USPTO-FDA Listening Session held on January 19, 2023. As provided below, AIPLA's written comments are in response to questions 1-7 and 9 as set out in the Notice, together with that which was previously submitted to the USPTO on January 17, 2023 in our statement directed to Question 2.

AIPLA is fully supportive of USPTO and FDA efforts to train patent examiners on publicly available FDA information and resources in an effort to supplement, but not replace, current patent searching requirements and criteria. AIPLA believes the existing duty of candor to the USPTO provides the necessary deterrent not to make a material, inconsistent statement.

[1] "Request for Comments on USPTO-FDA Collaboration Initiatives," 87 FR 67019 (Nov. 7, 2022).

AIPLA submits the disclosure of confidential information held by the FDA is not only impractical for use in patent examination and associated public disclosure in a prosecution file history, but the disclosure of FDA confidential information through any mechanism has not been shown to be necessary. The duty of candor and rules related thereto are sufficient. The system is working.

Likewise, in view of the pre-existing Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or the "Hatch-Waxman framework"), AIA proceedings do not function as a quicker, cost-effective, alternative to district court. Nor can an AIA proceeding avoid or replace district court litigation where a patent claim is challenged for reasons other than prior art. An AIA challenge in the Hatch-Waxman framework would be largely duplicative of the district court proceeding, increase time to resolve, and add delay and complexities into the process, as well as add costs for both parties. In short, any potential opportunity (or challenge) related to the use of an AIA proceeding to address the validity of patent claims in a generic challenge of a pharmaceutical patent is likely to delay the generic product launch and increase the cost of the generic drug product once made available to the public.

AIPLA submits that the Patent Term Extension ("PTE") application review process could be improved to be more efficient, less duplicative of work efforts, and offer the public and the applicant with clarity (early on) regarding a fairly restored lost patent term based on FDA regulatory review period provided under 35 U.S.C. § 156. In addition, other enhancements to information sharing of agency interactions, transparency and benefits to stakeholders and the public is welcomed.

These key comments together with other comments on other questions are each explained in greater detail below.

Responses to Questions

Question 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?

AIPLA Response

Pursuant to its mission to promote and protect public health, the U.S. Food and Drug Administration (FDA) has made a wealth of resources available regarding the products it regulates, including foods, pharmaceuticals, biologics, medical devices, cosmetics, supplements, selected laser products, tobacco products, and the ingredients or components of the foregoing products. While not offered for purposes of a patentability determination or sufficient to replace or otherwise satisfy a gap in USPTO resources, the information made available by the FDA can be used to educate examiners about the regulations and regulatory actions taken relevant to a regulated product and its manufacture.

Therefore, AIPLA submits that patent examiners should utilize currently publicly available FDA resources in determining allowability of a claim and, particularly, when addressing applicant remarks related to commercial considerations of a claimed product, the effect of which results in a focused prosecution based on relevant prior art.

For example, the following resources may have value to USPTO examiners:

- *Process and regulatory framework trainings produced by FDA's Center for Devices and Radiologic Health (CDRH), Centers for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER)* - These trainings are produced by experts in the centers responsible for evaluating new drugs, biologics, and medical devices and provide context for the relevant regulatory standards and timelines for review and existing alignment of the FDA, USPTO, and other agency policies (to the extent such policies exist).

- *Publicly available product clearance and approval databases, such as the searchable premarket notification database (510(k) database), premarket approval (PMA) database, establishment listing and registration database, and Drugs@FDA database, among others* - These databases contain information on products that have been evaluated by the respective review centers at the FDA and been determined to be legally marketed in the U.S. The information typically provided includes registered, cleared, or approved indications for use and product labeling. Further, they can provide information on medical products available prior to the priority or filing dates of relevant patent applications under examination before the USPTO, as well as their respective manufacturers, which can enhance the ability to identify relevant prior art.

- *Patent information provided by manufacturers in the FDA Orange Book (for drugs) and Purple Book (for biologics)* – This information is provided by the manufacturers of approved drug and biologic products and provides yet another means of identifying relevant prior art for similar commercially available drug and biologic compounds.

AIPLA recommends that guidance and training continue for examiners utilizing FDA publicly available resources while highlighting the different roles of the FDA and the USPTO in the commercialization of new, beneficial therapeutic products. The unique laws, practices, and standards directed to product safety and efficacy should not be imported or conflated into satisfying the requirements for patent protection, however.

Likewise, statements made to the FDA in support of clearance or approval, such as those based on substantial equivalence to a predicate product in 510(k) premarket notification, may appropriately coexist with statements of novelty or non-obviousness made to the USPTO for features of such products, which are in fact novel and non-obvious. An awareness of the unique laws, practices, and standards can assist in forming a well-grounded rejection – and alternatively to determinations for allowance. AIPLA believes that enhanced use of these available resources would not introduce additional burden or confusion to the USPTO so as to negatively impact the speed or quality of examination.

Overall, with appropriate guidance, existing tools and resources already available from the FDA can provide helpful context and connections to the examiner's tool kit without additional burden to examiners or applicants.

Question 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.

AIPLA Response

AIPLA, like the USPTO, believes that a patent examiner needs to know about inconsistent statements made in the same context. That is, a patent examiner needs to know about statements that can affect his or her determination that a patent claim is allowable, and a patent can be granted on that claim.

However, AIPLA is not aware that inconsistent statements are a widespread problem or that inconsistent statements have resulted in a significant number of patents being granted that should not have been granted. AIPLA believes the existing duty of candor to the USPTO provides a substantial deterrent not to make a material, inconsistent statement.

Generally, AIPLA is concerned that any attempt to share information between the agencies, regardless of the mechanism, will create significant burdens on both agencies and applicants. We are further concerned that confidential information will be disclosed, which will put trade secret protection at risk and result in a disincentive to innovation.

While avoiding inconsistent statements is a valid concern, AIPLA believes that the current duty of disclosure rules work.

AIPLA believes that the duty of disclosing information to the USPTO that has been disclosed to the FDA is already required by current 37 CFR § 1.56, to the extent it is known and material to patentability, and it is clear. The law requires every individual involved with a patent application to be candid with the USPTO. This duty of candor requires anyone associated with the prosecution of a patent application to disclose to the USPTO information material to patentability – including that on file with the FDA.

The effect of not abiding by the rules, the deterrent, is very serious: unenforceability of any subsequently issued patent right.

AIPLA believes that the obligations associated with the duties of disclosure, candor, and good faith are clear and diligently implemented and administered by the USPTO, and further supported by the judicial branch. Through enforcement of the associated regulations, the USPTO encourages patent applicants to provide accurate and material information of which it is aware.

Inconsistent statements made to the FDA and the USPTO pose a substantial risk to enforcement of potentially very valuable patents. Prudent applicants have a strong incentive to take precautions to avoid the risk of making inconsistent statements.

On a logistical level, any attempt to share information between the USPTO and the FDA will create significant burden on both agencies and all applicants.

Great care must be taken to ensure that the sharing of information be performed in a manner that avoids public disclosure and protects confidential/trade secret information. But the

determination of whether information is public (or can be made public) will take time and resources. This burden will not only stretch already limited resources, it will also take away from the focus of each agency's fundamental purpose.

Any new mechanism to share confidential information between agencies will be difficult. Drug applications are voluminous (e.g., tens of thousands of pages are often submitted over a period of years) and are in the context of drug safety and efficacy. The voluminous nature of these documents, many of which are not material to patentability, could easily overwhelm a patent examiner.

In fact, the burden would not only be on the agencies, but on all applicants. Resources within the USPTO and the FDA are limited. Such resources would have to be redirected to meaningfully allow for information sharing and review. Thus, all applicants, even in areas of technology outside of the pharmaceutical arts, would be impacted.

Moreover, the serious risk of delays at both the USPTO and the FDA due to additional burdens on the agencies is concerning. Such delays would likely lead to longer patent term adjustments and patent term extensions. More significantly, delays in regulatory approval for important therapeutics for patients can result in delayed access to promising new therapies.

AIPLA believes that Trade Secret Protection could be at risk – and such risk may provide a disincentive to innovate.

While protecting trade secrets does not overrule misrepresentation concerns, AIPLA is also concerned that information sharing could include trade secrets, and without proper safeguards in place, this could have a chilling effect on future innovation and be anticompetitive.

Trade secrets are recognized as fundamental building blocks that drive innovation, investment, and economic growth. Since 2016, in the United States, companies have been empowered to protect trade secrets from misappropriation through a federal private right of action.

Because the USPTO must make patent prosecution related information available to the public, this will present a significant risk to patent applicants and potentially runs counter to existing regulations and statutes. Injury via public disclosure of trade secrets is difficult to compensate and/or remedy. The risk of losing trade secrets can serve as a disincentive to innovation.

Question 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?

AIPLA Response

AIA proceedings were designed in part to provide a quicker, cost-effective alternative to district courts for patent challengers to raise and resolve patentability disputes. In some instances, the proceedings accomplish those goals for certain patent challengers. However, as

several letters between the USPTO and the FDA acknowledge, there have been relatively few filings of AIA proceedings on Orange Book listed patents and biologic drug patents. This comment will provide AIPLA's input on why generic and biosimilar product manufacturers may not view AIA proceedings as first choices in their efforts to bring lower cost copies of medicines to market safely and quickly.

The Hatch-Waxman Act has for decades served to encourage innovation in drug development while at the same time facilitating the copying and entry of low-cost generics into the marketplace. The Hatch-Waxman Act was specifically designed to promote these competing objectives via a carefully crafted, complex balance of incentives to new drug developers and generic drug manufacturers. For the reference drug sponsor, a limited period of regulatory exclusivity is awarded during which time the FDA will not approve any copying, i.e., generic versions of the drug. For generic manufacturers, an abbreviated approval pathway was created that permits the generic manufacturer to rely on certain data about the reference drug, rather than repeat burdensome clinical studies. In addition, the Hatch-Waxman Act encourages resolution of patent disputes prior to generic drug market entry by, *inter alia*: (1) deeming the filing of a generic drug application with the FDA an "artificial act of infringement," which confers subject matter jurisdiction for patent disputes to be litigated in district court prior to any commercial use or sale of the generic product; (2) providing for a 30-month stay of FDA approval of a generic drug if the reference drug sponsor files a patent lawsuit within 45 days of being notified of the patent challenge; and (3) rewarding exclusivity to generic drug manufacturers who are first to successfully challenge Orange Book patents (a 180-day period of marketing exclusivity) during which no other generic versions of the same drug will be approved. An analogous, but very different, framework of incentives was introduced specific to biologic drugs and biosimilar versions thereof in the Biologics Price Competition and Innovation Act ("BPCIA").

Over time, the Hatch-Waxman framework has resulted in a strongly competitive environment in the U.S. generic drug industry, with generic drug manufacturers striving to be "first to file" patent challengers and to litigate their patent disputes as expeditiously as possible, with the goal of obtaining the coveted 180-day generic marketing exclusivity. Through this system of incentives, many lower cost generic drug products were brought to market years or decades before expiration of the Orange Book listed patents. By design, the BPCIA may yield comparable advantages to all (e.g., expediting market entry for biosimilar drugs). Data needs to be collected to understand how the law works, as BPCIA proceedings are newer.

In view of the pre-existing, and efficient, Hatch-Waxman framework, AIA proceedings do not function as a quicker, cost-effective, *alternative* to district court. Rather, AIA challenges in the Hatch-Waxman framework are largely duplicative, adding delays, complexity, and cost for both parties.

Some challenges of laying AIA proceedings over the pre-existing framework for pharmaceutical disputes include:

Parallel District Court Litigation. To get the benefit of the statutory 30-month stay of approval, the reference drug sponsor must file a lawsuit in district court within 45 days of being notified of the patent challenge. If a generic manufacturer chooses to challenge one or more Orange Book listed patent at the PTAB by filing an IPR petition(s), the parties will need to simultaneously litigate the matter before two different tribunals. This adds burden, redundancy, inefficiency, delay, and complexity on all sides, frequently requiring the hiring of additional

counsel (PTAB practitioners in addition to district court litigators) and the retention of multiple experts.

Cost. Due to the parallel nature of these proceedings, as discussed above, they add substantial costs for both parties. Indeed, considering the complex nature of PTAB proceedings in the pharmaceutical space, often requiring the testimony of experts, parallel PTAB proceedings can contribute significantly more costs to reach a dispute resolution.

Accordingly, while AIA proceedings may provide a seemingly quicker, cost-effective forum for challenging patents in many technical areas, this is not the case in the context of Hatch-Waxman or BPCIA litigation. Within these two frameworks, district court litigation is both inevitable and encouraged. The parties to these patent disputes have found it relatively more efficient and cost-effective to litigate validity, infringement, unenforceability of all relevant patents in a single district court proceeding than to layer AIA proceedings on top of the litigation.

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.

AIPLA Response

AIPLA appreciates and underscores the importance of the rights to PTE under 35 U.S.C. § 156. PTE has been and continues to be an important mechanism by which the owners of patents that claim only specific, limited products (i.e., human drug products, medical device products, animal drug products, veterinary biological products, and food or color additive products) seek to *restore* lost patent term to limited, statutorily authorized patents. These patents are those in which the term is otherwise lost to the patent owner while requisite regulatory Agency approval is diligently sought. The right to such restored term has been very carefully considered, debated, litigated, and codified over time as the Hatch-Waxman Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282).

The Notice acknowledges that "a recent report found that the USPTO accurately and fairly grants patent term extensions based on FDA regulatory review periods," but that "USPTO will collaborate with the FDA to determine if there are any areas for improvement through information sharing or otherwise." AIPLA agrees that the current process for review of PTE applications has provided accurate and fair results, and commends the USPTO and the FDA for having implemented a robust system that accurately and fairly applies the intricate requirements for providing patentees with the rights granted by Congress under 35 U.S.C. § 156.

One potential area for improvement is for the USPTO and the FDA to take a more streamlined approach to the PTE Application review process to improve efficiency of the review process, reduce burden of duplicative work on the agencies, and provide the public and applicants with earlier clarity as to the fairly restored lost patent term (based on FDA regulatory review period provided under 35 U.S.C. § 156). Pursuant to MPEP § 2756, once the USPTO receives a PTE application, the USPTO sends a first letter to the FDA requesting information

regarding eligibility. The first letter is accompanied by a copy of the PTE application but does not request the determination of the applicable regulatory review period. After the USPTO reviews eligibility of the application, then the USPTO sends a second letter to the FDA requesting a determination of the length of the regulatory review period of the product.

Currently, the FDA calculates the applicable regulatory review period and publishes this information for public comments only after the second letter from the USPTO is provided. Third parties then have a 180-day period to file any due diligence petitions, alleging that the PTE applicant is eligible for less PTE resulting in a shorter patent term. After the 180-day notice period expires, and any outstanding due diligence petitions are resolved, a final determination of the regulatory review period is made. This process is often lengthy and can take approximately three years from initial filing of PTE application to granting of a PTE certificate.

AIPLA recommends that the USPTO and the FDA explore taking a more streamlined approach and consolidate this process into a single letter exchange between the USPTO and the FDA to reduce the burden on both agencies. MPEP § 2756 indicates that the USPTO first determines that there is "no clear reason to deny eligibility of patent term extension" before sending the first letter to the FDA requesting information regarding restoration of lost patent term. Therefore, the USPTO has already conducted an initial review regarding eligibility for restoration of lost patent term before any communication is sent from the USPTO to the FDA. AIPLA proposes that the USPTO consider providing a single letter (with a copy or link to the PTE application) to the FDA requesting necessary eligibility information regarding restoration of lost patent term. If the FDA does not identify any questions concerning eligibility for patent term and proceeds to make a determination of an applicable regulatory review period and publication of such a determination, then an additional, separate request from the USPTO is not required. This would streamline collaboration and exchange of information between the two agencies.

The Notice also considers whether there are any areas for improvement through information sharing between the FDA and the USPTO in the agencies' currently accurate and fair review process of PTE applications. One potential source of additional information that the FDA could provide to the USPTO is publicly available, non-confidential, redacted versions of letters, labels, package inserts, and FDA Application Review files that have been made available in the Drugs@FDA database (www.fda.gov/drugsatfda). However, presumably some of these materials are and have been available to the USPTO. Therefore, their value in enhancing the USPTO's activities should be carefully considered. These documents contain information about the drug or biologic product, but have been redacted -- and must be redacted to remove information that applicants consider trade secret or otherwise proprietary, confidential information. Failure to handle such information appropriately could harm important intellectual property. Furthermore, these documents are currently prepared as part of the FDA's Drugs@FDA database and therefore, an exchange of these document with the USPTO would not likely be a significant increase on the FDA's burden in the PTE application review process, if this type of information would be of value to the USPTO.

Furthermore, and similar to AIPLA's comments in response to Q2, AIPLA is concerned that any mechanism allowing the FDA to disclose confidential information and trade secrets not subject to public disclosure in connection with review of a PTE application will have a negative impact on future innovation and potentially destroy the value of sensitive trade secrets. AIPLA requests that the FDA and the USPTO provide further clarity as to what mechanisms may be put in place if any confidential information, such as trade secrets or other confidential

information redacted from the publicly available documents in the Drugs@FDA database, are provided by the FDA to the USPTO in their collaboration and information exchange.

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-termsextended-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?

AIPLA Response

The AIPLA thanks the USPTO for the centralized access to PTE applications filed, located at *www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156.* To enhance agency interactions, transparency, and to benefit the FDA, stakeholders, and the public, AIPLA suggests the following (listed in no order):

- The USPTO currently provides a downloadable spreadsheet ("PTE applications during last five years" (updated August 2022) [MS Excel]) that includes a list of all applications for patent term extension under 35 U.S.C. § 156 that have been filed within the past five years. The status of each application, including present *disposition,* is currently only available by reviewing the electronic file wrapper in the USPTO Patent Center. However, it would be valuable to include such information in this downloadable spreadsheet. The length of extension requested and category of patent claim (e.g., product, method of using the product, or method of manufacturing the product) may also be considered to be included. These changes would enable the FDA and stakeholders enhanced access and the ability to use the information more efficiently in collaboration with the USPTO.

- The USPTO may consider reducing complexity of the USPTO information by, for example, limiting the "PTE applications during the last five years" to patents listed in the Orange Book or Purple Book, or at least indicating in the downloadable spreadsheet which patents are listed in the Orange Book or Purple Book. This would also provide more opportunity for cross referencing non-confidential public information between the agencies.

- The USPTO notes that "nearly all patent term extension applications are available in Patent Center." For transparency and the benefit of the FDA and stakeholders, identification of the criteria for exclusion of applications in Patent Center would be beneficial if it were provided.

- As the USPTO indicates, additional information concerning patent expiration dates of human drug products can be obtained from the FDA's Center for Drug Evaluation and Research and The Patent and Exclusivity Addendum of the "Orange Book," the

Approved Drug Products with Therapeutic Equivalents Evaluations, which includes an alphabetical listing of human drug products according to generic name with related patent information. Cross referencing of this information (by inclusion of links) would facilitate transparency and benefit the FDA and stakeholders.

- Adjusted expiration dates taking into consideration disclaimers filed after the filing date of the PTE application and adjusted patent expiration due to the failure to pay maintenance fees would be beneficial if included.

- Potential updates to the website would benefit from a more focused survey of the most relevant stakeholders.

- The list of applications for patent term extension and list of patent terms extended under 35 U.S.C. § 156 updated monthly would be helpful.

- In the "PTE applications during the last five years" table a change in the heading "Trade Name Identified in PTE Application" to "Trade Name of Product (generic name, if applicable) Identified in PTE Application" would be helpful.

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'')?

AIPLA Response

As part of the Hatch-Waxman framework, the Food, Drug, and Cosmetic Act ("FDCA") requires a New Drug Application ("NDA") holder to submit information to the FDA regarding patents that claim the approved drug substance, drug product, and any "pending or approved method of use and related patent claim(s)." The FDA then publishes granted patents covering the approved drug substance, drug product, and method(s) of use in the Orange Book to provide potential generic filers notice of the approved product's granted patents that could be reasonably asserted based on the commercial marketing of their product.

For Orange Book method of use patent(s), the NDA holder must identify a "use code" that corresponds to the approved indication or method of use and the patent claim(s) covering same. As listed patents may claim both approved and unapproved uses, the use code fulfills a critical notice function of the Hatch-Waxman Act to identify which approved uses are covered by patent(s).

The FDA's role in the Orange Book patent listing process is purely ministerial as the FDA does not evaluate whether, for example, any given method of use patent is accurately listed nor whether any identified use code is overly broad. This is not the Agency's mandate; however, this is appropriate given that the FDA lacks authority, training, the resources, and the patent expertise necessary to evaluate patent claim listings. There is also no process in place for the USPTO to assist the FDA, should such assistance be needed in the FDA's ministerial role of patent listings. Inevitably, any new mechanism inserted into the patent listing process leads to complexity, with many downstream questions about implementation and impact on current patent enforcement proceedings.

For example, if the FDA, alone or together with the USPTO (using a new process), substantively evaluated patent listings, how would such listings be reviewed and under what standard of review? What if they disagree? As the notice feature of the Orange Book is a critical piece of the Hatch-Waxman framework, would there be a time element involved with such a review? If the FDA or FDA/USPTO disagreed with any aspect of the new process, would there be an opportunity for the NDA holder to appeal adverse listing decisions? How would such appeals be handled? And, if a generic drug sponsor launched "at risk" before a patent listing dispute was resolved, what would be the remedy to the NDA holder? In this scenario, would an "at risk" launch by a generic lead to increased litigation against the FDA or FDA/USPTO?

There is certainly no indication or evidence that such a mechanism would lead to generic applications being approved sooner or that generic drugs would enter the market any quicker. Presumably, an NDA holder could still enforce a patent with an adverse listing decision outside of the Hatch-Waxman framework. This may lead to an increased reliance on patent proceedings outside of the Hatch-Waxman framework and more complex patent litigation proceedings closer to the time of generic launch. But such a chilling effect could even have a further countereffect as innovators have also faced lawsuits for not listing patents in the Orange Book (Mut. Pharm. Co. v. Hoechst Marion Roussel, Inc., No. CIV. A. 96-1409, 1996 WL 34406666 (E.D. Pa. Feb. 23, 1996)). Regardless, claim analysis, claim interpretation, and any substantive mechanism of patent listings would counter the intent of the Hatch-Waxman Act as it would lead to greater delays to generic market entry and increased uncertainty to both brand and generic manufacturers and ultimately to patients.

This all goes against the very purpose of the Orange Book to provide timely notice to potential generic filers so they may analyze NDA holder patents early to develop a commercial case to bring generic drugs to market in a predictable and streamlined manner. This predictability better facilitates the approval of generic drug products and presumably the access of less expensive prescription drugs to the public. The Orange Book, in its current form, provides transparency to the existence of patents covering approved drug products that allows for efficient and systematic resolution of patent issues prior to a generic drug manufacturer marketing their product.

Lastly, there are already authorized procedures in place to dispute the accuracy of patent listings either directly to the FDA under § 314.53(f) and/or as a counterclaim in Hatch-Waxman litigation. Historically, there have been relatively few cases concerning listing disputes. Since 2017, the FDA reports that there have been 55 patent listing disputes with 28 resulting in no change to the patent listing and 27 resulting in an updated patent listing. There is nothing to indicate that the FDA's patent listing dispute process has not been successful. Rather, any subsequent patent listing disputes raised as counterclaims in the courts have been addressed. Per the *Caraco* decision, the court clarified that the scope of the use code can be no greater than the approved indications or other conditions or use and no greater than the scope of the patent (Caraco Phann. Labs., Ltd. v. Novo Nordisk AIS, 132 S. Ct. 1670, 1683, n.7 (2012). Other court cases have provided further clarity into patent listing disputes such as In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1 (1st Cir. 2020) (class action alleging improper listing of device patent in Orange Book). These types of questions are better left to the courts that have the resources and patent law expertise to lead to timely resolution of patent listings.

Question 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?

AIPLA Response

This question is directed in part to The Food and Drug Administration Amendments Act ("FDAAA") of 2007, which gave the FDA the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS program is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.[2] This question reflects comments already posted in this response to the Notice concerning whether a biopharmaceutical innovator should be able to patent a method, when the development of the method was specifically requested by the FDA in response to a concern over patient safety.

First, AIPLA agrees with the USPTO and the FDA that the patent system should incentivize innovation, but not *unjustifiably* delay generic and biosimilar competition *beyond that reasonably contemplated by the applicable law*.[3] However, with respect to this question, AIPLA is not aware that the patenting of REMS methods associated with FDA-approved biopharmaceutical products is a problem. Importantly, AIPLA is not aware of a significant number of patents being granted for such methods that should not have been granted based on the U.S. Patent Laws. Further, AIPLA is not aware that the current mechanisms available to a generic, 505(b)(2), or biosimilar applicant to challenge a patent containing method claims, including one claiming a REMS method, through the AIA or during Hatch-Waxman or biosimilar litigation in the courts, or through a request to delist a patent believed to be improperly listed in the FDA Orange Book, are not adequate.

According to the FDA website, "[w]hile all medications have labeling that informs health care stakeholders about medication risks, *only a few medications require a REMS*"[4] (emphasis added). According to the FDA REMS Public Dashboard, as of the time of this writing, there are only *60* active approved REMS programs (while only 301 REMS programs have been approved since 2008).[5] It is acknowledged that a biopharmaceutical innovator may also develop patient risk evaluation and mitigation strategies as part of its development process independently of a specific request from the FDA. Therefore, on its face, it appears that REMS programs and, by extension, the issuance of patents claiming such REMS programs are not common. This has not been challenged by the USPTO.

Second, AIPLA submits that raising a general concern over whether a biopharmaceutical innovator should be able to patent a method, when the development of the method was specifically requested by the FDA in response to a concern over patient safety, *overly simplifies the processes of the FDA and the U.S. patent system*, and ignores what the law

[2] See section 505-1(e) of the FD&C Act and section 505-1(f) of the FD&C Act.
[3] Executive Order on ''Promoting Competition in the American Economy,'' 86 FR 36987 (July 14, 2021).
[4] https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
[5] https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/dfa2f0ce-4940-40ff-8d90-d01c19ca9c4d/state/analysis; Note: FDA disclaimers.

requires for a claim to an invention to be patentable. The USPTO's determination of the patentability of a process and FDA approval of a method are entirely different analyses. A request by the FDA to address patient safety, including to establish a process or method for ensuring patient safety for a particular drug product, *is a proposal of a problem* that the biopharmaceutical innovator/applicant must solve. However, the FDA request or requirement does *not define the solution*; that is the job of the applicant in order to obtain approval for their drug product. The solution to the problem may in fact involve *significant* additional development work on the part of the biopharmaceutical innovator that can indeed result in a new invention that may be patentable, only if it meets the requirements of the U.S. Patent Laws under 35 U.S.C. §§ 101, 102, 103, and 112. In the course of approving any drug or biologic product, regardless of the approval pathway, it is standard practice in the fulfillment of its mission that the FDA *requests* that the applicant address questions of safety and/or efficacy of the drug product under evaluation. These requests *may* require the biopharmaceutical applicant to conduct additional clinical studies, modify dosing regimens, reformulate a product, evaluate a drug product in particular patient populations, establish appropriate patient warnings through data generation, develop new analytical or manufacturing methodology, and, while not commonplace according to the FDA itself, even establish a formal REMS program. Such additional development work may or may not result in a patentable invention, even in the case of a REMS distribution method, depending on many facts and the nature of the application for which a patent is sought. The fact that inventive work may occur during, and as a result of, the FDA review process (which may extend for years for some products), should not mean that the biopharmaceutical innovator cannot or should not pursue patentable inventions arising from such work.

AIPLA submits that whether a claimed invention meets the statutory requirements for patentability, including methods developed during and/or as a result of the FDA approval process, falls under the purview of the USPTO. As previously noted, AIPLA believes that the duty of disclosing information to the USPTO that has been disclosed to the FDA is already required by current 37 CFR § 1.56 and it is clear. Having this in mind, under what authority would the FDA or the USPTO seek to apply current patent law *differently* to a REMS method claim, or to another type of method claim, wherein such method claims result from innovative work done by a biopharmaceutical innovator to address an FDA concern or an FDA request during the drug approval process, if such method claim otherwise meets the requirements for patentability under the U.S. Patent Laws? How would the FDA or the USPTO determine when and how to apply a different standard or approach to such method claims? Which Agency would make the final determination? Additional questions raised previously in this letter regarding the sharing of information between the FDA and the USPTO should also be considered here.

In order to provide a constructive suggestion in response to the question, AIPLA suggests that, rather than approaching the question from the perspective of the USPTO and potentially putting restrictions on the ability of an innovator to patent new and inventive methods, the agencies focus instead on the FDA guidance and regulations with regard to the listing of patents in the FDA Orange Book. The FDA could expand its specific guidance over whether or not a method claim that is directed to a REMS distribution method, and is not directed to "one or more approved methods of using the approved drug product" as required for Orange Book listing,[6] can be properly listed in the FDA Orange Book (or Purple Book). AIPLA is not aware that the FDA has provided guidance or oversight on this issue, but this is an option for consideration. Generic applicants have mechanisms to challenge what they believe is the

[6] See 21 CFR 314.53(c)(2)(ii)(P).

improper or inaccurate listing of a patent in the Orange Book[7], and patent listing disputes can also be adjudicated during patent litigation.

Question 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?

AIPLA Response

Below are selected miscellaneous items provided for consideration regarding the proposed initiatives and future USPTO-FDA inter-agency collaboration.

The USPTO and the FDA should ensure that initiatives are necessary, being both effective and equitable across the intersecting spectrum of entities and products with which the agencies interact.

It is important for the USPTO and the FDA to remember that their respective agencies interact with a broad range of applicants, entities, and products with varying levels of sophistication and risk, generally united by their mandate to assist patients, healthcare providers, and other stakeholders in healthcare innovation. As such, it is important to remember that policies can affect these groups in very different ways. What may be a formality for a large applicant may be overly burdensome for a smaller applicant. The pace of innovation can be very different for different technologies – what would be considered an important incremental improvement in one section of the medical products industry is a giant leap forward in another section. A policy targeting pharmaceutical or biologic patents may have inadvertent consequences for medical innovations, such as medical device patents. Any policy must be understood in the context of the intersection of the products and entities that will be impacted, as well as its impacts on the pace of innovation in these various industries that make up the purview of these agencies.

While the suggested collaboration and cooperation between the USPTO and the FDA and any other two agencies may be beneficial, new rules and regulations directed to such collaborative efforts should not serve as a deterrent to innovation or to the public disclosure of new technological ideas. If an innovator or its investor risks losing a competitive advantage by disclosure of its new technology (or perceives it will lose a competition advantage) particularly where reaping the reward for disclosure is at risk, the rate of innovation and technological advancements could be slowed. This is a significant concern in areas such as medicines where the intellectual property rights are the product. Furthermore, the process for development of drugs, medical devices, and biologics is typically such that the timeline for examination of US and international patents is not entirely aligned with the review timeline of regulatory approvals or clearances. This is only one example of the risks of misunderstanding and misapplying laws, procedures, practices, etc. Moreover, misalignment of resources can frustrate efficiencies in the efforts of both agencies when evaluating the intellectual property and overcoming regulatory concerns, creating delays in one or both of the regulatory review or patent examination process, resulting in a slowdown on new product development and launch and ultimately a delay in the launch of generic drugs. Any such collaboration should be conducted with clear expectations of what is intended to be available for review to the respective agencies, clear timelines for such

[7] See 21 CFR 314.53(f)(1).

review, and clear lines of communication to both applicants and between the respective agencies.

The USPTO should consider expansion of programs already available for examiner education.

Pursuant to feedback from selected stakeholders in the January 19th Joint Listening Session, we agree that opportunities for all stakeholders, including patients, clinicians, end-users, and other advocacy groups to provide feedback should be considered. An example of such an activity may be to ensure such groups are eligible to participate in the Patent Examiner Technical Training Program ("PETTP") and Site Experience Education ("SEE"). Expansion of these programs will permit patent examiners to hear from end users' and patients' perspective on the challenges and products covered by their respective art groups. It may also be used to provide clinicians the opportunity to weigh in and show examiners how devices and drugs may be used in clinical practice, potentially at luminary clinical sites. The ultimate goal of such an expansion of these programs would be to provide a holistic view of the technical landscape and objective problems to be solved within that technical landscape, thus providing improved context for review of new applications.

AIPLA appreciates the efforts by the USPTO to improve and revisit the patent examination process. We thank you for the opportunity to provide such comments and are happy to discuss further.

Sincerely,

Brian H. Batzli
President
American Intellectual Property Law Association