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The author states that the *Therasense* high bar on deceptive intent carried over to the reissue context in *Rosuvastatin Calcium Patent Litigation* and questions whether a change to the relevant statute in the America Invents Act will have meaningful impact on the inequitable conduct defense.

Therasense Revisited: *In re Rosuvastatin Calcium Patent Litigation* And the Interplay Between Reissue and Inequitable Conduct

BY GINO CHENG

In the United States, patent applicants and their counsel owe a duty of candor and good faith to the Patent Office.[1] This duty is breached when the applicant or its counsel knowingly fails to disclose material prior art references prior to issuance. Where threshold levels of materiality of the reference and intent to conceal are found, a holding that inequitable conduct has occurred renders every claim in the offending patent unenforceable, a consequence that has often been characterized as ''the 'atomic bomb' of patent law.''[2]

Prior to the landmark *Therasense* holding in 2011, courts had used a sliding scale to determine whether the requisite factual showing of materiality and intent had both been met, whereby a reduced showing of intent nonetheless could be salvaged by a strong showing of materiality, and vice versa.[3]

Therasense established that ''accused infringer must prove both elements—intent and materiality—by clear and convincing evidence''[4] and that ''the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.' ''[5] The inequitable conduct doctrine has developed rapidly since the Federal Circuit's en banc decision in *Therasense* overhauled the substantive requirements to prove unenforceability, separating them into two independent in-

[1] 37 C.F.R. § 1.56(a) (2000) (''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 also*, *Therasense Inc. v. Becton Dickinson & Co.*, 649 F.3d 1276, 1309, 99 U.S.P.Q.2d 1065 (Fed. Cir. 2011) (en banc) (9 PLIR 661, 6/3/11) (majority discussing duty of candor of applicant and its counsel).

[2] *Therasense*, 649 F.3d at 1288.

[3] *Id.* at 1288 (citing *American Hoist & Derrick Co. v. Sowa & Sons Inc.*, 725 F.2d 1350, 1362, 220 U.S.P.Q. 763 (Fed. Cir. 1984)).

[4] *Id.* at 1287 (citation omitted).

[5] *Id.* at 1290 (citation omitted).

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quiries.[6] In rapid succession, the Federal Circuit in *1st Media*,[7] *Powell v. Home Depot*,[8] and *Outside the Box Innovations*[9] applied the new *Therasense* test for the materiality and the intent prongs of inequitable conduct.[10]

However, *Therasense* did not address whether the ''specific intent to deceive'' standard applies equally to reissue of a patent under 35 U.S.C. § 251 (1999). The Federal Circuit's latest decision in *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511, 105 U.S.P.Q.2d 1437 (Fed. Cir. 2012) (hereinafter ''*Astrazeneca*'') (10 PLIR 1587, 12/21/12), resolves this question. The post-*Therasense* heightened threshold showing of deceptive intent that would breach the applicant's duty of candor under 37 C.F.R. § 1.56 is the same as that for showing ''deceptive intention'' that would bar reissue under the pre-Leahy-Smith America Invents Act version of Section 251.

In *Astrazeneca*, the asserted patent (U.S. Patent No. RE37,314) was a reissue of an earlier patent (5,260,440) whose application was first filed in June 1992.[11] Prior to the filing, however, the applicant's in-house patent staff, Tomoko Kitamura, became aware of prior art that the court called ''the Sandoz application'' through various prior art search reports received in June and November of 1991.[12] Kitamura subsequently drafted claims broad enough to cover the prior art disclosures and filed the '440 patent application, but left the assignee company shortly thereafter.[13] Her successor in the in-house patent department, Takashi Shibata, similarly never filed an information disclosure statement to disclose any prior art, including the Sandoz application,[14] despite having received additional search reports in October 1992 and January 1993, each identifying the Sandoz application prior to the '440 patent's issuance on Nov. 9, 1993.[15]

Roughly four years thereafter, the patentee initiated reissue proceedings to narrow the claims and to disclose the previously omitted prior art. The reissue applicant asserted that the statutory error arose from having allegedly ''claimed more than [it] had a right to claim by reason of the disclosure of [the Sandoz application].''[16] The reissue applicant disclosed the Sandoz application along with other material prior art, including a ''Bayer'' reference.[17]

After the examiner rejected Claim 1 as obvious in view of the previously undisclosed Bayer reference, the applicant canceled all of the existing claims in favor of narrower claims that were distinguishable from both the Bayer reference and the Sandoz application.[18,19] The narrowed claims were subsequently allowed.

When the patentee brought suit over the reissued '314 patent, the defendants argued that (i) reissue could not rescue the '440 patent[20] under the well-settled principle that reissue cannot rehabilitate inequitable conduct that occurred during the prosecution of the original patent; and (ii) the '314 patent was improperly reissued because the statutory reissue requirement of error without deceptive intention had not been met.[21]

The *Astrazeneca* court thus confronted the issue of whether the ''without deceptive intention'' standard presented in the reissue statute[22] should be evaluated under the *Therasense* standard requiring specific intent. As the majority noted, no precedent was squarely on all fours with the presented facts to compel the court to invalidate the '314 patent for improper reissue.[23]

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[6] ''Intent and materiality are separate requirements. (citation omitted) A district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality.'' *Id*. at 1290. ''This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality.'' *Id*. at 1291. ''. . . [T]he accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.'' *Id*. at 1290.

[7] *1st Media L.L.C. v. Electronic Arts Inc.*, 694 F.3d 1367, 1374-77, 104 U.S.P.Q.2d 1315 (Fed. Cir. 2012) (reversing district court's inequitable conduct finding absent proof of intent to withhold three groups of prior art references).

[8] *Powell v. The Home Depot U.S.A. Inc.*, 663 F.3d 1221, 1235, 100 U.S.P.Q.2d 1742 (Fed. Cir. 2011) (applicant's failure to cancel petition to make special neither egregious misconduct nor but-for material).

[9] *Outside the Box Innovations L.L.C. v. Travel Caddy Inc.*, 695 F.3d 1285, 1294-95, 104 U.S.P.Q.2d 1890 (Fed. Cir. Sept. 21, 2012) (district court's finding of inequitable conduct reversed absent proof of applicant's deceptive intent when submitting false small entity status declaration).

[10] Although there was no disagreement in *Powell* about how the alleged misconduct failed the but-for materiality test, the distinctive fact pattern in *Outside-the-Box Innovations* divided the panel on the issue of materiality along familiar battle lines from the badly splintered 6-1-4 decision in *Therasense*.

[11] *Astrazeneca*, 703 F.3d at 514-515 and 519 (Fed. Cir. 2012).

[12] 703 F.3d at 532.

[13] *Id*. at 519 and 532-533.

[14] *Id*. at 519.

[15] *Id*. at 519, 532, and 533.

[16] *Id*. at 535.

[17] Although Kitamura possessed a copy of the Bayer reference prior to her departure (*see id*. at 520), it is unclear from the record exactly how the district court and Federal Circuit were able to determine that Shibata also knew about the reference.

[18] Of note, it appears that the reissue examiner's Section 103(a) rejection may have been based on the Bayer reference alone, rather than in combination with any other prior art reference *see id*. at 520 (''The reissue examiner then rejected the generic '440 claims as obvious in view of the Bayer reference.''), which further cements its materiality as part of the inequitable conduct inquiry. Ironically, while the patentee did not dispute the materiality of the Sandoz application, it had challenged the materiality of the Bayer reference, albeit at that time its position was not informed by the *Therasense* decision espousing the but-for materiality test. *In re Rosuvastatin Calcium Patent Litigation*, 719 F. Supp. 2d 388, 402 (D. Del. 2010) (Farnan, J.).

[19] *Id*. at 520 (''In response, [the patentee] limited the '440 patent to the specific compound rosuvastatin and its salts.'').

[20] *Id*. at 518. *Compare Therasense*, 649 F.3d at 1288 (''Unlike other deficiencies, inequitable conduct cannot be cured by reissue. . .'' (citing *Aventis Pharma S.A. v. Amphastar Pharmaceuticals Inc.*, 525 F.3d 1334, 1341 n.6, 87 U.S.P.Q.2d 1110 (Fed. Cir. 2008) (6 PLIR 597, 5/23/08)).

[21] *Id*. at 522.

[22] 35 U.S.C. § 251 (1999) (''Whenever any patent is, through error *without any deceptive intention*, deemed wholly or partly inoperative or invalid. . .the Director shall, on the surrender of such patent and . . . reissue the patent for the invention disclosed in the original patent. . .'' (emphasis added)). The AIA amended Section 251 to remove the ''without any deceptive intention'' language, effective Sept. 16, 2012.

[23] *Astrazeneca*, 703 F.3d at 524 (''. . .no precedent warrants a finding of deceptive intent in the situation herein. . .None of

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The *Astrazeneca* majority concluded that there was ''no sound basis'' for requiring ''less rigorous proof'' to meet the ''deceptive intention'' standard under the reissue statute compared to the ''deceptive intent'' prong for unenforceability in ordinary litigation.[24] The majority's reasoning appears to be purely policy-based, citing *Therasense* and its previous criticism that inequitable conduct accusations were overplayed and prone to mischief.[25] The majority ultimately held that the '314 patent was valid[26] and infringed, choosing to credit the district court's finding that the ''actions suggestive of malfeasance [were] no more than a string of mishaps, mistakes, misapprehensions and misjudgments on the part of inexperienced and overworked individuals,''[27] rather than clear and convincing evidence of the practice of deception during the '440 patent's prosecution.

In contrast, Judge Haldane Robert Mayer's dissent sidestepped the question of the patentee's deceptive intent, choosing to argue that the reissue had been improper due to the lack of ''error.''[28] Instead, he credited the theory that Kitamura had deliberately drafted Claim 1 to cover the compounds disclosed in the Sandoz application, in part based on her considerable prosecution experience and academic background.[29] Mayer also emphasized the fact that neither Kitamura nor her successor testified to misapprehending the Sandoz application[30] and thus inferred that they knew precisely the scope of Claim 1.

Although Mayer stopped short of saying that the patentee had the requisite deceptive intent to satisfy the *Therasense* standard, he was highly critical of the patentee's actions, which he was convinced would have constituted ''fraud'' under the pre-*Therasense* framework.[31] In addition, although he had a chance to open a side door for future panels to capitalize on—and came close to doing so[32]—he did not actually propose that ''deceptive intention'' in the reissue statute could be proved by a lesser showing than that for ''specific intent to deceive'' in a claim of unenforceability.

In sum, unless other panels distinguish *Astrazeneca* or it is reheard *en banc*, the case settles the question of whether the same, high bar for proving deceptive intent under *Therasense* applies to determining whether a patentee has forfeited its ability to seek reissue under the reissue statute due to its ''deceptive intention.'' The same standard for proving deceptive intent applies to both 37 C.F.R. § 1.56 and 35 U.S.C. § 251. In other words, *Astrazeneca* calls for symmetry, streamlining the court's treatments of these respective defenses. Accordingly, a defendant who cannot prove unenforceability under Rule 56 and its jurisprudence will have no better luck proving that the reissued patent was improper under Section 251 due to ''deceptive intention'' associated with the prosecution of the original patent.

As noted above, the *Astrazeneca* holding is applicable to patents whose reissue proceedings commenced before Sept. 16, 2012. *Astrazeneca* does not penalize (by maintaining a lower standard of proof for their opponents) patentees who, in an effort to pursue remedial action to raise a previously omitted reference, sought reissue of their patents prior to the effective date of the amended Section 251. Lest *Therasense* be applied retrospectively to this language in the reissue statute, patentees who had undertaken reissue proceedings pre-AIA would be disadvantaged, and at risk of litigating the propriety of those reissues, under the pre-*Therasense* sliding scale standard.[33]

So what effect does the AIA's removal of the ''without any deceptive intention'' phrase from Section 251 have on the same defense against patents reissued after Sept. 16, 2012, and against those going forward?[34] Re-

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these cases supports rejection of a reissue application for an unintentional failure to file an IDS.'').

[24] *Id*. at 525.

[25] *Id*. (''We discern no sound basis for this distinction, for the complexities of patent solicitation in all its stages have been shown susceptible to the 'plague' of opportunistic accusations. *See Therasense*, 649 F.3d at 1289.''). Judge S. Jay Plager joined the *Astrazeneca* opinion but concurred on a separate issue regarding liability for infringement. *Id*. at 529.

[26] *Id*. at 522 and 527.

[27] *Id*. at 521.

[28] *Id*. at 531 (Mayer, J., dissenting).

[29] *Id*. at 531 (Mayer, J., dissenting). The dissent's theory that the initially broad claim drafting and prosecution was not erroneous was further buttressed by the patentee's cancellation of dependent claims 2 and 3 (whose scope did not overlap with the Sandoz application) during the prosecution of the reissued patent. Rather, the cancellation of the original dependent claims and the addition of new claims narrowly directed to rosuvastatin appeared to be motivated by the abandonment of a competitor's pending patent application, after which there was no reason to tiptoe around claiming that compound. *Id*. at 534-36 (Mayer, J., dissenting). In other words, the applicant could have drafted narrow claims to cover rosuvastatin in the original '440 patent application but had chosen not to. This reasoning appears to be agnostic to any change of counsel between the prosecution of the original patent and that of the reissue.

[30] *Id*. at 532 and 533 (Mayer, J., dissenting).

[31] *Id*. at 535 (Mayer, J., dissenting) (''Prior to *Therasense*. . . this conduct would surely have been censored as fraud on the patent office. Even accepting arguendo that [patentee]'s malfeasance was insufficient to satisfy the standard for inequitable conduct articulated in *Therasense*, however, this does not mean that the '440 patent was validly reissued.'').

[32] *Id*. at 534 and 536 (Mayer, J., dissenting) (while noting ''the majority conflates the issue of whether [the patentee] was guilty of inequitable conduct with the question of whether it met the requirements for reissue under section 251,'' ultimately finding of improper reissuance based on ''through error'' portion of Section 251, second clause, rather than phrase ''without any deceptive intention'').

[33] Because *Therasense* merely heightened the standard for proving ''specific intent to deceive'' and did not address the standard for proving ''deceptive intention'' that would bar reissue, without the *Astrazeneca* ruling, the sufficiency of proof of a patentee's ''deceptive intention'' under the reissue statute may have continued to have been governed under the sliding scale framework of *American Hoist*, 725 F.2d at 1362.

[34] Legislative history behind the deletion is somewhat vague. *See* CONG. REC. S1378 (daily ed. Mar. 8, 2011) (statement of Sen. Jon Kyl (R-Ariz.)):

> At subsections (a) through (h), section 16 of the bill has been modified by reinserting language that eliminates various deceptive-intent requirements that relate to correcting the naming of the inventor or a joint inventor, obtaining a retroactive foreign filing license, seeking section 251 reissue, or enforcing remaining valid claims if a claim is invalidated. See generally *Kearney & Trecker Corp. v. Giddings & Lewis Inc.*, 452 F.2d 579, 596, 7th Cir. 1971. These changes were first proposed in section 5 of the original Patent Reform Act of 2005, H.R. 2795, 109th Congress, and have been advocated by universities and their technology-transfer offices. For reasons that are not entirely clear, subsequent bills maintained this section and its addition of substructure and titles to the affected code sections, but struck the substantive part of the section—i.e., its elimination of the deceptive-intent requirements.

moval of that language certainly forecloses the risk of applying different standards to proving deceptive intent. Defendants facing newly reissued patents will have but one route to challenge the reissued patent on inequitable conduct grounds, i.e., to prove such misconduct by the *Therasense* test[35] rather than to mount a collateral attack based on any deception-related deficiency in satisfying the statute's prerequisites, which is no longer available.[36] But one could argue that the new statute permits a patentee to wash its hands of past misconduct, if by chance it could initiate reissue proceedings based on some unrelated error and then opportunely identify all previously known but deliberately omitted prior art.[37] Indeed, from the standpoint of statutory interpretation, it would be difficult to reach the conclusion that the removal of the statutory language has absolutely no effect.

Nonetheless, while it is clear that patents reissued before the AIA effective date will have their fair shake under *Astrazeneca*, it is not certain how courts will treat those reissued after the effective date. The next (and first) district court to hear the well settled rule prohibiting the use of reissue to rehabilitate misconduct in the original prosecution invoked by a litigant defending against a patent whose reissue proceedings were commenced after Sept. 16, 2012, will have a choice.

The court may continue to apply the long-standing rule foreclosing rehabilitation, reiterated as recently as *Therasense* and *Aventis*.[38] Alternatively, and lacking any reliable legislative history on the point, a court may rely on the AIA's express amendment to Section 251 and absolve the reissue patent holder from any breach of candor that occurred during the prosecution of the original patent, thereby limiting the defendant to challenge enforceability based on any misconduct that occurred during the reissue proceedings only.[39] It will be an interesting test case to see, even more so if other district courts subsequently decline to follow suit.

In closing, looking further ahead, because it is not yet clear whether courts will continue to prohibit the use of reissue to cure the failure to disclose known prior art, patentees less confident about their chances of prevailing against a prospective claim of inequitable conduct may perhaps consider the route of requesting supplemental examination,[40] which is agnostic to past withholding of references and retroactively immunizes the examined patent against future inequitable conduct claims.[41]

Eliminating the various deceptive-intent requirements moves the U.S. patent system away from the 19th century model that focused on the patent owner's subjective intent, and towards a more objective-evidence-based system that will be much cheaper to litigate and more efficient to administer.

Without this language, future application of the previously well settled rule prohibiting the use of reissue to rehabilitate prior prosecution misconduct appears to be less sound, at least as to patents reissued since Sept. 16, 2012.

[35] Although the standard to be applied is clear, the operative question is whether the defendant is limited to pointing to misconduct that occurred during the reissue proceedings only, or whether it may also point back to misconduct that occurred during the original prosecution.

[36] Of course, the reissue applicant must still submit a declaration affirming that it committed an error. However, the Patent Office is not ideally situated to investigate the truth of the assertion, leaving that question for the court in subsequent litigation over the reissued patent.

[37] This scenario supposes that the reissue applicant will be able to draft allowable claims despite the materiality of the freshly disclosed prior art references. In addition, the patentee would need to take into account the intervening rights that the public would gain from the reissue. 35 U.S.C. § 252 (1999) (effect of reissue).

[38] Indeed, here the district court had also cited the same in its analysis. 719 F. Supp.2d at 401-402 (citing *Aventis*, 525 F.3d at 1341 n.6, and *Hewlett–Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1563 n.7, 11 U.S.P.Q.2d 1750 (Fed. Cir. 1989)).

[39] This may largely eviscerate the inequitable conduct defense, because by the time their reissue patents are being litigated, sophisticated patentees most likely will have already purged themselves, during the reissue proceedings, of any questionable conduct related to withholding previously known prior art and would have been savvy enough to avoid committing additional misconduct the second time around.

[40] This, provided that the patentee requests supplemental examination before an action for declaratory judgment finding inequitable conduct is brought against it (*see* 35 U.S.C. § 257(c)(2)(A) (2011)), or, in the case where the patentee is the plaintiff, the supplemental examination is concluded prior to its filing its infringement suit. 35 U.S.C. § 257(c)(2)(B) (2011).

[41] 35 U.S.C. § 257(c)(1) (2011) (''A patent shall not be held unenforceable on the basis of conduct relating to information that has not been considered . . . in a prior examination of the patent, if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.'').

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