

How To Quickly Defeat Meritless Inequitable Conduct Claims

By **Eric Evain** (April 26, 2013, 11:13 AM EDT)

The Federal Circuit's decision in *Therasense*, and Congress' establishment of a new supplemental examination procedure, are both designed to combat the "plague" of inequitable conduct allegations.[1] Each will undoubtedly serve to elevate our profession by helping to reduce meritless inequitable conduct claims. Combined, however, they create a formidable strategy to quickly address these allegations. To demonstrate how effective this strategy can be, we recently used a variation as the basis for a successful summary judgment motion of no inequitable conduct. Our adversary did not even try to respond to the motion. They simply withdrew their inequitable conduct allegations, with prejudice.



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Legal Gestalt

Therasense moved the ball forward considerably by creating a but-for standard for establishing the materiality element in inequitable conduct allegations.[2] Under *Therasense*, the court must find that if the so-called withheld information was provided to the U.S. Patent and Trademark Office, the patent claim would not have issued. If the claim is ultimately allowed, even if the information was used as the basis for an initial rejection, there can be no inequitable conduct. This is substantially higher than the pre-*Therasense* standard and should give pause to those who seem to allege inequitable conduct at every turn. In the end, however, the court still must decide materiality, so a litigant can boldly plead that information is "but-for material" and force extended litigation.

Supplemental examination was created by Congress as a way for patent holders to inoculate against future allegations of inequitable conduct.[3] "Information" can be submitted to the USPTO to consider, to reconsider, or to correct information believed to be relevant to the patent. The claims will be re-examined in light of this new information to determine whether it raises a substantial new question of patentability.[4] The USPTO's initial review must be completed within three months.[5] If the claims ultimately survive supplemental examination, a future adversary cannot base an inequitable conduct allegation on that information.[6] However, supplemental examination does not inoculate against existing inequitable conduct allegations.[7]

While each approach has its strengths and weakness, there is a powerful synergistic effect in the combination. Take, for example, a patent holder who is already accused of inequitable conduct for failing to disclose certain information during the original prosecution. While on the surface, supplemental examination may not seem worthwhile because the inequitable conduct allegations are already at issue so there will be no estoppel. However, if the information is submitted to the patent

office in connection with a supplemental examination, and the claims survive, either initially or after ex parte re-examination, then supplemental examination's estoppel provision may not bar further prosecution of the inequitable conduct allegations, but Therasense likely does.

Under Therasense, the court decides whether information is but-for material by assessing whether the patent claims at issue would have been allowed had the information been known to the examiner.[8] Supplemental examination gives the court that answer, and does so quickly. The inapplicability of supplemental examination's estoppel provisions to existing allegations is overcome by Therasense. Similarly, the need for protracted litigation, under Therasense, is overcome by the expedited nature of supplemental examination. The whole is far greater than the sum of its parts.

Alternative Approach

If a party is disinclined to seek supplemental examination, perhaps because of the fees[9] or because the USPTO's history of willingness to find substantial new questions of patentability in the re-examination context, there is still a way to utilize Therasense to address meritless allegations of inequitable conduct.

Prudent practice dictates keeping a continuing application (a divisional or continuation) pending in the USPTO while the corresponding issued patent is in litigation. This is particularly true in connection with Therasense. An recent case serves as a helpful illustration. Our adversary alleged that certain of our client's patent claims would not have issued had the USPTO been aware of certain information. Once Therasense issued, the pending continuation application presented an opportunity that was unavailable before. And at the time, supplemental examinations were not permitted.[10]

All the information that was the subject of the inequitable conduct allegations against our client was disclosed to the USPTO in connection with the pending continuation application. This included our adversary's briefs that purported to explain why the information was somehow patent defeating. The pending application was then amended to include the exact claims that had already issued and were already subject of the litigation. This was fully explained to the examiner.

The examiner properly issued a rejection of those duplicate claims based on statutory, same-invention double patenting, 35 U.S.C. § 101. No rejection was made to these duplicate claims based on the information that was the subject of the existing inequitable conduct allegations. And to be clear, an examiner should raise all possible rejections in an office action, not just double patenting rejections.[11] While the absence of any rejection of these duplicate claims over the information disclosed theoretically established that it was not but-for material, a simple second step eliminated any doubt.

The duplicate claims that stood rejected for same-invention double patenting were then modified slightly. In essence, they were split into two claims that, combined, covered the identical subject matter as the duplicate claims (think of splitting a Markush group into separate claims). The examiner withdrew the same-invention double patenting rejection and issued an obviousness-type double patenting rejection of the newly amended claims. A terminal disclaimer overcame that rejection and the claims were allowed to issue. The new claims covered the same subject matter as the claims that our adversary contended would not have issued had the information been disclosed. A motion for summary judgment of no inequitable conduct for the lack of materiality then was filed and, instead of attempting to respond, our adversary withdrew the inequitable conduct allegations with prejudice. This provided our client with a cost effective way to defeat a meritless inequitable conduct allegation.

Conclusion

Therasense places the court in the shoes of the examiner and asks whether the patent claims would have been allowed over the withheld information. Consider instead having the USPTO itself answer that question, either through supplemental examination or by amending a pending continuation application as discussed above. While there is no guarantee that a court will be guided by the actions taken by the USPTO, to rule otherwise would require finding that what the USPTO may have done is contrary to what the USPTO actually did.

Finally, the prudent practitioner will recognize the risk that the USPTO may deny claims based on this new information. It has been our experience, however, that many inequitable conduct allegations are so lacking in merit that the risk is minimal. Nevertheless, each case must be assessed on its merits.

Note: The referenced case is Evonik Degussa GmbH v. Materia Inc. et al, civil action nos. 1:09-636; 10-200-NLH-JS (consolidated) (D. Del). Co-authors Evain and Hutz, and their firms, continue to represent Evonik Degussa in that ongoing litigation. Co-author Silverstein previously represented Evonik Degussa. The motion for summary judgment and stipulation of dismissal with prejudice appear at docket entry nos. 394 and 409.

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[1] Therasense Inc. v. Becton Dickinson and Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011) (citing Burlington Indus. Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988)).

[2] Therasense, 649 F.3d at 1291.

[3] 35 U.S.C. § 257; see also 37 C.F.R. § 1.601 et seq.

[4] 35 U.S.C. § 257(a).

[5] Id. If a substantial new question of patentability is raised by the new information, the USPTO orders an ex parte reexamination. 35 U.S.C. §257(b).

[6] 35 U.S.C. § 257(c)(1).

[7] 35 U.S.C. § 257(c)(2).

[8] Therasense, 649 F.3d at 1296.

[9] As of the date of this article, the required fee for a supplemental examination is \$16,500. 37 C.F.R. § 1.20(k). \$4,400 of that amount is for the supplemental eExamination, §1.20(k)(1), and \$12,100 is for ex parte re-examination. §1.20(k)(2). If ex parte re-examination is not ordered, the \$12,100 is refunded.

[10] Supplemental examination was not permitted before Sept. 16, 2012. Leahy-Smith America Invents Act §12(c); Pub. L. 112-29, 125 Stat. 327 (Sept. 16, 2011).

[11] 37 C.F.R. § 1.104(b); Ex parte Ionescu, 222 U.S.P.Q. 537, 540 (Pat. & Tr. Office Bd. App. 1984).