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Sent: Monday, September 19, 2011 7:40 AM
To: AC58.comments
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Subject: Comments on Proposed Revision of the Materiality Standard of 37 CFR 1.56 and 1.555

The United States Patent and Trademark Office (USPTO) is to be commended for its efforts to revise 37 CFR 1.56 and 1.555 to take account of of the recent en banc Therasense decision. However, it is urged that the USPTO should take this opportunity to clarify the following key points:

- The record against which the materiality of information at issue is to be judged. I urge that it be the record of the proceeding before the USPTO which is at issue, whether a patent application prosecution or a patent reexamination. It should not include consideration of any evidence which is not of record in the proceeding. The case law, as recently reaffirmed in Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc. (Fed. Cir. 2011), establishes that evidence which comes into existence after a USPTO proceeding has terminated, such as in the grant of a patent, must be considered in assessing the validity of a patent claim. For instance, a showing of unexpected results based on experiments undertaken after the grant of a patent must be considered in assessing validity. Such evidence should not be considered in assessing materiality.
- When the submission of less than all the experimental data or related background information available to an applicant or patentee that relates to the patentability of a claim is affirmative egregious misconduct. I urge that the submission of less than all can not be affirmative egregious misconduct unless the omitted data is a fairly representative result according to accepted scientific principles or the data actually presented is not a fairly representative result according to accepted scientific principles. Thus the failure to present flawed data, as was urged to be the case by the patentee in Cargill v Canbra (476 F3d 1359), or the failure to provide information about the relationship of declarants to the applicant or patentee as was the case in Ferring v Barr Labs (437 f3d 1181), would only be material under the affirmative egregious misconduct standard if the patentability determination had been made on data not fairly representative of the scientific position urged. This would not be the case if the omitted data in the hands of the applicant or patentee were flawed in some way so it could be disregarded by a reasonable scientist, or fairly representative data or a scientifically reasonable position had been presented in a declaration by someone with a relationship to the applicant or patentee, which had not been disclosed.
- Careful consideration should be given to the concerns raised by Rene D. Tegtmeyer in 1992, when he was Assistant Commissioner of Patents and the current version of 37 C.F.R. 1.56 was adopted, relating to the impact of the Rule on the reporting of data in his article "A Refocusing on Inequitable Conduct in New Rule 56", 20 AIPLA Q.J. 191 (1992). A number of his warnings were later realized in case law such as Cargil and Ferring.While Therasense has done much to clarify this area of the law, the handling of experimental data was not an issue in that case and the decision does not explicitly deal with it.
- It is appropriate for the USPTO to promulgate clarifications to the Duty of Disclosure which go beyond the clarifications of the Therasense case. The Court is somewhat limited by the particular issues before it in a given case but the USPTO has the tools via proposed rule making to take a wider view. It can obtain and consider views of the patent bar and other interested parties that go into issues not presented to the Court by the briefing in that case which was focused on the issues in that case.

In other words, the USPTO in adopting the proposed revisions should take steps to prevent the exception to the "but for" rule from swallowing the rule and explicitly require that the affirmative egregious misconduct have had a realistic potential to impact patentability.

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