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VIA EMAIL: 2014_interim_guidance@uspto.gov

The Honorable Michelle K. Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulaney Street
PO Box 1450
Alexandria, VA 22313

Re: Docket No. PTO-P-2014-0058: 2014 Interim Guidance on Patent Subject Matter Eligibility

Dear Director Lee:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members in response to the Request for Comments on the 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (December 16, 2014). PhRMA's members appreciate the PTO seeking comments on the Interim Guidance and would welcome further dialogue on it.

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

Sincerely,

David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America Regarding the United States Patent and Trademark Office's *2014 Interim Guidance on Patent Subject Matter Eligibility*

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments regarding the United States Patent and Trademark Office's (PTO's) *2014 Interim Guidance on Patent Subject Matter Eligibility,* 79 Fed. Reg. 74618 (December 16, 2014) ("Interim Eligibility Guidance" or "Guidance").

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 $51 billion in 2013 in discovering and developing new medicines. We offer the comments below from the perspective of research-based biopharmaceutical companies who depend on the patent system for the development of new drugs and biologics.

Comments

PhRMA appreciates the PTO's outreach to stakeholders regarding the matters discussed in the Interim Eligibility Guidance, and the PTO's consideration of both PhRMA's comments and the comments of others during this process. The Interim Eligibility Guidance is a substantial improvement over the PTO's now superseded *March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products* ("March 2014 Procedure"). It provides more straightforward guidance to examiners and aligns more closely with Supreme Court case law.

PhRMA offers a few suggestions for improving the Interim Eligibility Guidance and the examination of relevant patents.

- ***Provide Greater Emphasis on Streamlined Eligibility Analysis:*** Although the Interim Eligibility Guidance mentions at page 74625 that a streamlined eligibility analysis can be undertaken such that a full section 101 analysis is unnecessary, the Guidance does not emphasize this analytical pathway. PhRMA encourages the PTO to highlight this pathway by discussing it more prominently in the Guidance, by including it in the flowchart, and by noting that it is broadly available for all types of technologies. PhRMA also suggests a few related edits in the Guidance:
    - The PTO should remove the term "clearly" from the following statement at page 74622 of the Interim Eligibility Guidance: "For claims that may recite a

judicial exception, but are directed to inventions that clearly do not seek to tie up the judicial exception, see Section I.B.3. regarding a streamlined eligibility analysis." The term "clearly" discourages the use of a streamlined eligibility analysis; such discouragement is inappropriate, given that the Interim Eligibility Guidance speaks to exceptions to patent eligibility.

- The PTO should remove the following sentence at page 74623 of the Interim Eligibility Guidance, which is confusing: "When there is no naturally occurring counterpart to the nature-based product, the comparison should be made to the closest naturally occurring counterpart." If there is no naturally occurring counterpart, then the product is not directed to a judicially recognized exception, and thus is patent eligible. If the PTO intended this sentence to encompass the scenario of a nature-based product produced by combining multiple components, then this concept is already separately covered in the Guidance. Therefore, the sentence is superfluous and unnecessary.

- ***Provide Practical Guidance to Examiners:*** In any revision of the Interim Eligibility Guidance, and in any training materials and training sessions, the PTO should remind examiners of a few key points as they examine applications and issue Office Actions.

  - ***First,*** examiners should recognize that the law surrounding subject matter eligibility issues is directed to the exception rather than the rule. Exceptions to patent subject matter eligibility should be read narrowly, not extended beyond the specific decision of the Supreme Court, and findings of subject matter eligibility should be encouraged if at all possible. The term "markedly different" also should be narrowly construed, so as to not conflate eligibility with obviousness. As we noted in our previous comments, the Supreme Court has cautioned against an overbroad reading of the laws of nature exception to patent eligibility under 35 U.S.C. § 101. In *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.* 132 S. Ct. 1289, 1293 (2012), the Court "recognized . . . that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." This concern was reiterated in *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107, 2116 (2013), and most recently in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) ("At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law.").

  - ***Second,*** if an examiner issues an Office Action raising new section 101 issues in view of the Interim Eligibility Guidance (or if an examiner did so

previously in view of the now superseded March 14 Procedure), the Office Action should not be made final. As noted in MPEP §706.07(a), a second or subsequent action should not be made final "where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement" filed under certain circumstances. Moreover, given that the March 14 Procedure has been superseded, any prior section 101 rejections made pursuant to the March 14 Procedure should be withdrawn by the examiner and only replaced by a non-final rejection based on the Interim Eligibility Guidance if warranted after analyzing the pending claims according to the Guidance.

- ***Third***, we urge the PTO to reiterate to examiners that they must examine each pending claim, including dependent claims, when assessing patentability issues, including subject matter eligibility issues. Pursuant to 37 C.F.R. §1.104, "[i]f the invention is not considered patentable, or not considered patentable as claimed, the claims, or those considered unpatentable will be rejected" by the examiner. In order to follow proper examination procedure, an examiner cannot distinguish which claims are and are not considered patentable under 35 U.S.C. § 101, unless each pending claim is considered separately on its merits.

Conclusion

PhRMA applauds and thanks the PTO for reaching out to stakeholders regarding the Guidance. The PTO's willingness to engage with stakeholders during this process has resulted in a much-improved Guidance. We would welcome further dialogue with the PTO about the Guidance.