

September 19, 2011

Via Electronic Mail: AC58.comments@uspto.gov

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Hiram H. Bernstein, Senior Legal Advisor

Re: Eli Lilly & Company's (Lilly) Comments to the United States Patent and Trademark Office (Office) Notice of Proposed Rulemaking entitled: *Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications* (Federal Register / Vol. 76, No. 140 / Thursday, July 21, 2011 / Proposed Rule 43631)

Dear Under Secretary Kappos:

Lilly appreciates the opportunity to comment on this Proposed Rule and commends the Office for timely proposing and seeking comments on new regulations directed to the materiality standard for submissions of information in matters or proceedings before the Office.¹ Enactment of the America Invents Act with its extraordinary patent reforms and the recent Federal Circuit decision in *Therasense*² provide an historic opportunity to rethink the full implications of the

¹ 37 C.F.R §1.56

² *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense)*, en banc, Appeal No. 2008-1511, 2011 U.S. App. LEXIS 10590 (Fed. Cir. May 25, 2011)

current judicial standard of materiality and the new public role in the patenting process through new rulemaking.

Lilly believes the Office should thoughtfully respond to these twin developments decisively and comprehensively, with the objective of facilitating the more efficient grant of high quality, wholly valid patents. In doing so, it can advance the judicial efforts to stem the “plague” of inequitable conduct allegations in the courts. The definition of successful rulemaking, therefore, should be that it encourages patent applicants to submit only the most significant information to the Office, information necessary to make an accurate determination of patentability, while minimizing submissions of marginally relevant or even irrelevant information that is actually unhelpful to the process of issuing valid patents.

For reasons set out in detail below, Lilly urges the Office to undertake a further review of possible options for codifying the “duty of disclosure,” rather than proceeding at this time through to final rulemaking on the basis of the rules as proposed. One purpose which might be served by such a further review would be to identify one or more alternatives to the Proposed Rule that might more fully vindicate the policy behind, and the purpose of, the duty of disclosure in light of the America Invents Act. Importantly, Lilly believes that a more significant set of changes to the “duty of disclosure,” may better achieve the objectives that the Office itself has laid out for proceeding with the proposed rulemaking. Finally, Lilly would further request that, based on such a review, the Office consider the appropriateness of issuing a substitute notice of proposed rulemaking that would incorporate the substantive provisions set out in the attachment to this letter.

As outlined by the majority decision in *Therasense*, the “duty to disclose” at the core of the “duty of candor and good faith,” however well intentioned, can produce unintended consequences to the near exclusion of the intended ones. The “side effects” of the current disclosure obligations imposed upon patent applications through the Office’s rulemaking include increased adjudication cost and complexity from the plague of misconduct allegations that they have spawned in patent infringement litigation, the complications these allegations create in seeking to settle patent lawsuits and the consequent reduced likelihood of settlements, the huge burdens on the courts forced to deduce the “intent” behind allegedly missing or incorrect information in the patent examination record, the strain on Office resources from the well-documented “over disclosure” and “under explanation” that is engendered among patent practitioners, the resultant backlog in patent examination that larger and less helpful submissions of information contribute to, and the impaired patent quality.³

Indeed, the fluctuating standards used to assess inequitable conduct have made it exceedingly difficult for even the most prudent practitioners to foresee what a court a decade in the future may deem to have been beyond the bounds of acceptable behavior in interacting with the Office.

³ See: *Therasense* at 2011 U.S. App. LEXIS 10590, at *31-32.

Therasense cites one study estimating *eighty percent* of patent infringement cases include allegations of inequitable conduct.⁴

Furthermore, obligations to the Office, in particular, disclosing information to the Office, extend beyond licensed practitioners who are expected to stay abreast of case law and regularly attend conferences and other discussions to make informed attempts to predict what conduct may or may not later be labeled inequitable. Attorneys, agents, scientists, engineers and others around the world who play a part in the patenting process, albeit many are involved only once in a lifetime, are subject to a duty to disclose information to the patent office – a daunting, independent duty that isn't currently dischargeable by providing information to a licensed practitioner.

The unintended consequences identified by the Court in *Therasense* have been well known to patent practitioners and the courts to be a *plague* on the entire patent system for decades,⁵ and have been publicly acknowledged by the Office: “[T]he [inequitable conduct] doctrine results in counterproductive behavior before the USPTO. It discourages many applicants from conducting a search and leads others to be indiscriminate in the information they submit.”⁶ “[A]pplicants or their attorneys fear that the legal doctrines of inequitable conduct and unenforceability may unfairly punish them with draconian penalties Anything the court deems that a reasonable examiner would find important can be material and the evidence necessary to show intent varies according to the nature of the omission. Accordingly, the inequitable conduct standard is uncertain and the potential penalties severe.”⁷

Therefore, although the recent judicial and legislative developments reinforce the need for a thorough and thoughtful review of 37 C.F.R §1.56, it is in view of a formidable backdrop that the Office Notice of Proposed Rulemaking seeks to accomplish the following three laudable goals by harmonizing its materiality standard with the standard set forth in *Therasense*.⁸

First, the Office asserts the *Therasense* materiality standard should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently

⁴ *Therasense* at 2011 U.S. App. LEXIS 10590, at *29-30 (Committee Position Paper at 75; *see also* Christian Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009)).

⁵ *See, e.g., Therasense* at 2011 U.S. App. LEXIS 10590, at *29-30 (*Inequitable* conduct “has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system.” *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984). “[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately, perhaps.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995); *Molins*, 48 F.3d at 1182.

⁶ Statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, before the Committee on the Judiciary United States Senate “Patent Reform: The Future of American Innovation” June 6, 2007, available at <http://www.uspto.gov/web/offices/com/speeches/2007jun06.htm>.

⁷ *Id.* at <http://www.uspto.gov/web/offices/com/speeches/2007jun06.htm>.

⁸ The Office refers to the materiality standard articulated in *Therasense* as a “but-for-plus materiality standard - “but for” the deception, the PTO would not have allowed the claim. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. The “plus” takes in to account an exception for “affirmative acts of egregious misconduct.” *See: Therasense* at 2011 U.S. App. LEXIS 10590, at *37-40.

reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicants to be more forthcoming and helpful to the Office.

Second, the *Therasense* materiality standard should continue to prevent fraud on the Office and other egregious forms of misconduct.

Third, the Office believes harmonizing the Office's and the *Therasense* standard should result in a simpler patent system.

After decades of litigating inequitable conduct cases, prosecuting thousands of patent applications, and much careful consideration, Lilly concludes there are many reasons to believe the Office's goals will not be achieved should the Office's affirmative steps be limited to those stated in its Proposed Rule. After stating reasons for its conclusion, Lilly provides a specific proposal that Lilly believes if embraced by the Office, will provide an improved opportunity for achieving the Office's goals – goals that have been for years shared by the entire patent community, but have remained unattainable.

Patent Office Goal #1: The Therasense materiality standard should reduce the frequency with which applicants and practitioners are being charged with inequitable conduct, consequently reducing the incentive to submit information disclosure statements containing marginally relevant information and enabling applicants to be more forthcoming and helpful to the Office.

Therasense does indeed provide a step in the right direction and a glimmer of hope that the newly stated standards may someday provide some degree of welcome relief from the onslaught of inequitable conduct allegations. However, even in the unlikely event the percentage of inequitable conduct allegations would diminish ten-fold, to a mere eight percent of patent lawsuits, there are reasons why the Office's goals are unlikely to be attainable with its current proposal, and why prudent practitioners are likely to remain skeptical that allegations of inequitable conduct will soon sufficiently diminish such that there is no longer the need for less defensive Office information disclosure practices.

1- Although the *Therasense* court recognized the remedy imposed by a court of equity should be commensurate with the violation, the “neutron bomb” of patent law remains the potential threat to the enforceability of the entire patent (or even an entire patent family) if a would be infringer can successfully establish that a breach of a disclosure obligation resulted in issuance of a single claim in an otherwise valid patent (the “doctrine should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving *an unwarranted claim.*”⁹).

⁹ *Therasense* at 2011 U.S. App. LEXIS 10590, at *38

Although the inequitable conduct “neutron bomb” rarely detonates and results in killing the enforceability of all patent claims, prudent behavior by patent practitioners necessitates building the equivalent of a “bomb shelter” during patent prosecution constructed of thick, neutron-proof walls of “prior art” – vast amounts of information that patent examiners must shift through by themselves to determine its materiality and impact on patentability.

2- Unfortunately, for many reasons, courts – including the Federal Circuit – have during the decades since the inception of the inequitable conduct doctrine simply been unable to offer meaningful guidance to patentees on when information will, *free from second-guessing in later litigation*, establish alone or in combination with other information, a prima facie case of unpatentability; be deemed “but for material” to patentability; be considered “cumulative” to information of record; be construed together with any other information to render a claim obvious; be construed as inconsistent with a statement in the application or prosecution history; et cetera.

Although *Therasense* states prior art is “but-for material” if the Office would not have allowed a claim had it been aware of the undisclosed prior art applying the preponderance of the evidence standard and giving claims their broadest reasonable construction,¹⁰ the difference between this newly articulated standard and previous standards employed by the Office and courts remains to be fully articulated through subsequent jurisprudence. Thus, it may be a decade or longer before the patent procurement process fully benefits from a confident understanding by patent practitioners about what information must be disclosed and what disclosures can be dispensed with, free from second-guessing in later litigation.

Patent practitioners can be expected to decipher the meaning of the new “but-for-plus” materiality standard, but even if that standard is codified in Office rulemaking, it will not immediately – or in the near term – address the residual risks to their clients (not to mention themselves) that will be associated with disclosing less information to the Office. While the consequences to the Office and public from “over-disclosing” information to the Office form a huge drag on the patent system in the aggregate, the consequences to an individual applicant of a wrong guess if one item of missing information is deemed later to be material to patentability, by whatever standard is then employed, will almost certainly outweigh any altruistic impulse to advance the social good in light of the individual risk. This paradigm driving patent applicant conduct will not, sadly, be immediately diminished by *Therasense* or the Office’s Proposed Rule. Furthermore, with respect to avoiding the wrath of the inequitable conduct’s “intent prong,” whenever an applicant is aware of information, significant risk is discharged by mere disclosure of the information to the Office (“In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision to withhold a known material reference.*”¹¹

¹⁰ *Therasense* at 2011 U.S. App. LEXIS 10590, at *37

¹¹ *Therasense* at 2011 U.S. App. LEXIS 10590, at *32

3-*Therasense* is not the Court's first attempt to reign in the allegations of inequitable conduct which have for decades been viewed as a plague on the patent system. Unfortunately, even after the *en banc* decision in *Kingsdown*,¹² patent owners have forfeited patents in recent years for reasons prudent practitioners often question (for example, a patent attorney failed to explain a search that had been undertaken was not a full search of the prior art but a more limited one; a few paragraphs in a patent specification was partially in the past tense describing work that had not been done in precisely the manner described; a technical expert providing credible and unimpeachable evidence in a declaration failed to set out a consulting relationship with a patent owner; and an inventor who had discovered surprising effects for a patented invention failed to explicitly state that he had not done so through confirmatory testing).

While the court in *Therasense* acknowledged that establishing a higher intent standard in *Kingsdown* failed to stem the problem of over disclosure of marginally relevant prior art to the PTO,¹³ we are best in an experimental phase of research with respect to whether the *Therasense* materiality standard will provide more than a hope that litigant behavior will be meaningfully impacted. Patent applicants cannot reasonably be expected to willingly offer up their valuable inventions as test cases to assist in developing this newly stated and yet to be defined materiality standard.

4-*Therasense* also makes clear courts may continue to infer intent to deceive the Office from indirect and circumstantial evidence.¹⁴ Although the so-called materiality and intent sliding scale is supposed to become a relic of the past, it may remain a legitimate and tempting litigation tactic to assert intent to deceive the Office should be inferred from not disclosing information fiercely asserted in litigation to be highly material to the patentability of a claimed invention in a patent or otherwise alleged to qualify as some form of "affirmative egregious misconduct."

5-Although we know neither *mere nondisclosure* of prior art references to the Office nor failure to mention prior art references in an affidavit constitutes "affirmative egregious misconduct,"¹⁵ and the Court's intent appears to be that this exception to the *Therasense* "but for" materiality standard be narrowly construed consistent with Supreme Court precedent, quite reasonably practitioners are somewhat skeptical of how this exception may evolve in the courts. Likewise, skillful litigators will no doubt exploit the uncertainties of this new "affirmative egregious misconduct" exception based on behavior that may today seem innocuous to patent applicants and the Office. Whatever its eventual boundaries, *Therasense* certainly provides no safe harbor for the applicant who is considered to have grossly erred in making a bold attempt at being more forthcoming and helpful to the Office.

Accordingly, although *Therasense* may be viewed by some as a step, perhaps even a leap in the right direction to improving the patent system, unless the Office takes more decisive action, this single pronouncement isn't likely to erase the realities or memories cast by the *shadow of a*

¹² *Kingsdown Medical Consultants v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988)

¹³ *Therasense* at 2011 U.S. App. LEXIS 10590, at *34

¹⁴ *Therasense* at 2011 U.S. App. LEXIS 10590, at *34

¹⁵ *Therasense* at 2011 U.S. App. LEXIS 10590, at *39

hangman's noose on practitioners, such that patent prosecutors are likely to rely on their instincts, which will include, burying examiners with the same deluge of prior art references, most of which have marginal value. The result will be to continue the status quo that is negatively impacting patent quality, greatly complicating the process of obtaining patents, and injecting substantial uncertainty and costs into patent licensing and enforcement.

Patent Office Goal # 2 - The Therasense materiality standard should continue to prevent fraud on the Office and other egregious forms of misconduct.

In assessing the Office's need for assistance from Applicants in the examination process, the Office is reminded there is no shortage of sanctions, apart from sanctions flowing from the inequitable conduct doctrine, to deter those contemplating in engaging in misconduct before the Office.

The provisions of 18 U.S.C. §1001(a) more than adequately provide for civil and even criminal sanctions for all types of misconduct before the Office, including for both material omissions and misrepresentations. Such misconduct would encompass willful false statements in oaths or declarations and material omissions and misstatements with respect to information that would impact the validity of a claimed invention.

If a registered patent attorney or patent agent is involved in the misconduct (such as, knowingly providing false or misleading information to the Office), the misconduct could represent a violation of the Office's disciplinary rules for these practitioners. These Office rules on misconduct appear at 37 C.F.R. §10.23, and provide where grounds for discipline exist, a practitioner may be excluded or suspended from practicing before the Office for a period of time, reprimanded, censured, or placed on probation. 37 C.F.R. §10.23.

In addition, the attempted enforcement of an invalid patent procured through misconduct creates potential liability under antitrust laws. In *Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), the Supreme Court made clear that damages from the patent owner under the antitrust laws could be obtained if appropriate showings of materiality and intent were shown in connection with the misconduct. Under *Walker Process*, private litigants have a cause of action directly against the person engaged in a knowing effort to enforce invalid patent claims obtained through misconduct. As with other antitrust law causes of action, damages can be trebled and attorneys fees awarded.

Therefore, even absent sanctions involving inequitable conduct, available sanctions exist to deter those contemplating in engaging in misconduct before the Office, including criminal liability, professional disbarment, and antitrust liability.

Patent Office Goal #3 - Harmonizing the Office's and the Therasense materiality standard should result in a simpler patent system.

Harmonizing with the Federal Circuit's materiality standard is unlikely to simplify patent practice. In fact, this proposed path forward may further complicate patent practice.

Without question the unpredictable standards used to assess inequitable conduct have made it exceedingly difficult for practitioners to foresee what a court a decade in the future may deem to have been beyond the bounds of acceptable behavior in interacting with the Office. The *Therasense* court acknowledged this: "Tying the materiality standard for inequitable conduct to PTO rules, which understandably change from time to time, has led to uncertainty and inconsistency in the development of the inequitable conduct doctrine."¹⁶

There is, however, a reciprocal concern that tying the Office's materiality standard to the decisions of the Federal Circuit, which have been anything but uniform, may equally establish a moving target for applicants – a moving target being altered by those who are perhaps less experienced than the Office with what is indeed important to the examination of a patent application (*See: Therasense* "since the court's inequitable conduct precedent emerged from the unclean hands doctrine, the standards for intent to deceive and materiality have often fluctuated").¹⁷

It's also apparent from the concurring and dissenting opinions in *Therasense* that Federal Circuit judges have disparate views of how the inequitable conduct doctrine should develop, leaving evolution of the doctrine, and the materiality standard the Office proposes to adopt, unpredictable and unlikely to yield the benefits hoped for by the Office. More likely, wholesale adoption of an evolving materiality standard that will be applied to disclosure practices which occurred years earlier – before the case law advances to shed light on behavior that again may have been considered previously acceptable by patent practitioners and the Office - will result in the most conservative information disclosure practices too familiar to the Office.

More importantly, the Office has the authority, expertise and responsibility to state a clear materiality standard, consistent with the "but for materiality" standard, that will provide the Office only the most relevant information it needs, and liberate applicants from their current quagmire which too often results in over disclosure to and under communicating with the Office. As noted in *Therasense*, courts have in the past and Lilly believes will in the future, continue to look to the expertise of the Office as a starting point for determining what is material to patentability.¹⁸

¹⁶ *Therasense* at 2011 U.S. App. LEXIS 10590, 43-44.

¹⁷ *Therasense* at 2011 U.S. App. LEXIS 10590, at *24.

¹⁸ *Therasense* at 2011 U.S. App. LEXIS 10590, at *43.

Essential Elements of the Office's Proposed Rule Directed to the Materiality Standard for Submissions of Information in Matters or Proceedings Before the Office

Lilly believes there are certain essential elements to the decisive action required by the Office to pave the way for the Office to achieve its above-stated goals.

First, the Office should seize the opportunity to harmonize not with the Federal Circuit, but with the majority of other patent offices in the world, by affirming it is the Office's responsibility to identify and apply publicly available information that might be material to the patentability of an application before the Office. In addition, information available to the public that has not been cited by the Office during patent examination should be deemed to have been considered by the Office but found not to be material to the patentability of any claimed invention in the application.

Although this is an entirely new commitment on the part of the Office, it is consistent with the commitment made by other major patent offices, and is completely justified in view of the Office's ability to obtain this publicly available information itself, though third-party submissions of prior art and the availability of other public resources from which publicly available information of material importance to patentability can be accessed, *e.g.*, through open resources on the Internet.

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. As litigation-driven allegations of "inequitable conduct" in presenting such information have mounted over the years, patent applicants have presented more and more publicly available information for patent examiners to digest. The result is that patent examiners are sometimes left to the exhaustive task of seeking to identify the most material information within a "haystack" of disclosed information.

This new commitment is also justified and should be considered in view of the very different patent system that will exist upon implementation of the America Invents Act, as opposed to the patent system that existed when the Office first promulgated its disclosure rules. America Invents Act implementation will result in patent procurement being a remarkably different process - all patent applications will be promptly published after the patent is initially sought; the entire record of the patent procurement process will be available to the public in real time through the Internet; most information needed to assure complete and accurate patent examination will be publicly accessible information, equally available to inventors and other members of the public alike; the public will have the opportunity to participate in the patenting process before a patent issues by providing material information that must be considered by a patent examiner before the patent can issue; and once the patent issues, the public will have a full and fair opportunity to have the Office reconsider the grant of the patent, including during proceedings with opportunities for discovery and judicial review.

Second, the Office should preemptively abrogate any duty on the part of the patent applicant to disclose to the Office publicly available information for the purpose of deciding on patentability of a claimed invention. It should be clear that a patent applicant may elect to remain silent, even if the publicly available information known to the applicant would have prevented a patent from issuing had the information been known to the Office before a decision to issue the patent was made by the Office. In the absence of this important second step, Applicants will continue to err on the side of over disclosing information to the Office.

Again, this new responsibility assumed by the Office aligns the practice before the Office with the practice before other patent offices throughout the world that have adopted procedures permitting significant public input into the patenting process, through either pre-grant or post-grant opportunities to submit information or to challenge the patentability or validity of claims in a patent or application for patent.

Third, to strike a fair balance between over and under disclosure of information to the Office, and to ensure publicly available information provided to the Office by applicants will be of optimal value in facilitating a patentability determination, an applicant should only be permitted and encouraged to submit publicly available information that the applicant regards as being the most significant or pertinent to patentability of a claimed invention. When an applicant makes such a submission, it should be required to assist the Office by identifying the manner in which the item potentially bears on a question of patentability. The office should establish a “safe harbor” to encourage patent applicants to make such non-required disclosures of the most significant or pertinent information without fear that the selection or characterization of the information disclosed would be a basis in support of a misconduct allegation.

Fourth, a further “safe harbor” should be provided to persons involved in a matter or proceeding before the Office that disclose information to their respective attorneys or agents authorized to practice before the Office. The “safe harbor” provision operates to insulate such persons from any allegation of having violated a duty of candor or other obligation of acting in good faith with respect to any information that has been disclosed to an attorney or agent representing the person involved in the matter or proceeding. This is accomplished in part by deeming any disclosure of information made by the involved person to its legal representative before the Office as sufficient by itself to discharge the person from any further duty to disclose.

Fifth, the Office should adopt the currently articulated “materiality” standard of the Federal Circuit with respect to disclosures to the Office of information that is *not available to the public*. The intent of this threshold, as in *Therasense*, is to focus issues of misconduct before the Office on truly consequential omissions and errors in submissions made to the Office.

For the Office to once and for all unleash practitioners and the Office from their unproductive over disclosure, under communication quagmire, will require bold leadership from the Office – in short, Rule 56 needs to be decisively modified to more clearly state what information the Office will require applicants to submit to the Office, and equally important, what information the Office does not expect applicants to submit during patent examination. In a substantially public process, with the right of the public to participate from beginning to end, that relies almost

entirely on publicly accessible information, and for which other criminal, civil and administrative sanctions will remain to assure the integrity of the process, now is the time for the Office to take this decisive action.

Accordingly, Lilly proposes that the Office replace 37 C.F.R §1.56, as amended effective March 16, 1992, with 37 C.F.R §1.56 to read as follows:

(a) Persons involved in matters or proceedings before the Office, when providing information to the Office in connection with such matters or proceedings, must make submissions of such information in a manner consistent with section 1001(a) of title 18, United States Code.

(b) During the examination of an application for patent, the Office assumes the responsibility for identifying and applying information that is available to the public for the purpose of deciding the patentability of each claimed invention in the application. An applicant for patent has no affirmative duty or responsibility to provide to the Office information that is available to the public. Applicants may elect to provide such information to the Office in the manner set out under subsection (c).

(c) Applicants for patent providing to the Office information that is available to the public for the purpose of assisting the Office in the examination of their applications must confine submissions of such information to items regarded by the applicant as being of the most significance or pertinence to patentability and, for each item provided, must concisely identify the manner in which the information contained therein may potentially bear on a question of patentability for a claimed invention and, if applicable, how an item may be pertinent to or distinguished from any claimed invention. A submission of information under this subsection shall not be deemed to be in violation of any duty of candor or other obligation of acting in good faith based upon other publicly available information that was known and not disclosed or upon the manner in which, or correctness with which, publicly available information provided to the Office was characterized or otherwise described in the submission.

(d) A person's duty of candor or other obligation of acting in good faith in connection with providing information to the Office in a matter or proceeding before the Office is deemed satisfied by providing such information to a representative who is acting on such person's behalf in connection with the matter or proceeding and who is registered to practice before the Office under regulations promulgated pursuant to section 2(b)(2)(D) of title 35, United States Code. The representative shall be responsible for submitting any such information required to be provided to the Office in an accurate and complete manner, as part of the representative's professional responsibilities to the person under such duty or other obligation. A person providing information to its representative under this subsection shall not be deemed to have violated any duty of candor or other obligation of acting in good faith before the Office because of the failure

of the representative to discharge the representative's professional responsibilities to such person.

(e) Nothing in this section shall be construed to require the disclosure to the Office of information that is not available to the public, or of a correction to such information once disclosed, in connection with a matter or proceeding before the Office, unless such information or correction is required for the Office to avoid reaching an incorrect determination on the issue under consideration by the Office.

(f) Information available to the public that has not been cited by the Office during examination of an application for patent shall be deemed to have been considered by the Office but found to be of no relevance to the patentability of any claimed invention in the application.

Lilly appreciates the Office's efforts to seek public comment regarding new regulations relating to the materiality standard for submissions of information in matters or proceedings before the Office. Lilly urges the Office to undertake a further review of possible options for codifying the "duty of disclosure," rather than proceeding at this time through to final rulemaking on the basis of the rules as proposed. The Office has an historic opportunity to vindicate the policy behind, and the purpose of, the duty of disclosure in light of the America Invents Act while facilitating the more efficient grant of high quality, wholly valid patents. Lilly asks the Office to consider the appropriateness of issuing a substitute notice of proposed rulemaking that would incorporate the substantive provisions set forth herein.

If there are questions regarding our comments or if further explanation of any of our comments is desired, please feel free to contact the undersigned.

Sincerely,

Robert A. Armitage
Brian P. Barrett
MaCharri Vorndran-Jones
Eli Lilly and Company
Indianapolis, IN 46285

Attachment

Eli Lilly & Company's (Lilly) Comments to the United States Patent and Trademark Office (Office) Notice of Proposed Rulemaking entitled: *Revision of the Materiality to Patentability Standard for the Duty To Disclose Information in Patent Applications* (Federal Register / Vol. 76, No. 140 / Thursday, July 21, 2011 / Proposed Rule 43631)

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(b) During the examination of an application for patent, the Office assumes the responsibility for identifying and applying information that is available to the public for the purpose of deciding the patentability of each claimed invention in the application. An applicant for patent has no affirmative duty or responsibility to provide to the Office information that is available to the public. Applicants may elect to provide such information to the Office in the manner set out under subsection (c).

(c) Applicants for patent providing to the Office information that is available to the public for the purpose of assisting the Office in the examination of their applications must confine submissions of such information to items regarded by the applicant as being of the most significance or pertinence to patentability and, for each item provided, must concisely identify the manner in which the information contained therein may potentially bear on a question of patentability for a claimed invention and, if applicable, how an item may be pertinent to or distinguished from any claimed invention. A submission of information under this subsection shall not be deemed to be in violation of any duty of candor or other obligation of acting in good faith based upon other publicly available information that was known and not disclosed or upon the manner in which, or correctness with which, publicly available information provided to the Office was characterized or otherwise described in the submission.

(d) A person's duty of candor or other obligation of acting in good faith in connection with providing information to the Office in a matter or proceeding before the Office is deemed satisfied by providing such information to a representative who is acting on such person's behalf in connection with the matter or proceeding and who is registered to practice before the Office

under regulations promulgated pursuant to section 2(b)(2)(D) of title 35, United States Code. The representative shall be responsible for submitting any such information required to be provided to the Office in an accurate and complete manner, as part of the representative's professional responsibilities to the person under such duty or other obligation. A person providing information to its representative under this subsection shall not be deemed to have violated any duty of candor or other obligation of acting in good faith before the Office because of the failure of the representative to discharge the representative's professional responsibilities to such person.

(e) Nothing in this section shall be construed to require the disclosure to the Office of information that is not available to the public, or of a correction to such information once disclosed, in connection with a matter or proceeding before the Office, unless such information or correction is required for the Office to avoid reaching an incorrect determination on the issue under consideration by the Office.

(f) Information available to the public that has not been cited by the Office during examination of an application for patent shall be deemed to have been considered by the Office but found to be of no relevance to the patentability of any claimed invention in the application.

Commentary:

New 37 C.F.R §1.56 provides regulations relating to the submission of information disclosures in matters or proceedings before the Office. Certain provisions of new Rule 56 apply specifically to patent applicants submitting information in connection with their respective applications for patent. Other provisions relate more generally to information disclosures and apply, for example, to the parties to any contested proceeding before the Office, *e.g.*, requesters seeking institution of the new post-grant review and inter partes review proceedings under chapter 31 and chapter 32 of title 35.

37 C.F.R §1.56(a) – Bar to Knowing and Willful Withholding or Misrepresentation

Under new subsection (a), all parties to all matters and proceedings before the Office are barred from knowingly and willfully engaging in any of the following:

- (1) falsifying, concealing, or covering up by any trick, scheme, or device a material fact;
- (2) making any materially false, fictitious, or fraudulent statement or representation; or
- (3) making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

See 18 U.S.C. §1001(a). This provision, therefore, bars misleading or deceptive conduct on the part of any party to any proceeding before the Office. This provision is intended to assure that participants in the new proceedings authorized under chapters 31 and 32 of title 35, United States Code, do not engage in any form of misconduct before the Office, *e.g.*, the requesters in such

proceedings offering false evidence upon which the Office might cancel the claims of a patent owner based upon invalidity contentions grounded upon such false contentions.

37 C.F.R §1.56(b) – Sole Responsibility of the Office for Publicly Available Information

Under new subsection (b), the Office takes sole responsibility for using its resources for searching and examining applications for patent to identify any and all publicly available information that might be material to patentability of an application for patent before the Office. Likewise, the Office takes sole responsibility to apply such information to make its determinations of patentability. This is an entirely new commitment on the part of the Office and is undertaken in part because of the Office's ability to accept third-party submissions of prior art and the availability of other public resources from which publicly available information of material importance to patentability can be accessed, *e.g.*, through open resources on the Internet.

As a result of the Office assuming sole responsibility for identifying and applying material information that is available to the public, new subsection (b) takes the further step of preemptively abrogating any duty on the part of the patent applicant to disclose to the Office publicly available information for the purpose of deciding on patentability of a claimed invention. A patent applicant, under new subsection (b), may elect to remain silent, even if the publicly available information known to the applicant would have prevented a patent from issuing had the information been known to the Office before a decision to issue the patent was made by the Office.

The new responsibility assumed by the Office aligns the practice before the Office with the practice before other patent offices throughout the world that have adopted procedures permitting significant public input into the patenting process, through either pre-grant or post-grant opportunities to submit information or to challenge the patentability or validity of claims in a patent or application for patent.

Under new subsection (b), applicants may elect to provide publicly available information that is not required to be provided. However, applicants are required, should such information be provided, to conform to the requirements under subsection (c).

37 C.F.R §1.56(c) – Requirements for Providing Publicly Available Information

Under new subsection (c), patent applicants are placed under stringent requirements where they elect to provide publicly available information to the Office. Specifically, applicants are required to restrict submissions to items of information that the applicant regards as being the most significant or pertinent to patentability of each claimed invention in the application. This restriction is intended to eliminate the possibility that patent applicants will provide long listings or items of prior art for consideration by the Office during patent examination.

Additionally, where the election to submit is made, the applicant's submission must identify, for each item of information provided, the manner in which the item potentially bears on a question of patentability. This can be done through a citation of the claims relevant to the item and the specific, relevant statutory requirement for patentability. In general, the submission must additionally identify the manner in which the information in question is or may be pertinent to a claimed invention and the manner in which it might be distinguished from the claimed invention. The intention is that such submissions by the patent applicant of information available to the public will be of optimal value to the Office in considering the bearing of the information on patentability.

Subsection (c) further contains a "safe harbor" for patent applicants that make submissions of publicly available information. Under the "safe harbor," information cannot be regarded as a violation of any duty of candor or any other obligation of acting in good faith because the patent applicant failed to disclose other information available to the public in addition to the information disclosed. In addition, the same "safe harbor" applies with respect to any incorrect information in such a submission to bar allegations of as a similar violation. The intent of this comprehensive "safe harbor" provision is to encourage patent applicants to make such non-required disclosures without fear that the selection or characterization of the information disclosed would be a basis in support of a misconduct allegation.

37 C.F.R §1.56(d) – Patent Applicant "Safe Harbor" for Information Disclosed to Its Attorney

Under subsection (d), a further "safe harbor" is provided to persons involved in a matter or proceeding before the Office that disclose information to their respective attorneys or agents authorized to practice before the Office. The "safe harbor" provision operates to insulate such persons from any allegation of having violated a duty of candor or other obligation of acting in good faith with respect to any information that has been disclosed to an attorney or agent representing the person involved in the matter or proceeding. This is accomplished in part by deeming any disclosure of information made by the involved person to its legal representative before the Office as sufficient by itself to discharge the person from any further duty to disclose.

Subsection (d) further obligates the person's legal representative to submit any or all of such information provided by the person in an accurate and complete manner to the extent such disclosure is required. As an example, where information is required to be provided to the Office in order to respond to an official action rejecting claims in an application for patent, the patent applicant cannot be regarded as having violated any duty to disclose information if the information in question was provided to its patent attorney, but its patent attorney elected not to disclose or disclosed but mistakenly characterized the information.

The intent of this provision is to assure that patent applicants who are fully candid with their legal representatives can be fully insulated from allegations of possible misconduct if such

information, for whatever reason, is not fully or accurately provided to the Office. A further objective of this provision is to make explicit the professional responsibility of attorneys and agents registered before the Office to make all required disclosures on behalf of their clients in matters and proceedings before the Office, once apprised of such information.

37 C.F.R §1.56(e) – Materiality Threshold for Non-Public Information Requiring Disclosure

Under subsection (e), the Office adopts the essence of the currently articulated “materiality” standard of the Federal Circuit with respect to disclosures to the Office. The standard in subsection (e) specifically applies to information that is not available to the public and requires disclosure or correction of such information only where necessary so that the Office can avoid reaching an incorrect determination on the issue under consideration.

The intent of this threshold, as in *Therasense*, is to focus issues of misconduct before the Office on truly consequential omissions and errors in submissions made to the Office.

37 C.F.R §1.56(f) – Information Deemed Considered by the Office During Examination

Under subsection (f), a rule of construction is provided that deems all information available to the public, but not cited by the Office as part of the examination of a patent application, as having been considered by the Office in connection with the application but determined to be of no relevance to patentability. The intent of this provision is to obviate any incentive on the part of patent applicants to disclose voluminous quantities of information for the sole purpose of positioning themselves to contend that all such information was considered by the Office and the decision of the Office of patentability should, therefore, be entitled to greater deference.

Conclusions

Under new Rule 56, matters and proceedings before the Office should be conducted with greater alacrity, greater accuracy, and improved fairness. These consequences should result from an improved focus on the information most important to making correct determinations on issues before the Office.