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On Behalf of the American Intellectual Property Law Association (AIPLA)
Joint USPTO-FDA Collaboration Initiatives:
Public Listening Session and Request for Comments
January 19, 2023

The American Intellectual Property Law Association is a national bar association of approximately 7,000 members who are engaged in private or corporate practice, in government service, and in the academic community. AIPLA thanks the Offices for the invitation to comment on issues relating to pharmaceutical patenting and for the opportunity to be heard in this listening session

AIPLA intends to submit written comments that address a number of the questions presented by the USPTO. But, today, AIPLA will speak primarily to Question 2, namely:

> What mechanisms could assist patent examiners in determining whether patent applicants or owners have submitted inconsistent statements to the USPTO and the FDA, and whether such mechanisms present confidentiality concerns.

To be clear, AIPLA, like the USPTO, believes that a patent examiner needs to know about inconsistent statements that is, statements that can affect his or her determination that the 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 any 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.

But, in answer to the question, one mechanism to be considered could be to permit the USPTO to make direct requests to the FDA regarding specific inventions and to request information that may be material to patentability.

This request could come after a specific issue comes to light during patent prosecution, or the patent examiner is aware of documents containing information material to patentability are on file with the FDA. While it is already possible for the USPTO to ask applicants for information under 37 CFR Section 1.105, a request for specific information could also be made to the FDA in a similar manner as requests are made to applicants.

The authority under which the USPTO and FDA work are completely different, however. Title 35 versus Title 21. Information brought before the USPTO is related to an invention defined by claims, whereas the FDA is concerned about drug safety and efficacy.

Therefore, any mechanism requesting information sharing between these agencies raises questions regarding the scope and implementation of such request for information.

For example:
What issues raised in patent prosecution will mandate the need for additional information from the FDA? How will the FDA determine what information to give to the USPTO and/or what kind of information can be subject to USPTO review? How will trade secret information submitted to the FDA be handled to avoid public disclosure? Will the patent applicant be involved in this process? How will the review of confidential information by the examiner be documented in the file history – if at all?

AIPLA would appreciate a better understanding of the answers to these and other similar questions before providing additional comments on the feasibility of this possible mechanism.

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 Section 1.56 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 it with accurate and material information.

Inconsistent statements made to the FDA and USPTO pose a substantial risk to enforcement of potentially very valuable patents. Prudent applicants, thus, 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 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) and are often submitted over a

period of years. 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 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.

On behalf of AIPLA, I thank you for your time and for your consideration of these views. I also note again that we will continue to consider these issues and will supplement these comments with a written comment letter.