**David E. Korn**
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PhRMA

October 19, 2011

**VIA EMAIL: AC58.comments@uspto.gov**

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Hiram H. Bernstein, Senior Legal Advisor, Office of Patent Legal Administration

Dear Mr. Bernstein,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members in response to the notice on "Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications," 76 Fed. Reg. 43631 [Docket No.: PTO-P-2011-0030]. PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Patent protection is an important incentive to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA's members on the subject matter discussed in the notice. PhRMA's members appreciate the PTO seeking comments in the area, and would welcome further dialogue with the PTO 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**
**October 19, 2011**

## Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Revision of the Materiality Standard for the Duty To Disclose Information in Patent Applications

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO") Request for Comments on Revision of the Materiality Standard for the Duty To Disclose Information in Patent Applications.[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. Like innovators across the spectrum of American industries, pharmaceutical companies rely on patents to protect their inventions and provide an opportunity to recover their research and development investments. Patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements.[2/] Bringing new life-saving and life-improving products to people is the central mission of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members particularly appreciate the efforts of the PTO to develop sound and stable intellectual property policies.

The patent doctrine of inequitable conduct and the related duty of patent applicants to disclose material information to the PTO during the examination of a patent application are of significant importance to PhRMA member companies, and we submit that both are in need of reform. Allegations of inequitable conduct have been made in the vast majority of patent challenges brought against nearly all pharmaceutical products under the Hatch-Waxman Act. These allegations significantly increase the costs and complexity of pharmaceutical patent litigation. Most of these allegations have been meritless, but the cost of defending such allegations is high. And PhRMA companies have spent much time and effort ensuring compliance with the duty to disclose information to the PTO. We believe that the court's decision in *Therasense, Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*), raises the bar for bringing and proving allegations of inequitable conduct and properly adopts a "but-for" standard for determining materiality of information. *Therasense* also raises

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1/ 76 Fed. Reg. 43631-34 (July 21, 2011).

2/ Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JOURNAL OF INT'L ECONOMIC LAW 849-60 (2002). Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk. Barfield, Claude, and Calfee, John. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007. It has been estimated that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (Feb. 1986) at 173-181.

the standard for proving the intent required for an inequitable conduct finding. Similarly, we submit that the duty of disclosure should now be reformed in order to ease the burden on both applicants and examiners to disclose and review information and to focus the examination on the most relevant art. We view the PTO's proposal as an opportunity to redefine the duty to disclose information and to clarify the roles of the Office and the applicant in bringing relevant information forward for consideration in the examination of patent applications.

In response to the PTO's proposal to revise the definition of "material" information, we propose below a differently worded definition of material information under the "but-for" test adopted by the court in *Therasense*. In addition, we outline further steps the PTO could take to bring greater clarity to the PTO's role in searching for relevant art.

### *A. The PTO's proposed definition for Material Information is ambiguous and is not likely to change current disclosure practice*

The PTO has requested comments on its proposed Revision of the Materiality Standard for the Duty To Disclose Information in Patent Applications, which proposal is intended to align the PTO's materiality standard to the standard set out in *Therasense*.[3/] Specifically, the PTO proposes to amend 37 C.F.R. §§ 1.56(b) and 1.555(b) (Rules 56 and 555) as follows:

> (b) Information is material to patentability if it is material under the standard set forth in [*Therasense*]. Information is material to patentability under *Therasense* if:
>
> (1) The Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction; or
>
> (2) The applicant engages in affirmative egregious misconduct before the Office as to the information.[4/]

While we understand the PTO's intent is to strictly align the PTO's standard for material information with the language used in the *Therasense* decision, we suggest that this language is cumbersome and leads to ambiguity in what should be disclosed. The focus of the standard becomes (i) what the Office would do in disallowing a claim in view of certain information, under (ii) a preponderance of the evidence standard, and (iii) giving the claim its broadest reasonable construction. Each of these three elements has much room for argument, and as a result, patent practitioners may continue to be encouraged to disclose a voluminous amount of prior art in view of these standards. That is, applicants will still have an incentive to err on the side of disclosure because the difference between the old rule of materiality as information sufficient to "establish[]…a *prima facie* case of unpatentability"[5/] and the new rule of "[t]he Office would not allow a claim" is unclear. This lack of clarity is compounded by the fact that a "preponderance of the evidence" burden of proof and a broad claim construction are imposed on

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3/ 76 Fed. Reg. at 43632.

4/ *Id*. at 43634.

5/ 37 C.F.R. § 1.56(b)(1), 37 C.F.R. § 1.555(b)(1).

the inquiry. While we recognize that the examination of applications is performed under these standards, it is confusing to include these standards in a definition of what information is material, and such inclusion provides further points of challenge in later reviews of what was and was not disclosed. More importantly, until the PTO articulates the difference between these two standards, applicants will likely continue to disclose what may be perceived as an excessive number of prior art references, many of which may be of only marginal relevance, for fear of omitting a "material" reference and being accused of inequitable conduct.

We also believe that including an "egregious misconduct" definition for material information is confusing as it equates conduct with materiality in what becomes a circular definition of what information should be disclosed. Again, this ambiguity will likely lead to no change in current practice of disclosure as applicants will continue to be encouraged to disclose all so as to avoid a later allegation of affirmative egregious misconduct.

Further, in our view, the PTO's Rules 56 and 555 need not be strictly aligned with court decisions on inequitable conduct. The PTO rules are intended to define how applicants and their attorneys interact with the Office to bring information forward in examination. The goal of these rules for both the Office and the applicants should be to have the most relevant prior art considered by the examiner so that valid patents are issued by the Office. The proper role for the inequitable conduct doctrine, as explained by the court in *Therasense*, is to deter applicants from intentionally withholding invalidating art or otherwise intentionally misleading the examiner. Because the goals are different, we submit that the rules need not be strictly aligned. Moreover, the application of these principles in the courts changes with court decisions addressing different sets of facts. The PTO rules should not change with each new decision in the courts. Rather, we suggest that the PTO should define how applicants should interact with the Office to ensure the best examination occurs, and any space between the PTO rules and current court decisions will become closed in subsequent case decisions.

### *B. PhRMA's proposal for defining Material Information provides more clarity and would be more likely to change current practice*

While we view the PTO's proposed amendment as a step in the right direction, we submit that the proposal does not go far enough to change incentives underlying current practices and reduce the onerous disclosure burdens on patent applicants and the review of such voluminous submissions by the examiners. PhRMA believes that the PTO should take advantage of this opportunity to further revise and clarify the duty of disclosure to ensure that patent quality is improved while unnecessary burdens on applicants and examiners are removed.

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."

We believe that this proposed language adopts the essence of the "but-for" test stated by the court in *Therasense* – an objective view of information that results in the invalidity of one or more claims in the application – and clarifies that only such invalidating information needs to be disclosed. It eliminates unnecessary reference to the standard of proof (preponderance of the evidence) and the construction given to the claim. In our view, this "unpatentability" standard would allow inventors and practitioners to make good faith determinations of what information is material and should be disclosed, and we submit that the adoption of this standard should significantly reduce the burden of disclosure on the applicants. This proposal also retains the "not cumulative" [6/] language of the current standard which is important to avoid submission of multiple references with the same disclosure.

### *C. Additional steps the PTO can take to increase the effectiveness of applicant disclosures under Rules 56 and 555*

In addition to amending the definition of "material information" as discussed above, we suggest the PTO take the following steps to clarify the role of the examiners in searching public databases and to reduce the burden on both applicants and examiners. These steps could be the subject of additional rulemaking, e.g., further refinements to Rules 56 and 555, or be adopted as rules of practice in the MPEP. Undoubtedly, many examiners already conduct the searches described below as part of their examination process, but adopting them as rules will clarify the burden on applicants to bring information forward and allow more focused submissions by the applicant.

#### *1. The PTO should take responsibility for searching U.S. patent prosecution documents, public foreign prosecution documents, and non-patent literature available on publicly available databases.*

One of the current areas of perceived over disclosure of voluminous, and largely irrelevant, information to examiners centers on co-pending applications and the office actions and responses related to those applications. Under current standards and practices, applicants may feel the need to submit whole copies of prosecution records from another application. This imposes a real burden on the applicant and the examiner. We submit that the PTO should adopt the responsibility to search its own databases for relevant patent applications, issued patents, and the associated patent prosecution documents in the PTO files for such applications and patents. Such searches can easily be done by inventor name, assignee and by subject. [7/] Similarly, the PTO should have the responsibility to search for published foreign counterpart patent applications, patents, and associated foreign patent prosecution documents. The relevant results of such searches would be reported by the examiner in the next office action for the applicant to see.

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6/ 37 C.F.R. § 1.56(b), 37 C.F.R. § 1.555(b).

7/ The PTO already performs this search to some extent when it prepares to allow an application by conducting an Interference Search. *See* Manual of Patent Examining Procedure § 1302.08 (8th ed. 2001) (Rev. 8, July 2010).

Patent examiners should also have the responsibility of searching publicly available databases for non-patent literature. A list of references considered by the examiner would be reported in the next office action. The applicant can then choose, but is not obligated, to supplement those references considered with other art known to the applicant and believed to be useful for consideration by the examiner (i.e., references that help to establish the state of the art).

### *2. Provide a safe harbor so applicants can provide a brief description of the relevance of the information submitted and/or how the claimed invention differs from the prior art.*

Although current PTO rules do not prevent applicants from commenting on the relevance of information submitted to the PTO, applicants may refrain from doing so to avoid statements that could later be construed to be incorrect and thus become fodder for charges of inequitable conduct. We suggest that if there was a safe harbor provided for such descriptions, more applicants might provide such descriptions to assist the examiner in properly positioning the claimed invention in view of the prior art. To facilitate these useful exchanges, we propose that Rules 56 and 555 be amended to encourage, but not require, applicants to submit a brief description of the disclosed references and how the references relate to the claimed invention and/or how the claimed invention differs from the disclosure of the submitted references. In doing so, the PTO would make it clear that it will not rely on the applicant's description of the references in its patentability determination but will undertake its own review of the cited references and make its own determination of the patentability of the claims without giving any consideration to applicant's brief description. Under the "but-for" standard, having the PTO adopt such a 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 misleading the examiner. Fostering such a disclosure by the applicant would be a considerable aid in furthering prosecution as it could allow the Examiner to better understand how an applicant views the invention in light of the prior art.

The following language could be added to the end of Rules 56(b) and 555(b):

> "(b) Information is material to patentability …
> …
> In making disclosures under this section, applicants are encouraged, but are not required, to submit a brief description of the relevance of the information and/or how the claimed invention differs from such information. Submitting information pursuant to this section is not an admission that such information is legally relevant to the issues of patentability under 35 U.S.C. §§ 102 or 103 and will not be relied upon by the Office in making a determination of patentability."

## Conclusion

PhRMA appreciates the PTO's efforts to amend its materiality standard in light of the Federal Circuit's decision in *Therasense*. PhRMA supports a materiality standard based on the "but-for" concept; however, it encourages the PTO to clarify and further amend the disclosure

requirements so as to reduce the burden on applicants and promote efficiency and higher quality patents as outlined above. It is in the interest of the applicants, the Office and the public to ensure that patent applications are examined in light of the most relevant art and that the burden to submit and review less relevant art is eliminated. PhRMA and its member companies are committed to helping the PTO find solutions to these issues and other challenges it faces today and in the years to come.