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December 23, 2016

VIA EMAIL: AC58.comments@uspto.gov

The Honorable Michelle K. Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulaney Street
PO Box 15450
Alexandria, VA 22313
Attention: Matthew Sked, Legal Advisor
Office of Patent Legal Administration

Re: Docket No. PTO-P-2011-0030: Revision of the Duty to Disclose Information in Patent Applications and Reexamination Proceedings

Dear Director Lee:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members in response to the proposed revisions to the materiality standard for the duty to disclose information in patent applications and reexamination proceedings. PhRMA's members appreciate the PTO seeking comments on the proposed revisions and would welcome further dialogue on the issue.

Please feel free to contact me if you have any questions.

Sincerely,

David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No. PTO–P–2011-0030
December 23, 2016

Comments of the Pharmaceutical Research and Manufacturers of America on the PTO's Request for Comments on the Revision of the Duty to Disclose Information in Patent Applications and Reexamination Proceedings

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office's ("PTO" or "Office") Request for Comments on the Revision of the Duty to Disclose Information in Patent Applications and Reexamination Proceedings (the "PTO's Notice").[1]

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompasses both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supports a total of 4.4 million jobs throughout the economy, and directly employs more than 854,000 Americans.[2] The industry's overall economic impact is substantial, accounting for nearly $1.2 trillion in economic output.[3]

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), representing about 17% of dollars spent on all R&D by U.S. businesses.[4] PhRMA member investment in discovering and developing new medicines reached over an estimated $58.8 billion in 2015.[5] Medicines developed by the biopharmaceutical sector have produced large improvements in health across a broad range of diseases. The rapid growth of biomedical knowledge has created opportunities for profound advances against our most complex

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[1] 81 Fed. Reg. 74,987-997 (Oct. 28, 2016).

[2] TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: National and State Estimates*, at 1, 11, May 2016, http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf.

[3] *Id.* at 1, 10.

[4] PhRMA analysis of National Science Foundation, Business Research, Development, and Innovation Survey (BRDIS) 2011, 2014.

[5] PhRMA, *2016 PhRMA Annual Membership Survey*, at 5, T.1., 2016, http://phrma-docs.phrma.org/sites/default/files/pdf/annual-membership-survey-results.pdf.

and costly diseases. However, developing a new medicine takes between 10 and 15 years of work and costs an average of $2.6 billion of investment in R&D.[6] Only two of every ten marketed drugs return revenues that exceed or match the R&D investment.[7]

Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that yield new and improved medicines in reliance on a legal regime that provides protection for any resulting intellectual property. In particular, PhRMA's members rely on patents to protect their inventions and provide an opportunity to recover their R&D costs and fund new research. Patents are critical for biopharmaceutical innovation given the research-intensive nature of this sector and the substantial upfront investment needed to discover and develop products that meet FDA approval requirements.[8]

Bringing new and improved life-saving and life-improving products to people is the driving mission of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members appreciate the efforts of the PTO to revise the duty to disclose information in patent applications and reexamination proceedings. Issues surrounding inequitable conduct and the duty of disclosure are of importance to PhRMA member companies. Patent owners continue to face allegations of inequitable conduct, including in patent challenges brought under the Hatch-Waxman Act. These allegations significantly increase the costs and complexity of litigation. PhRMA companies have also spent a significant amount of time and effort to ensure compliance with the duty to disclose information to the Office.

The Federal Circuit's decision in *Therasense, Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*), raised the bar for bringing and proving allegations of inequitable conduct and adopted a "but-for" standard for determining whether information is material. *Therasense* also raised the standard for proving the intent required for finding inequitable conduct. We believe that the duty of disclosure should also be reformed to reduce the burden on both applicants and examiners to disclose and review information that is marginally relevant. Such reform would allow examiners to focus on the most relevant information.

After the *Therasense* decision, the PTO proposed revisions to 37 C.F.R. §§ 1.56 and 1.555(b) in its July 21, 2011 Revision of the Materiality to Patentability Standard for the Duty to

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[6] Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. Health Econ. 20-33, at 26 (2016).

[7] John A. Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, 19 Health Econ. 1002-1005, at 1004 (2010).

[8] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* at 1–2 (AEI Press 2007), https://www.aei.org/wp-content/uploads/2013/12/-biotechnology-and-the-patent-system-book_121440333605.pdf ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); *see generally* Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, at 2 (2014), http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849 (2002).

Disclose Information in Patent Applications ("July 2011 Notice").[9] PhRMA provided comments in response to the PTO's July 2011 Notice on October 19, 2011 ("PhRMA's October 2011 Comments"), which are herein incorporated by reference. PhRMA appreciates the PTO's consideration of our prior comments and issuance of a new proposal. While the current proposed rules include some improvements over the July 2011 Notice, a number of problematic issues identified in PhRMA's October 2011 Comments remain, and the newly proposed rules introduce additional issues of concern. PhRMA's comments address each of these issues.

I. The PTO's Proposed Definition for Material Information is Ambiguous and is Not Likely to Change Current Disclosure Practice.

The PTO's Notice is intended to "harmonize" the PTO's materiality standard with the standard set forth in *Therasense* for establishing inequitable conduct.[10] In particular, the PTO proposes amending 37 C.F.R. §§ 1.56(b) and 1.555(b) (Rules 56 and 555) as follows:

> 37 C.F.R. § 1.56(b)
>
> (b) Information is but-for material to patentability if the Office would not allow a claim if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.[11]
>
> 37 C.F.R. §§ 1.555(b)
>
> (b) Information is but-for material to patentability if, for any matter proper for consideration in reexamination, the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.[12]

We understand that the PTO is attempting to apply the same standard for material information in patent prosecution and reexamination proceedings as is applied by the courts in determining inequitable conduct under *Therasense*, and we believe that the PTO's proposed amendment is a step in the right direction. However, it is our view that the proposed language will lead to ambiguity as to what information should be disclosed. The focus of the standard for materiality becomes: (1) what the Office would do in disallowing a claim based upon certain information, (2) using a preponderance of the evidence standard, and (3) giving the claim the broadest reasonable construction consistent with the specification. There is room for argument as to what information must be disclosed under each of the three parts of the proposed rule and, as a result, patent applicants will continue to have an incentive to disclose a large amount of prior art to

[9] 76 Fed. Reg. 43,631-634 (July 21, 2011).

[10] 81 Fed. Reg. at 74,988.

[11] *Id.* at 74,996.

[12] *Id.* at 74,997.

ensure compliance with the standard – and avoid a charge of having engaged in inequitable conduct by having withheld prior art – even if that art is only marginally relevant. Furthermore, it is not clear how the new rules differ from the old rules,[13] despite the differing language. The lack of clarity in the new rules is compounded by the "preponderance of the evidence" standard and the use of the broadest reasonable claim construction. Until the PTO further explains how the newly proposed rules differ from the rules currently in place, patent applicants may continue to disclose a disproportionate number of prior art references to avoid potentially omitting a reference that is deemed material and being accused of inequitable conduct.[14]

The PTO's Notice asserts that "[a] unitary materiality standard is simpler for the patent system as a whole."[15] However, as stated in PhRMA's October 2011 Comments, we do not believe that Rules 56 and 555 need to be strictly aligned with the standard for inequitable conduct outlined by the courts since they have different goals. In particular, the PTO rules are meant to define how applicants and practitioners interact with the Office to ensure that information is brought forward during the examination process. These rules should encourage that the most relevant prior art is considered by examiners so that valid patents are issued by the PTO. On the other hand, the goal of inequitable conduct, as explained in *Therasense*, is to deter applicants from intentionally withholding relevant prior art or intentionally misleading the examiner.[16]

Below, PhRMA proposes a definition of material information that is meant to ensure that the best examination occurs by the Office and provides applicants and examiners with more clarity as to what information is "material." In order to accomplish these goals, PhRMA suggests that the term "material" in 37 C.F.R. §§ 1.56(b) and 1.555(b) be defined as follows:

> (b) Information is material to patentability when it is not cumulative to information already of record or being made of record in the application and it establishes the unpatentability of one or more claims in the application.

It is our view that the proposed language is consistent with the goal of the "but-for" test in *Therasense*—to have an objective standard for the type of information that results in at least one claim being found unpatentable—and clarifies that only invalidating information needs to be disclosed to the Office. PhRMA's proposed rule eliminates the reference to the preponderance of the evidence standard and the broadest reasonable construction standard, as PhRMA believes that such standards are unnecessary to include in the definition of "material information." The rule

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[13] 37 C.F.R. § 1.56(b)(1) (information is material when it establishes "a prima facie case of unpatentability"); 37 C.F.R. § 1.555(b)(1) (same).

[14] The PTO's Notice states that it expects that its newly proposed rules will result in fewer allegations of inequitable conduct and reduce the volume of marginally relevant information submitted to examiners. *See* 81 Fed. Reg. at 74,989. PhRMA, however, believes that the newly proposed rules will still result in confusion, and thus not impact the large number of inequitable conduct charges that are alleged or eliminate the incentive to submit marginally relevant information during the examination of an application.

[15] 81 Fed. Reg. at 74,989.

[16] *See, e.g.*, *Therasense*, 649 F.3d at 1290.

proposed by PhRMA would allow applicants and practitioners to disclose only relevant prior art, without being forced to submit voluminous references that are only marginally relevant, fearing a charge that they have withheld prior art. It is our view that these rules would significantly reduce the burden of disclosure on applicants, would allow applicants to be more certain that their submissions of prior art comply with the rules, and would also reduce the burden on examiners as they would only review the most relevant prior art.

In addition, PhRMA's proposal retains the "not cumulative" language that is currently in Rules 56 and 555.[17] It is our view that any new rule should retain this language to avoid the submission of multiple references that have the same disclosure. In the PTO's notice, the PTO stated that it is not seeking cumulative information and that cumulative information would not be material under the but-for standard;[18] however, without explicit language in the rule itself, applicants and practitioners may still feel compelled to submit cumulative information to ensure compliance. For this reason, PhRMA resubmits that the definition of material information should retain the "not cumulative" language.

II. The PTO Should Remove the Addition of "any matter proper for consideration in reexamination" from the Proposed Revision to 37 C.F.R. § 1.555(b).

In the PTO's Notice, the Office further revised the definition of material information in 37 C.F.R. § 1.555(b) for reexamination beyond the current definition. In particular, the PTO added that "material information" includes information as to "any matter proper for consideration in reexamination."[19] In the PTO's Notice, the Office stated that the change to the proposed rule is meant to include more than just patents and printed publications in that it also includes admissions by the patent owner.[20]

It is our view that this addition to Rule 555 is unnecessary and will lead to further confusion because it is vague and ambiguous as to whether it includes other types of information beyond patents, printed publications, and patent owner admissions. Furthermore, PhRMA does not believe that there is a need for the PTO to expand the rule beyond printed publications and patents. It is our view that the proposed language does not address any outstanding problem and that adding it into Rule 555 will only lead to further uncertainty. For this reason, we propose removing the addition of "any matter proper for consideration in reexamination" from the proposed 37 C.F.R. § 1.555(b).

[17] 37 C.F.R. § 1.56(b); 37 C.F.R. § 1.555(b).

[18] 81 Fed. Reg. at 74,991.

[19] *Id.* at 74,997.

[20] *Id.* at 74,990.

III. The PTO Should Take Responsibility for Searching U.S. Patent Prosecution Documents, Public Foreign Prosecution Documents, and Non-Patent Literature that is Publicly Available.

In addition to amending the definition of "material information" as discussed above, we believe that the PTO can take additional steps to clarify the role of examiners in searching public databases and reduce the burden on both applicants and examiners. These proposals could be the subject of additional rulemaking, *e.g.*, further refinements to Rules 56 and 555, or be adopted in the Manuel of Patent Examining Procedure as rules of practice. Indeed many examiners may already conduct the searches described below as part of the examination process, but adopting them as rules would clarify the burden on applicants to bring information forward and allow more focused submissions by the applicant.

Currently, applicants may feel that they need to disclose voluminous, and largely irrelevant, information regarding co-pending applications including complete copies of prosecution histories. The production of these huge records imposes a significant burden on both the applicants and the examiners who review this information. To alleviate this burden, PhRMA proposes that the PTO adopt rules making examiners responsible for searching the PTO's own databases for relevant patent applications, issued patents, and the patent prosecution documents in the PTO files that are associated with those patents and patent applications. These searches can easily be done by looking at the inventor name, assignee, or the subject. Similarly, examiners should be required to search for published foreign counterpart patent applications, issued patents, and the associated prosecution documents. The examiner would report the relevant results from its searches in the next office action for the applicant to review.

Finally, examiners should be responsible for searching publicly available databases for non-patent literature. The examiner would report a list of the references it considered in the next office action. The applicant could then choose, but would be under no obligation, to supplement the identified references with other art known to the applicant and believed to be useful for consideration by the examiner (*e.g.*, references that help establish the state of the art).

In the PTO's Notice, the Office stated that an applicant is not under a duty to submit information from related applications, unless that information is but-for material.[21] As explained above, however, the current rule and the proposed rule are unclear as to what is and is not "material information." Applicants may continue to feel compelled to produce all or substantially all information from related applications to avoid a charge of inequitable conduct. The PTO also stated in its Notice that the applicant is in the best position to know of any material information,[22] that there is "no guarantee" that examiners will find publicly available information, and that requiring the examiner to look for information that the applicant is already aware of results in the Office expending additional resources and adding to the time of review.[23] However, requiring

[21] *Id*. at 74,994.

[22] *Id.*

[23] *Id.* at 74,995.

applicants to submit information under an ambiguous standard could result in the PTO being forced to expend resources reviewing large volumes of materials that are only marginally relevant. By having the examiner review publicly available non-patent literature, it would allow the examiner to focus his/her energy on the prior art that he/she deems most relevant.

Finally, the PTO explained that it is working on an initiative to provide examiners with information such as prior art, search reports, etc. from related applications as early in the review of a patent application as possible.[24] This is a step in the right direction that could be supplemented by PhRMA's other proposals recited above.

IV. Conclusion

PhRMA appreciates the PTO's efforts to revisit the rules regarding the duty of disclosure in patent applications and reexamination proceedings. PhRMA supports a materiality standard in Rules 56 and 555 based on the "but-for" standard in *Therasense*, but encourages the PTO to further amend and clarify the disclosure requirements beyond that standard. In particular, PhRMA encourages the PTO to adopt PhRMA's proposed definition of "material information" in order to better clarify for applicants what information they must submit, which could reduce the burden on applicants and promote greater efficiency by examiners. Applicants, the Office, and the public are best served by a standard of "material information" that ensures patent applications are examined in light of the most relevant prior art. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces now and in the future.

[24] *Id.* at 74,994.