**Biotechnology Innovation Organization**
**1201 Maryland Avenue SW**
**Washington DC 20024**

The Honorable Michelle Lee
Under Secretary of Commerce for Intellectual Property,
Director of the U.S. Patent & Trademark Office

Mail Stop Comments—Patents,
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450,
Att.: Matthew Sked, OPLA

Via e-mail to AC58.comments@uspto.gov

Re: Revision of the Duty To Disclose Information in Patent Applications and Reexamination Proceedings, Fed. Reg. Vol. 81, No. 209 (October 28, 2016); 74987

Washington, D.C., December 27, 2016

Dear Under Secretary Lee:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the U.S. Patent & Trademark Office's (USPTO) proposed revisions to 37 C.FF.R. §§ 1.56((b) and 1.5555(b) as set forth in the above-identified Federal Register notice dated October 28, 2016. BIO believes the *Therasense* decision marked an important positive step in the evolution of the inequitable conduct doctrine, and appreciates and applauds its quick embrace by the USPTO. As set forth below, BIO believes that the decision, in conjunction with the Leahy-Smith America Invents Act of 2011 (hereinafter, the "AIA"), offers opportunities to re-think and restructure administrative applicant disclosure obligations in ways that go beyond what would be possible under the USPTO's proposed revised Rule alone. Accordingly, BIO encourages the Office to continue its deliberations on this important initiative, with further opportunities for public review and comment as additional details and approaches are proposed.

Background

BIO is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO members are involved in the research, development, and commercialization of health care, agricultural, industrial, and environmental biotechnology products. Patents often count among a biotechnology company's most valuable business assets. They facilitate the technology transfer, partnering, access to capital, and investment and product development decisions without which biotechnological innovation could not flourish. Because the ability to procure valid,

enforceable patents is central to the biotechnology business model, BIO's members have a strong interest in clear, efficient, and transparent rules governing their disclosure obligations in the USPTO.

BIO members have long been concerned about the operation of the doctrine of inequitable conduct and its interplay with administrative disclosure requirements in the USPTO. BIO believes that the doctrine has historically created pressure on applicants to make prophylactic submissions of large amounts of information that examiners neither want nor consider material, resulting in a disclosure burden that is without parallel in the industrialized world. The prospect that any undisclosed reference would later be used to subject the patent to inter partes review has only further exacerbated the need for voluminous prior art submissions during patent prosecution. Together with the doctrine of prosecution history estoppel, the inequitable conduct doctrine also constitutes one of several reasons why applicants would adopt a "no-comment" approach as the most prudent course of patent prosecution, where the sufficiency of office actions is frequently attacked on legal grounds alone, and where on-the-merits discussions about prior art are avoided or minimized. Likewise, the submission of affidavits or expert declarations, however helpful they may be to examiners, is deemed fraught with litigation risk. Thus, examiners realistically can expect little help from wary applicants concerned about future allegations of concealment or misrepresentation, or future serial validity attacks in the Patent Trial and Appeal Board (PTAB). At a time of lively public discourse about supposedly poor patent quality and examination efficiency, this predictable consequence of current policy is unsustainable. Surely, unlocking the economic potential of hundreds of thousands of inventions now idly awaiting a patent requires a fundamental re-thinking of the duty of disclosure.

Comments on the proposed revisions to Rule 56

Congress has vested the USPTO with "plenary authority" over its own administrative practice. *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004). Within this limited delegation of authority, the Office must balance a number of policy objectives to achieve its mission: It must examine patent applications timely and accurately; review prior art found by examiners, applicants, or third parties; seek efficient interactions with patent applicants; promote candor and good faith in dealing with the Office, and sanction wrongdoing by registered practitioners.[1] To balance these sometimes competing objectives, the USPTO has at its disposal a number of regulatory and statutory enforcement mechanisms. The Office defines applicants' disclosure obligations and the information it regards as material to examination. It specifies the procedures for the submission of such information. It authorizes its examiners to request additional information from applicants when necessary, and to consider references submitted by members of the public during prosecution or reexamination. In cases where fraud on the Office was attempted or perpetrated, or

[1] The provisions at 35 U.S.C. § 2 (b)(2) empower the USPTO to "establish regulations, not inconsistent with law" in order to "govern the conduct of proceedings in the Office" 35 U.S.C. § 2(b)(2)(A); to "facilitate and expedite the processing of patent applications" 35 U.S.C. § 2(b)(2)(C); and to govern the conduct of persons practicing before it 35 U.S.C. § 2(b)(2)(D).

disclosure obligations violated, the Office may, in its enforcement discretion, investigate and sanction individuals registered to practice before the Office.

These and other provisions provide the USPTO with a flexible framework of requirements, incentives and sanctions under which it can advance its policy goal of timely, efficient and quality examination by incentivizing the submission of the most relevant information patent applicants regard as material. For a long time, however, courts have applied the inequitable conduct doctrine in ways that, in effect, directly regulate the amount and kinds of information that must be disclosed to the agency, and the penalties for noncompliance, thereby interfering in ways not contemplated by Congress with the USPTO's ability to exercise its "plenary authority" over its own administrative practice.

Paradoxically, the development of the inequitable conduct doctrine was driven, at least initially, by the well-intentioned belief that the judicial enforcement of applicant disclosure obligations in private actions to which the USPTO is not a party would nevertheless help the USPTO in getting its job done. Accordingly, courts over time have commonly looked to USPTO's Rule 56 for the applicable materiality standard, from the "fraud" standard in its original promulgation in 1949, to the "reasonable examiner" standard of the 1977 version, to the current 1992 standard. In *Therasense*, the en banc U.S. Court of Appeals for the Federal Circuit declined to adopt the USPTO's definition of materiality as the judicial standard, recognizing that its prior efforts to enforce the USPTO's materiality standards had actually contributed to the problems that led the court to take up this case in the first place.

BIO believes that, by proposing to import the judicial materiality standard into its Rule 56, the USPTO would run the risk of making the very mistake the Federal Circuit sought to avoid. BIO's members are not convinced that the proposed revisions would contribute measurably to greater stability in the law, legal certainty, or meaningful changes in applicant disclosure practices, as described in more detail below.

<u>The proposed revisions do not contribute to greater stability in the law</u>

The USPTO proposes to import the judicial materiality standard into its Rule 56. There is good reason to believe, however, that the *Therasense* standard, in the course of judicial interpretation, will be subject to drift in the courts over time. By adopting the judicial standard the USPTO would allow the evolution of its own administrative disclosure standards to be driven entirely by private litigation to which the USPTO is not a party, and where self-interested litigants are expected to argue over proper prosecution conduct without the USPTO's institutional interests in mind. It is only a matter of time until a post-*Therasense* court decides a question of "whether the USPTO would not have allowed a claim" in a way with which the USPTO might, perhaps, disagree. Likewise, skillful litigators will eventually identify instances of affirmative "egregious misconduct" that may seem, from the USPTO's perspective, not particularly egregious. In short, most BIO members do not expect that administrative adoption of a judicial standard that is sure to evolve – and possibly erode – over time is the approach that will most benefit the USPTO and the applicant community.

The proposed revisions do not contribute to greater legal certainty

The USPTO's proposed revised Rule 56 does not create significantly greater legal certainty about the prior art applicants would need to submit. Under current Rule 56, applicants need to submit information that would be sufficient for a *prima facie* case of invalidity. If the *Therasense* standard were adopted by regulation, applicants would need to submit "but-for" material information – i.e., information that would be sufficient to maintain a rejection and make it final. The "delta" between the two standards is not clear, and possibly not very large. For the most part, applicants likely will not be able to predict the sufficiency of references for a final determination of unpatentability with significantly greater certainty than they can predict the sufficiency of the same references for a *prima facie* case. From an applicant's *ex ante* perspective, the proposed adoption of the *Therasense* materiality standard is thus not very helpful as a guide for applicants in deciding which art to disclose.

The proposed revisions are unlikely to cause significant changes in applicant disclosure practices

BIO members believe the USPTO's proposed rule may accomplish less than the Office might hope. For the reasons stated above, it is unlikely applicants would feel comfortable disclosing less art to the USPTO,[2] unless the Office provides applicants additional safeguards that are not provided in the Proposed Rule. The advent of inter partes review proceedings in particular has created powerful incentives to make voluminous prior art submissions during prosecution, in the hope of later benefiting from whatever little presumption of validity the PTAB might be willing to afford the patent. With respect to non-prior art "affirmative" disclosures, e.g., responses to foreign office actions or arguments in related cases ("inconsistent positions"), adoption of the *Therasense* standard may provide at least some relief, as such disclosures would be measured under a higher "egregiousness" standard. However, even for these affirmative non-prior art disclosures, applicants may be hesitant to alter their disclosure practices until the new and uncertain egregiousness standard is better developed in the law.

The continued need for a regulatory duty of disclosure is unclear

The USPTO has not provided a clear explanation of why it continues to need Rule 56. If the PTO wants only the *Therasense* standard, then there would seem to be no need for the rule – it is already the law. If the intention is to prevent fraud, lying, falsification, perjury and the like, federal statutes such as Section 1001 of Title 18 of the U.S. Code provide the applicable standard and the appropriate reach. The USPTO should affirm that it seeks nothing more. In addition, Rule 56 is enforceable only against registered practitioners anyway; notably, practitioners are bound by ethical canons and standards of professional conduct and could surely be sanctioned for serious misconduct even if no Rule 56 existed. Moreover, the America Invents Act expanded the USPTO's authority to sanction practitioner

[2] BIO members also have observed that the practice of over-disclosing information is unlikely to change by adoption of the *Therasense* materiality standard because making a decision to withhold information, even under *Therasense,* continues to create an increased risk in view of the inequitable conduct's "intent prong" relative to the significant risk reduction caused by disclosing information. In other words, there is little downside to disclosing more, rather than less.

misconduct. It is thus not clear why Rule 56 continues to be necessary at all. If, as stated in the proposed rule, the USPTO's intent is to encourage the submission and discussion of only the most relevant prior art and to facilitate examiner-applicant interactions, the proposed rule falls short.

The America Invents Act has changed the picture

The America Invents Act has surely reduced the need for Rule 56, and any modification to Rule 56 should take into consideration these significant reforms. The Act established new post-grant and inter partes review proceedings, expanded the Director's reexamination authority, and provided increased opportunities for third-party submissions of prior art and patentee representations about claim scope, amongst other provisions that enhance transparency and public participation in the patent examination and review process. These new provisions provide strong and effective checks on instances of nondisclosure and misrepresentation during patent prosecution. The need to address nondisclosure of information through regulation, in particular in relation to information that is publicly available and readily obtainable by the USPTO, now seems much diminished. Moreover, the USPTO must balance the benefits of maintaining a rule that punishes nondisclosure and misrepresentation against the inevitable result of over-disclosure and "no comment" prosecution.

Ironically, alarmingly high institution and invalidation rates in the new AIA PTAB trial proceedings have created their own powerful incentives for applicants to "bulk up" their prosecution histories with additional prior art references. Today, no rational applicant would want to rob itself of at least the opportunity to later argue to the PTAB that references presented in an IPR petition were originally presented and considered by the examiner. Thus, to the extent the Federal Circuit's post-*Therasense* inequitable conduct jurisprudence has reduced the need for overdisclosure during prosecution, the PTAB's application of 35 U.S.C. § 325(d) has taken up the slack.

Suggestions for alternative approaches

A common theme in member feedback received by BIO was that Rule 56 should be re-conceptualized not as a "punitive" rule, but as a "positive" rule that defines and rewards productive and helpful disclosure practices. Rather than vaguely defining the kinds of information whose nondisclosure is punishable (a determination that is, at any rate, most often made by the courts), the USPTO should think about positive steps and assurances that help applicants affirmatively engage with examiners. This can be done fully consistent with *Therasense*. Under *Therasense*, applicants have to disclose "but-for" material information. As discussed above, from an applicant's *ex ante* perspective, the practical difference between "but for" materiality and *prima facie* materiality is small and uncertain. Accordingly, applicants need to be able to disclose everything that even arguably could be sufficient for a final rejection. Under an obviousness scenario, for example, it is impossible to predict whether an examiner would maintain a rejection first made on the basis of a combination of references that rendered a claim *prima facie* obvious, such that applicants would still have to fear that nondisclosure of any such reference could meet the *Therasense* materiality standard. Accordingly, BIO does not believe that applicants will, for the time

being, significantly cut back on the amount of prior art they submit. To the contrary, with the expansion of statutory prior art under the America Invents Act, applicants will have to think about additional kinds of prior art, such as foreign sales or public uses, or information that is "otherwise available to the public." Until the practical parameters of post-AIA prior art, and the judicial implementation of *Therasense* become more clear, the USPTO should expect that applicant prior art disclosures may not dramatically drop off.

However, voluminous prior art submissions, made out of an abundance of caution, are only one side of the coin. *Therasense* arguably did create greater relief from the fear of later being accused of misrepresentation than from fear of being accused of nondisclosure. Under *Therasense*, applicant representations about prior art references that were disclosed or discovered by the USPTO would only accede to the judicial materiality standard if they qualify as "affirmative, egregious misconduct," such as false affidavits and falsifications, and the like. This higher standard may alleviate longstanding fear of being accused of misrepresenting prior art references. Accordingly, *Therasense* may, over time, create an opening for USPTO incentives for applicants to voluntarily identify, explain, and discuss art they view as most relevant.

In general, feedback received from BIO members suggests that the USPTO's proposed revisions to Rule 56 should be guided by the following goals:

- Lessen the burden on applicants to make voluminous submissions of prior art and the burden on examiners to review such submissions;
- Clarify administrative disclosure obligations in the USPTO so that applicants can make better disclosures and are able to assist the examiner more in clarifying the invention in light of the prior art, without the ever present cloud of potential inequitable conduct hanging over every submission;
- Focus disclosures on facts and information and away from attorney argument, especially arguments made in foreign patent office proceedings;
- Eliminate the need to cite and submit co-pending applications, office actions and responses in co-pending applications; and
- Make clear that any duty to not compromise the integrity of USPTO processes extends to all persons who make submissions to the USPTO, including third parties and their declarants during post-grant proceedings, not just applicants and patentees.

There are categories of information that the USPTO is so well-equipped to find, such as patents and applications, that there would seem to be little reason to compel their disclosure by applicants. In fact, almost all of the information that is disclosed to the Office, and that complicates the examination process by making it more difficult for examiners to identify the most material information, is readily searchable and is now at least as available to the USPTO as it is to applicants. Given that, in almost all situations, the applicant's help is not "needed" – a notion that is underscored by empirical studies showing that examiners rarely rely on IDS submissions for art-based rejections [3] – BIO members have proposed a

[3] Cotropia, Lemley, and Sampat, "Do Applicant Patent Citations Matter? Implications for the Presumption of Validity"; available at: http://www.law.northwestern.edu/searlecenter/papers/Cotropia_patent_citations.pdf

variety of possible approaches for reducing the need for voluminous prior art submissions, such as those described below.

Some BIO members believe that applicant disclosure obligations, to the extent they must be imposed by regulation at all, should be imposed only for non-public material information that is not accessible by the USPTO or by members of the public. Because the AIA established public availability as a defining characteristic of all prior art except prior applications, applicants should not be under a Rule 56 obligation to submit prior art to the USPTO, consistent with practices in other major patent offices. According to these BIO members, searching, identifying and applying prior art is the inherent, primary responsibility of patent examining authorities around the world – the USPTO should not, by regulation, split this responsibility or shift it to applicants in departure from the practices of all other major patent offices.

Some other BIO members believe that disclosure obligations should extend only to obscure prior art that would reasonably be expected to be outside the reach of the USPTO, such as foreign public uses or sales, limited distribution pamphlets, obscure foreign language documents, and the like. Applicants should not be under a Rule 56 obligation to submit widely-available publications that are standard in their fields, or patents, applications and mainstream materials that are readily accessible. Because the bulk of unnecessary prior art submissions consists of such mainstream materials, limiting the Rule 56 disclosure obligation in this way would go a long way to reducing the disclosure burden on applicants and examiners.

Other BIO members suggest that the USPTO should step back from defining required disclosures in terms of unpatentability, at least with respect to art that may be relevant for an obviousness determination.[4] Instead, the USPTO could deem the applicant's disclosure obligation discharged if the applicant submits those references he or she regards as the "closest prior art." This approach would avoid the problems inherent in requiring the applicant to draw an *ex ante* legal conclusion about the effect of any given reference on the invention's patentability. The decision to submit or withhold any given reference would instead be made in the applicant's scientific or technical, not legal, judgment about the "closeness" of the reference. Consistent with *Therasense*, the determination of which references are deemed the "closest" would be a subjective one – those references believed by the applicant to constitute the closest prior art. This would provide insulation against a later charge of inequitable conduct, as such an allegation should be made only in instances where a reference was withheld with intent to deceive. Such a subjective standard also should eliminate the need to disclose duplicative references that contain basically the same disclosure. Notably, the concept of "closest information" already exists in subsection (a)(2) of Rule 1.56.

In each case, the applicant's disclosure obligations should be deemed discharged if the material information is provided to the registered practitioner who prosecutes the application for the applicant. Such an explicit limitation would only make sense, because

[4] These BIO members observe that, in most situations, evidence establishing the lack of novelty of claims should be rare, because the attorney or agent would not consciously draw claims that are anticipated by the art. But when the applicant is aware of such art, a disclosure obligation for anticipatory references should attach.

registered practitioners are the only ones against whom Rule 56 is practically enforceable anyway. Moreover, such a safe harbor provision would provide some insulation from later inequitable conduct charges for inventors and employees of the patentee who in good faith provided their attorney or agent with what they believed to be the scientifically most relevant information about the invention or prior art.

Many BIO members recommend that any such changes in the USPTO's disclosure requirements should be supplemented by incentives and safe harbors to further facilitate applicant-examiner interactions. For example, it is suggested that the USPTO should encourage applicants to voluntarily submit a brief, factual description of the disclosed references and how they relate to the claimed invention, and/or how the claimed invention differs from the disclosure of the submitted references. In doing so, the USPTO should make explicit (by regulation and in the prosecution history) that it will not rely on an applicant's description of the references in its patentability determination, but will undertake its own review of the cited references and make its independent determination of the patentability of the claims. Under the "but for" standard, such an explicit USPTO position should permit applicants to be able to describe the invention in the context of the prior art without fear of being accused later of having misled the examiner, or of having induced the USPTO's reliance on the applicant's description. Fostering such a disclosure by the applicant would be a considerable aid in furthering prosecution, as it allows the examiner to more quickly focus her or his own examination efforts on the most significant information.

Finally, BIO members also generally agree that any duty to not compromise the integrity of USPTO processes should extend to all participants in Office proceedings, not just applicants and patentees. Standards of conduct should, for example, include reexamination requesters and post-grant review or inter partes review petitioners and their declarants. BIO members believe that this is particularly important in light of increased third-party participation in USPTO proceedings under the AIA.

Conclusion

BIO believes the *Therasense* decision marked an important positive step in the evolution of the inequitable conduct doctrine, and appreciates and applauds its embrace by the USPTO. For the reasons stated above, BIO believes that the decision, in conjunction with the America Invents Act, offers even more opportunities to re-think and restructure administrative applicant disclosure obligations than would be possible through a mere importation of the key *Therasense* holdings alone. Accordingly, BIO encourages the USPTO to engage in additional deliberations, with further opportunities for public review and comment as more specific details and approaches are proposed. With this understanding, we look forward to engaging further on this important effort in partnership with the USPTO and other industries and stakeholders.

Respectfully submitted,

Biotechnology Innovation Organization