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From: Marcellina Dunbar
Sent: Friday, September 08, 2006 3:57 PM
To: AB95 Comments
Cc: David Korn
Subject: Comments form PhRMA

Please contact us with any questions about the filing.

Marci

Marcellina Dunbar
Administrative Assistant
Legal
PhRMA
950 F Street, N.W.
Suite 300
Washington, DC 20004
Tel. 202-835-3497
Fax 202-715-7028

David E. Korn
Assistant General Counsel

PhRMA

September 8, 2006

VIA EMAIL – AB95.comments@uspto.gov

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

Attention: Hiram H. Bernstein
Senior Legal Advisory

Dear Under Secretary Dudas:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members on the proposed "Changes To Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38,808 [Docket No.: PTO-P-2005-0024]. PhRMA's members are leading pharmaceutical research and biotechnology companies, devoted to inventing and making available medicines that allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding new cures, as well as in developing critically important improvements in existing therapies. Strong patent protection is required in order to promote the ongoing research of PhRMA members. This research, in turn, further promotes pharmaceutical innovation and benefits patients.

PhRMA's members understand that the PTO's goals in proposing these rules are to improve Office efficiency and quality, and PhRMA's members support these underlying goals. However, as discussed in the attached comments, PhRMA members are concerned that the proposed rules might not achieve those goals, and instead could harm legitimate patent stakeholders. Accordingly, PhRMA urges you to reconsider the PTO's proposed rule. Please feel free to contact me with any questions or concerns you may have.

Sincerely,

David E. Korn

Attachment

Comments of the Pharmaceutical Research and Manufacturers of America on Proposed Rule Changes To Information Disclosure Statement Requirements and Other Related Matters

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines, a 6.5% increase over 2004 R&D expenditures.[1] In 2005, PhRMA member companies invested a record 19.2 percent of domestic sales on U.S. R&D.[2] The societal benefits from such investment are undeniable. "New medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000."[3]

PhRMA's members appreciate the importance of innovation to technological progress and social well-being. They also have an intimate appreciation of the importance of patent rights. In an industry where research and development is expensive and competition is fierce, strong patent protection is necessary for PhRMA's members to be able to recoup the costs of their investments.[4] Commentators have suggested that without confidence in the availability and enforceability of such protection, the amount of such investment — and the pace of pharmaceutical improvements — would slow dramatically.[5]

PhRMA writes to comment on the proposed "Changes To Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38,808 [Docket No.: PTO-P-2005-0024], which was published in the Federal Register on July 10, 2006.

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1 Press Release, PhRMA, R&D Investments by America's Pharmaceutical Research Companies Near Record $40 Billion in 2005 (Feb. 13, 2006), *at* http://www.phrma.org/news_room/press_releases/_r&d_investment_by_pharmaceutical_companies_tops_$38_billion_in_2004/.

2 *Id.*

3 PhRMA, *Pharmaceutical Industry Profile 2006*, p. 64, *at* http://www.phrma.org/files/2006%20Industry%20Profile.pdf.

4 See Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries, in Science and Cents: Exploring the Economics of Biotechnology* 87, 88-92, 99-101 (John V. Duca & Mine K. Yücel eds., 2003).

5 *See* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,* at ch. 3, p. 11 & n. 48 (Oct. 2003) (reporting an estimate that, without patent protection, pharmaceutical innovation "would decrease by approximately 60%"); *see also* Grabowski, *supra* n.4, at 88.

PhRMA believes that any proposed United States Patent and Trademark Office ("PTO") practice reform should focus on addressing perceived and actual abuses of PTO practice and should not harm legitimate patent stakeholders. PhRMA agrees with the PTO that any proposed reform should focus on improving the quality and efficiency of the examination process. However, PhRMA believes that the proposed rules would not achieve that goal. Instead of reducing the amount of information before the examiner and enabling the examiner to focus on the relevant portions of information submitted with an Information Disclosure Statement ("IDS"), the proposed rules instead could have the perverse effect of increasing the volume of information submitted to the examiner for consideration:

- The PTO justifies the proposed rules as an attempt to improve the efficiency and quality of the examination process. However, to the extent the proposed rules seek to limit the number of references disclosed to the PTO by "provid[ing] an incentive to the applicant to cite only the most relevant documents," 71 Fed. Reg. at 38,810, they present a conflict with Federal Circuit case law, which provides a much stronger incentive for applicants to disclose all potentially material information to the PTO to avoid allegations of inequitable conduct.

- The proposed rules would also conflict with the PTO's own guidance with respect to information disclosure to the PTO, which encourages the disclosure of information in close cases. Thus, the proposed rules may not result in the citation of fewer references to the PTO because patents that the PTO ultimately issues and that are litigated in the courts would be subject to the more stringent Federal Circuit rules.

- The proposed rules could perversely impose additional disclosure requirements on applicants, resulting in the disclosure of more, rather than less, information to patent examiners.

- The proposed rules would also substantially harm the interests of legitimate applicants, including PhRMA members, by imposing burdensome requirements that open up substantial new avenues for patent infringers to allege inequitable conduct during the prosecution of the infringed patents, returning to the days where such claims "ha[d] become an absolute plague." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

- Furthermore, the proposed rules would disproportionately and adversely affect PhRMA's members because the proposed rules would impose arbitrary and

overly constrained thresholds for additional disclosure requirements based on the number of prior art references cited in a patent application.[6]

PTO PROPOSED RULES

The PTO proposes amending 37 C.F.R. §§ 1.97 and 1.98 to require that an applicant disclosing more than twenty documents in an IDS or combination of IDSs must provide an "explanation" for each cited document. 71 Fed. Reg. at 38,810. The PTO also proposes that an applicant disclosing in an IDS "English-language documents over twenty-five pages" or "non-English-language documents of any length" must provide an "explanation" for each such document. *Id.* Such an "explanation" "must provide additional disclosure, such as an identification of a portion of a document that caused it to be cited, and an explanation of how the specific feature, showing, or teaching of the document correlates with language in one or more claims" or, in rare instances, with "a specific portion of the supporting specification." *Id.* Whenever the claims are amended, the "explanation" "for all previous information disclosure statements must be reviewed and updated where necessary in view of the amendment(s)." *Id.* at 38,822.

The PTO also proposes that "[m]ore extensive disclosure requirements would apply to documents submitted in an IDS after a first Office action on the merits," pursuant to which the applicant must provide both (1) an "explanation" or a copy of a recently issued foreign search or examination report and (2) a "non-cumulative description," which "describes a disclosure in the cited document that is not present in any other document of record," for each additional reference cited in such an IDS. *Id.* at 38,810.

The PTO proposes that even more extensive disclosure requirements would apply to IDS submissions after "the mailing date of a notice of allowability or a notice of allowance under [37 C.F.R.] § 1.311," requiring such submissions to include (1) an "explanation"; (2) a "non-cumulative description"; and (3) a "patentability justification," which includes "reasons why the claims are patentable over the cited document(s)." *Id.*

The PTO also proposes that, where an applicant receives "large amounts of unsolicited information from third parties," the "applicant may opt to provide written consent to the filing of a protest by the third party based on such information." *Id.*

The PTO proposes to create a so-called inequitable conduct "safe harbor" for an individual subject to 37 C.F.R. § 1.56 "who, in good faith and to the best of the person's knowledge, information, and belief, formed after a reasonable inquiry under the

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[6] *See* Allison, John R. & Lemley, Mark A., *The Growing Complexity of the United States Patent System*, 82 B.U. L. Rev. 77, 121-22 (2002) (indicating that, of the patents surveyed that issued between 1996 and 1998, those in the pharmaceutical, biotechnology, and medical device fields cite the most prior art references, all near or above the threshold of twenty set by the proposed rules).

circumstances, took reasonable steps to comply with the additional disclosure requirements." *Id.* at 38,811. Although noting that this so-called "safe harbor" does not bind the courts in their inequitable conduct determinations, the PTO nevertheless "is hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account." *Id.* at 38,812.

The PTO also reminds applicants and their representatives that any submissions under the proposed rules would be "subject to the provisions of [37 C.F.R.] § 10.18." *Id.* at 38,809. Thus, the proposed rules would require that each submission pursuant to the proposed rules "be reviewed to assure its submission does not cause unnecessary delay or needlessly increase the cost of examination." *Id.* The proposed rules would also require that each submission be reviewed to ensure that it does not result in obscuring material information. *Id.*

THE PROPOSED RULES WOULD NOT MAKE THE OFFICE MORE EFFICIENT OR IMPROVE THE QUALITY OF ISSUED PATENTS BECAUSE THEY MAY NOT RESULT IN THE CITATION OF FEWER REFERENCES

The PTO's Asserted Justification for the Proposed Rules is at Odds with Both Federal Circuit Precedent and the PTO's Own Guidance

37 C.F.R. § 1.56 and the Federal Circuit both require applicants and those substantively involved in the filing and prosecution of patents to disclose to the PTO material prior art known to them. 37 C.F.R. § 1.56 (2006) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."); *see, e.g., Brasseler U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 n.2 (Fed. Cir. 2001) ("In accordance with 37 C.F.R. § 1.56, inventors and their representatives are under a duty to disclose all material information known to them."). However, they impose dramatically different standards for materiality. Section 1.56(b) provides:

> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.
>
> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is

> unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b).

In contrast to the PTO, the Federal Circuit has held that courts may apply at least five different standards of materiality: (1) "the objective 'but for' standard, where the misrepresentation was so material that the patent should not have issued"; (2) "the subjective 'but for' test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so"; (3) "the 'but it may have' standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution"; (4) the standard embodied in the previous version of section 1.56, which stated that "information is material 'where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent'"; and (5) the current section 1.56 standard. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-15 (Fed. Cir. 2006) (quoting 37 C.F.R. § 1.56 (1977)). This creates the prospect of considering no less than five different materiality standards in determining what, if any, information should be submitted to avoid an allegation of inequitable conduct. *See id.* at 1316.

Nor is it clear which materiality standard a court will apply, even to applications prosecuted pursuant to the current section 1.56 standard. The Federal Circuit has noted that "the extent, if any, to which the Patent Office rulemaking [amending section 1.56] was intended to provide guidance to the courts concerning the duty of disclosure in the context of inequitable conduct determinations is not clear." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003). Nevertheless, the Federal Circuit has chosen in some cases to apply "the PTO's formulation at the time an application is being prosecuted before an examiner of the standard of conduct it expects to be followed in proceedings in the Office" and to apply the current section 1.56 standard. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1353 (Fed. Cir. 2005); *see also Purdue Pharma LP v. Endo Pharms., Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) (same). In other cases, however, the Federal Circuit has applied the previous section 1.56 standard. *Digital Control, Inc.*, 437 F.3d at 1316; *see also, e.g., Dayco Prods., Inc.*, 329 F.3d at 1364. Furthermore, the Federal Circuit has made clear that other standards of materiality may apply. *See Digital Control, Inc.*, 437 F.3d at 1316. This creates the prospect that one could conceivably fully and faithfully comply with the PTO's stated view of materiality pursuant to section 1.56 and yet still be held to have committed inequitable conduct if the court, years down the road, applies a different standard for materiality.

In addition, the Federal Circuit has stated that applicants must disclose *all* information known to them that is material under those standards. *See, e.g., Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990) ("Essentially,

Manville had a duty to disclose *all* information, including uses and sales of its invention more than one year before it filed its application, if such information would be deemed 'material.'" (emphasis in original)). That is so because it is the examiner — "an official of the PTO . . . with years of experience and clothed with the PTO authority to take whatever action the PTO deem[s] appropriate" — not the applicant, who has the authority to make the ultimate determination of a reference's materiality. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1568 (Fed. Cir. 1983). Only if the examiner is given all material information can the examiner make an appropriate decision regarding the patentability of claims in an application. Thus, the Federal Circuit has explained, the applicant is "required" to "submit[] and explain[] all of the material facts and permit[] the Examiner to draw on his own evaluative expertise and reach his own decision with knowledge equal to [the applicant]." *Id.*

The PTO asserts that the proposed rules are necessary because "applicants and practitioners mistakenly believe that people associated with a patent application must submit questionably or marginally relevant documents in order to ensure compliance with the § 1.56 duty of disclosure." 71 Fed. Reg. at 38,809. However, this assertion appears to conflict with earlier pronouncements by courts and even the PTO itself. The Federal Circuit has stated that "[i]t is axiomatic that '[c]lose cases should be resolved by disclosure, not unilaterally by applicant.'" *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (quoting *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992)) (second alteration in original); *see also LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001) ("[A]s this court has emphasized, when a question of materiality is close, a patent applicant should err on the side of disclosure."); *Brasseler U.S.A. I*, 267 F.3d at 1380 ("To avoid a finding of inequitable conduct, doubts concerning whether information is material should be resolved in favor of disclosure.").

In *LaBounty*, the Federal Circuit stated that, in close cases, it is "all the more necessary" for the applicant to disclose information to the examiner, rather than unilaterally determining that the information is not material. 958 F.2d at 1076. In fact, in another case, the court stated that it is "incumbent" on the applicant to disclose the information in such a situation. *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001).

The PTO has stated in the Manual of Patent Examining Procedure ("MPEP"):

> When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant." *See also LaBounty Mfg.,*

> *Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

MPEP § 2004(10) (8th ed., rev. 4 2005). The MPEP also recognizes that inequitable conduct concerns lead applicants to submit information in close cases:

> Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive.

MPEP § 2001.04; *see also id.* § 2001.05 ("The Office believes that most applicants will wish to submit [not material] information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.").

The concerns that lead patent applicants to disclose all information that is even potentially material could apply particularly to patents and patent applications in the fields of pharmaceuticals and biotechnology. Because litigation relating to such patents often involves such high stakes, alleged infringers virtually always assert inequitable conduct. And, in these cases, the Federal Circuit has found a medley of information to be material, not just prior art that establishes a prima facie case of unpatentability, including test results allegedly inconsistent with statements made during prosecution, *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1384 (Fed. Cir. 2005), and a declarant's past relationships with the applicant, *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1188 (Fed. Cir. 2006). Indeed, the Federal Circuit has held that seemingly irrelevant information, such as the existence of copending patent applications, can be material, even where those applications are otherwise unrelated to the patent application being prosecuted because they would not result in a shorter patent term for any patent that issued from that application. *Dayco Prods., Inc.*, 329 F.3d at 1365.

The foregoing has created a strong incentive for PhRMA members in particular, therefore, to err on the side of disclosure. Patent applicants may err on the side of disclosure of information if it bears even the smallest relevance to the patent application, rather than attempt to guess what a court might consider in the future to be material under the many materiality standards that may apply. Accordingly, the proposed rules would not result in the PTO's goal of attaining more efficient and effective patent examination by reducing the amount of information that applicants disclose to the PTO. Merely setting an arbitrary limit on the number of references that may be disclosed before the

applicant must include "explanations" of the cited information will not preclude patent applicants from submitting all potentially material information to the PTO.[7]

The Proposed Rules Could Increase, Rather Than Reduce, the Amount of Information That the Applicant Must Submit for the Examiner to Review

Furthermore, the proposed rules may not result in more efficient or effective patent examination because they could increase, rather than reduce, the amount of information that the applicant must submit and the examiner must consider, in conflict with the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.* (2000). The proposed rules would impose substantial new burdens on patent applicants, requiring them to provide "explanations" of certain references cited during prosecution. Under the proposed rules, the "explanation" "must provide additional disclosure, such as an identification of a portion of a document that caused it to be cited, and an explanation of how the specific feature, showing, or teaching of the document correlates with language in one or more claims" or, in rare instances, with "a specific portion of the supporting specification." 71 Fed. Reg. at 38,810. Whenever the claims are amended, the "explanation" "for all previous information disclosure statements must be reviewed and updated where necessary in view of the amendment(s)." *Id.* at 38,822. In addition, the proposed rules would require that applicants provide a "non-cumulative description," which "describes a disclosure in the cited document that is not present in any other document of record," and a "patentability justification," which includes "reasons why the claims are patentable over the cited document(s)," for certain references cited in an IDS. *Id.* at 38,810.

All of these additional requirements in the proposed rules could perversely increase the amount of information that the examiner must consider, as the examiner would be required to consider the additional information submitted by the applicant along with the references cited by the applicant. In addition, some of the submissions would require regular updates, thus placing still more information before the examiner and imposing further burdens on patent applicants. Some patent applications in the fields of biotechnology and pharmaceuticals involve hundreds of references cited, along with hundreds of claims. Prosecution of such an application would involve a tremendous burden of updating the submissions, which must be borne by both the applicant and the examiner. Each time the applicant amended even one of the claims, the applicant would be required to review each of the cited references to ensure that the submission remained accurate and complete and to update the "explanation" for each reference where necessary. The examiner would face a corresponding burden of reviewing the amended "explanation." The amount of information before the examiner could thus increase, not decrease, as a result of the proposed rules.

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[7] Nor can the PTO justify its proposed rule changes based on a hope that they would reduce the filing of unreviewed or irrelevant documents with the PTO because, as the PTO itself recognizes, such submissions are already prohibited pursuant to the existing rules.

Furthermore, the examiner would be required to reject applications that do not meet the standards of the proposed rules, in turn requiring the applicant to file a revised IDS or a petition to have the information considered by the Office. Thus, the proposed rules could ultimately result in far more information before the PTO, not less.

THE PROPOSED RULES WOULD IMPOSE NEW OBLIGATIONS LIKELY TO RESULT IN ADDITIONAL CHARGES OF INEQUITABLE CONDUCT

The proposed rules would create an array of new disclosure obligations that require patent applicants to submit information that future infringers would scour for any inconsistencies in an attempt to raise an inequitable conduct claim. During patent litigation, infringers search the file history of the patent application seeking inconsistencies and errors in the prosecution of the patent. The additional requirements would provide more avenues for infringers to challenge patents as unenforceable due to inequitable conduct, returning patent litigation to the days where such claims "ha[d] become an absolute plague." *Burlington Indus.*, 849 F.2d at 1422.

As Judge Newman of the Federal Circuit recently noted, before the Federal Circuit's landmark decision in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988), allegations of inequitable conduct were rampant:

> For example, an inventor is required to provide the Patent Office with all prior art references known to the inventor that are "material to patentability"; if the inventor provided selected references, he was accused of inequitable conduct in the selection; and if he provided an entire search report, he was accused of burying the significant references. The inventor was also required to provide a one-sentence statement about each reference that he listed; much was made of whatever was and was not in that sentence.

Ferring B.V., 437 F.3d at 1196 n.1 (Newman, J., dissenting). The proposed rules would impose additional disclosure requirements, like the one-sentence statements to which Judge Newman refers,[8] for which much would be made of whatever is or is not in that

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[8] The PTO's proposed rules would reimpose a requirement similar to the one that the PTO eliminated in 1992 in response to such concerns. Until 1992, an information disclosure statement required "[a] concise explanation of the relevance of each listed item." 37 C.F.R. 1.98(a) (1991). When the regulation was revised in 1992, that requirement was eliminated in response to "[a] number of comments." Duty of Disclosure, 57 Fed. Reg. 2,021, 2,030 (Jan. 17, 1992). Thus, the new regulation was designed to "facilitate the filing of information since the burden of submitting information to the Office has been reduced by eliminating, in most cases, the requirement for a concise statement of the relevance of each item of information listed in an information disclosure statement." *Id.* at 2,024.

disclosure in future patent litigation. Indeed, the Federal Circuit "has recognized that a 'patentee's oversights are easily magnified out of proportion by one accused of infringement.'" *Id.* at 1196 (quoting *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) (quoting *Pfizer, Inc. v. Int'l Rectifier Corp.*, 538 F.2d 180, 186 (8th Cir. 1976))). The additional disclosure requirements could provide a medley of opportunities for patent infringers to seize upon such an oversight in an attempt to render legitimate patents unenforceable.

Thus, the proposed rules could lead to additional burdens on the patent system as a whole. Applicants would be required to review materials not only for materiality to the patent examination process, but also for potential inequitable conduct concerns that could be raised in future litigation. As Judge Newman notes, accused infringers routinely accuse patentees of inequitable conduct based on the patentee's disclosures to the PTO during the prosecution of the patent. If the patentee did not disclose information with even the most tenuous relevance to the prosecution of the patent, the accused infringer alleges that the lack of disclosure was inequitable conduct. As a result, applicants may continue to disclose or identify as relevant large portions of cited references, despite the added burdens the proposed rules would impose, eliminating any potential benefits to efficiency and effectiveness that the proposed rules might otherwise offer.

However, not even full disclosure can shield applicants from allegations of inequitable conduct. Even if an applicant were to disclose all potentially relevant information, the applicant may still face allegations that it committed inequitable conduct by "burying a particularly material reference in a prior art statement containing a multiplicity of other references." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).[9] Thus, the proposed rules would not alleviate the burdens on the patent

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[9] Indeed, much may be made in future litigation of the following statement:

> Applicants and their representatives are reminded that the presentation of an IDS, like any other paper filed in the Office, is subject to the provisions of § 10.18. The reasonable inquiry mandated by §§ 10.18(b)(2) and 10.18(b)(2)(i) requires that information in an IDS be reviewed to assure its submission does not cause unnecessary delay or needlessly increase the cost of examination. Failure to review can also implicate obligations of registered practitioners under §§ 10.23(b) and (c), and § 10.77(b). Likewise, when an IDS includes several documents of marginal relevance, combined with other evidence suggesting that the marginally relevant information was submitted with the intent to obscure material information, this may run afoul of the duty of candor and good faith set forth in § 1.56(a). In such circumstance, an inference that the applicant or their

(continued...)

system; rather, they could increase the burden on the system. Applicants could continue to submit information to the examiner to avoid allegations of inequitable conduct, while the proposed rules could increase the burden in future patent litigation as accused infringers bring additional inequitable conduct allegations stemming from the additional disclosures the proposed rules would require.

The proposed rules would be replete with new traps for unwary practitioners to be subject to allegations of inequitable conduct for inadvertent errors or good-faith attempts at appropriate levels of disclosure. Each of these proposed rules may affect PhRMA members disproportionately:

- The proposed rules would provide that the applicant may "submit only a portion of a document and is encouraged to do so where that portion can be considered without further context and is the only portion that is relevant to the claimed invention." 71 Fed. Reg. at 38,813. Applicants who choose to submit portions of documents, such as an excerpt of test results, in accordance with the proposed rules may face allegations that they committed inequitable conduct in doing so because of the imprecision inherent in determining whether "that portion can be considered without further context and is the only portion that is relevant to the claimed invention." The Federal Circuit has held that test results showing that a particular compound "was capable of stabilizing" a particular formulation were material to statements that another compound "was generally superior . . . in stabilizing" that formulation. *Syntex (U.S.A.) LLC*, 407 F.3d at 1384. Thus, applicants who submit only test results for the most pertinent compounds, rather than every compound tested, may face allegations that they committed inequitable conduct by withholding other results from the PTO. Applicants who do not do so may face allegations that they attempted to bury the pertinent disclosure in violation of *Molins PLC*.

- The proposed rules would provide that applicants must "identify at least one appearance in the document (a representative portion) of a specific feature, showing, or teaching for which the document is being cited. Where applicant is aware that such feature, showing, or teaching appears in more than one portion of the document, applicant would not need to specifically point out more than one occurrence, although applicant may wish to, particularly where the additional appearance may not be apparent to the examiner and may have some additional significance over its first identified appearance." 71 Fed. Reg. at 38,814. For example, pharmaceutical companies may disclose a reference that identifies a particular set of compounds repeatedly throughout the reference. An applicant who identifies only one occurrence of such a

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representative attempted to cover up or conceal a material reference could be drawn.

71 Fed. Reg. at 38,809.

compound may face allegations of inequitable conduct in doing so because "the additional appearance[s] may not be apparent to the examiner" or "may have some additional significance." Conversely, applicants who identify all occurrences of the relevant compounds may face allegations that they attempted to bury the pertinent disclosure in violation of *Molins PLC*.

- The proposed rules would provide that, where an applicant "believes that an entire document or most portions thereof are relevant and caused the document to be cited, applicant may make such statement so long as applicant establishes such fact by sufficient recitation of examples from the document. Sufficiency of recitation of examples will vary on a case-by-case basis." Any such statement, such as a statement that a claimed pharmaceutical compound exhibits superior results over all other related compounds, may be challenged as an attempt to bury pertinent information in violation of *Molins PLC*, while the sufficiency of examples from the document, such as the identification of only test results involving the most closely-related compounds, may be attacked as either too much information or too little information.

- The proposed rules would also make clear that any IDS submission pursuant to the proposed rules must "be reviewed to assure its submission does not cause unnecessary delay or needlessly increase the cost of examination," and that it does not result in obscuring material information. 71 Fed. Reg. at 38,809. Thus, many IDS submissions themselves may be challenged as constituting inequitable conduct pursuant to the proposed rules. Furthermore, although 37 C.F.R. § 1.291 of the proposed rules provides an avenue for an applicant to consent to a third party protest rather than submitting unsolicited information from the third party in an IDS, the proposed rules also make clear that "nothing in § 1.291 is intended to relieve a person subject to § 1.56(c) from submitting to the Office information that is subject to the duty of disclosure under § 1.56." *Id.* at 38,823. Thus, the burden would remain on the applicant to submit material information, even if the applicant were to consent to a protest. An applicant who submits only a portion of the information from the third party may be accused of inequitable conduct for failure to disclose material information, while an applicant who submits all of the informaiton from the third parties may be accused of attempting to bury pertinent information in violation of *Molins PLC*.

In an attempt to resolve the myriad of inequitable conduct concerns raised by the proposed rules, the PTO proposes to create a so-called inequitable conduct "safe harbor" for an individual subject to section 1.56 "who, in good faith and to the best of the person's knowledge, information, and belief, formed after a reasonable inquiry under the circumstances, took reasonable steps to comply with the additional disclosure requirements." *Id.* at 38,811. While PhRMA supports the concept of a "safe harbor" shielding those patent applicants who comply with the PTO's rules in good faith from allegations of inequitable conduct, the "safe harbor" as formulated in the proposed rules may provide little protection for patent applicants facing allegations of inequitable conduct.

As the PTO itself notes, the regulation would not bind the courts in their inequitable conduct determinations. Although the PTO "is hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account," *id.* at 38,812, the courts may continue not to apply the PTO's rules in the context of litigation, *cf. Dayco Prods., Inc.*, 329 F.3d at 1364 (refusing to apply the PTO's current section 1.56 standard for materiality and noting that "the extent, if any, to which the Patent Office rulemaking [amending section 1.56] was intended to provide guidance to the courts concerning the duty of disclosure in the context of inequitable conduct determinations is not clear"), even though the courts should defer to the PTO on such procedural matters. Thus, the "safe harbor" would provide no guarantee of protection for patent applicants.

Furthermore, even if courts chose to apply the "safe harbor," the "safe harbor" itself is replete with avenues for potential litigation. Initially, it is unclear whether the patentee would have the burden of proving that he or she acted "in good faith" and to the best of his or her knowledge, information, and belief, along with whether he or she "took reasonable steps to comply with the additional disclosure requirements." Furthermore, regardless of the allocation of the burden, each of these issues may be heavily contested in future patent litigation involving allegations of inequitable conduct. The so-called "safe harbor" thus would provide little certainty or protection for patentees facing allegations of inequitable conduct. Coupled with the additional requirements that would provide many avenues for an infringer to allege inequitable conduct during the prosecution of the patent, the proposed rules may have the effect of multiplying claims of inequitable conduct.

In any event, the PTO should not implement rules that could substantially increase allegations of inequitable conduct in future litigation while Congress considers substantial changes to the law of inequitable conduct. Several bills have recently been proposed in Congress that would substantially alter the law of inequitable conduct to reduce such allegations. *See* Patent Reform Act of 2006, S. 3818, 109th Cong. § 5 (2006); Patent Act of 2005, H.R. 2795, 109th Cong. § 5 (2005). These bills come in the wake of reports criticizing the current inequitable conduct doctrine by the Federal Trade Commission and the National Research Council of the National Academies. *See* Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; Comm. on Intellectual Prop. Rights in the Knowledge-Based Economy, The National Academies, *A Patent System for the 21st Century* 119 (Stephen A. Merrill et al. eds., 2004), *available at* http://www.nap.edu/html/patentsystem/0309089107.pdf. Thus, rulemaking in this area that could add to the burden borne by patentees related to inequitable conduct charges would be premature while changes to the law of inequitable conduct to reduce that burden are pending before Congress.

THE PROPOSED RULES WOULD INCLUDE ARBITRARY AND INEQUITABLE LIMITATIONS THAT WOULD HAVE A DISPROPORTIONATE IMPACT ON PARTICULAR TYPES OF PATENT APPLICANTS, INCLUDING PhRMA MEMBERS

The proposed rules would also impose an arbitrary limitation on the number of references required before the applicant must provide an "explanation" of each such reference. An "explanation" would also be required for references including more than twenty-five pages and references written in foreign languages. The PTO states that the twenty document limitation "best balances the interests of the Office and of the applicants" because, in its survey of applications allowed in a six-week period, twenty references or fewer were cited in approximately eighty-five percent of the applications. 71 Fed. Reg. at 38,809-10. However, these arbitrary limitations in the proposed rules ignore both the trend of increasing references cited to the PTO and the PTO's own actions that are likely to cause an increase in the number of references cited. In addition, regardless of the proportion of applications that would be affected by the proposed rules, the imposition of the limitations in the proposed rules would have a disproportionate impact on particular types of patent applicants, including PhRMA members. Nor is there an equitable reason to distinguish between an applicant who discloses nineteen documents and one who discloses twenty, or between an applicant who discloses a twenty-four page document and one who discloses a twenty-five page document.

"Patents issued in the 1990s cited vastly more prior art than patents issued in the 1970s." Allison & Lemley, *supra* n.6, at 80; *see also id.* ("Overall, patents in the 1996-98 sample cited almost three times as much total prior art, and more than ten times as much non-patent art, as patents in the 1976-78 sample."). This trend is likely to continue, and other proposed PTO rules would make it even more likely that the number of references cited on IDSs would increase in the future.

For example, the PTO has proposed amending section 708.02 of the MPEP, which allows for accelerated examination of certain patent applications, to require a preexamination search for prior art and "[a]n accelerated examination support document [which] must include an information disclosure statement (IDS) in compliance with 37 CFR 1.98." Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 Fed. Reg. 36,323, 36,325 (June 26, 2006) [Docket No.: PTO-P-2006-0014]. Similarly, the PTO has proposed amending section 1.75(b)(1) to require that an applicant must submit an examination support document if the applicant seeks to have more than ten independent or representative claims examined. Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 67 (Jan. 3, 2006) [Docket No.: 2005-P-067]. Pursuant to proposed section 1.261, such an examination support document must include "[a]n information disclosure statement in compliance with § 1.98." *Id.* at 68. Such requirements, if they are imposed, are likely to increase the number of references cited to the PTO in IDSs. Thus, an arbitrary limitation that already encompasses fifteen percent of patent applications would likely encompass far more in the future under the proposed rules.

In addition, the proposed rules essentially abdicate the PTO's responsibility to examine patent applications pursuant to 35 U.S.C. § 131, shifting the burden from the Office to the applicant to determine patentability. For example, if the applicant seeks to submit information after the mailing date of a notice of allowability or a notice of allowance, the applicant must provide a "patentability justification" that includes "reasons why the claims are patentable over the cited document(s)." 71 Fed. Reg. at 38,810. In addition, an applicant who seeks to avoid making such a "patentability justification" may be foreclosed pursuant to other PTO proposed rules from filing a Request for Continued Examination if the application is a continuation or a previous Request for Continued Examination has been filed. *See* Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006) [Docket No.: 2005-P-066].

Furthermore, the limitations in the proposed rules would have a disproportionate impact on particular types of patent applicants, including PhRMA members. Although the PTO asserts that the proposed rule changes "would not require a change in practice for most applications," 71 Fed. Reg. at 38,810, the impact of the changes would fall most heavily on applicants seeking patents in the pharmaceutical, biotechnology, and medical device fields. Allison & Lemley's data show that, in the 1996-98 time frame, patents in the pharmaceutical field cited an average of 18.55 references, while those in the field of biotechnology cited an average of 23.86 references and those in the medical device field cited an average of 25.84 references. Allison & Lemley, *supra* n.6, at 125. The average patent in each of these fields thus is already near or above the limitation that would be imposed by the proposed rules, placing a substantial additional burden on the applicant. In addition, the trend of increasing citations to references in patents has particularly affected the pharmaceutical field. *Id.* at 54 (noting that "the pharmaceutical industry, which cited the least references in the 1970s, cited more than average by the 1990s"). Therefore, the proposed limitation on the number of references cited before an "explanation" is required for each reference, which is arbitrary in any event, could affect patent applicants in particular fields, including PhRMA members, disproportionately.

Similarly, PhRMA members often must submit references that exceed twenty-five pages or are written in a foreign language. Indeed, many patents are longer than the twenty-five page limit the proposed rules would impose. Furthermore, a great deal of information relevant to patent applications involving pharmaceuticals and biotechnology is published in foreign languages, along with an English-language abstract. The proposed rules would require a patent applicant to submit all of such information along with an "explanation" for each reference, rather than allowing the applicant to submit the information in order to allow the examiner to determine the materiality of the reference based on the abstract. Thus, the proposed rules regarding references longer than twenty-five pages and foreign language references could also have a disproportionate impact on PhRMA members.

ALTERNATIVE PROPOSAL

The PTO may choose to consider an alternative system to that of the proposed rules that would not impose the proposed rules' burdensome additional disclosures that patent applicants must supply and examiners must review. Instead of requiring additional information from applicants, thereby increasing the likelihood of inequitable conduct allegations in future litigation, the PTO could consider increasing fees for references submitted to the PTO that do not fall within certain guidelines. Such fees would help the PTO achieve its goals of providing more efficent and effective patent examination without imposing on patent applicants and examiners the substantial burdens that would be involved in preparing and reviewing the additional submissions that the current proposed rules would require. Nor would the imposition of such fees create the risk of additional inequitable conduct issues for patentees in the future that the current proposed rules would create.

For example, the PTO could consider imposing a fee for each document in excess of twenty documents submitted in either a single IDS or multiple IDSs, rather than requiring applicants to prepare an "explanation" for each such document. The PTO could also consider imposing a similar fee, rather than requiring an "explanation," for each document submitted by an applicant that exceeds twenty-five pages in length and each foreign language document that is not accompanied by a translation. The increased fees would address the PTO's concerns regarding the submission of references bearing little or no relevance to the patent application by creating an incentive for applicants to avoid submitting references that would cause the applicant to incur such a fee. In addition, the increased fees could be used to defray the costs of the additional burdens of examination that the citation of large numbers of references, voluminous references, and foreign language references can impose on the PTO.

The PTO could also encourage the submission of information before the first Office action by imposing a fee schedule imposing higher fees for IDSs submitted after the first office action or imposing the additional information requirements of the proposed rules only on IDSs submitted after the first Office action.

CONCLUSION

PhRMA wishes to express its appreciation to the PTO for this opportunity to comment for the record on the agency's proposed rulemaking. PhRMA and its members are committed to assist the PTO in finding solutions to the many challenges facing the PTO today and in the years to come. However, PhRMA believes that the PTO's proposed changes to patent application practice and procedure are ill-suited to achieving the improvements to the patent examination system that are necessary and desirable. PhRMA encourages the agency to consider extending the dialogue with stakeholders, through additional notice and comment proceedings that include public hearings, in order to ensure a fully transparent process and encourage the broadest possible input. PhRMA would also welcome the opportunity to meet with the PTO in order to develop reforms that would focus on making the PTO more efficient and improving the quality of issued

patents without imposing obligations on patent applicants that would likely lead to an increase in allegations of inequitable conduct before the PTO and causing a disproportionate impact on PhRMA members.

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