

Will Inequitable Conduct Finally Be Reformed?

Law360, New York (June 29, 2010) -- Congress was considering inequitable conduct legislation again this year in connection with the Patent Law Reform Act of 2010,[1] but we understand that effort failed when Congress enacted the Patient Protection and Affordable Care Act.

The Federal Circuit may instead judicially reform inequitable conduct through its April 26, 2010, grant of a request for en banc rehearing on this issue in *Therasense Inc. v. Becton Dickinson & Co.*, No. 2008-1511, 2010 WL 1655391 (Fed. Cir. 2010). The Federal Circuit's order suggests that it plans to significantly re-examine the doctrine.

In this article, we explore the background to the inequitable conduct reform, including both legislative and judicial, and the impact for the future.

Historical Background

The Creation of the "Plague" of Inequitable Conduct

In 1984, the Federal Circuit suggested that "gross negligence" was sufficient to support a finding of inequitable conduct. *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984); *J.P. Stevens & Co. Inc. v. Lex Tex Ltd. Inc.*, 747 F.2d 1553, 1560 (Fed. Cir. 1984). Litigants began charging inequitable conduct in nearly every major patent case and the Federal Circuit referred to the charge as a "plague" on the patent system. *Burlington Indus. Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

In an effort to combat the "plague," the Federal Circuit's en banc *Kingsdown* decision overruled



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cases suggesting that “gross negligence” was sufficient, making clear that specific intent to deceive is a crucial element of the defense. *Kingsdown Med. Consultants Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). This was the last time the Federal Circuit opined en banc on inequitable conduct.

Statistics suggest that Kingsdown had an impact on the frequency with which inequitable conduct allegations were subsequently raised. For example, inequitable conduct decisions increased starting in 1984 — coinciding with the *Driscoll* and *J.P. Stevens* cases — and reached a peak in 1989 — coinciding approximately with the Kingsdown decision.[2]

After Kingsdown, the number of inequitable conduct cases decided by the Federal Circuit dropped to some of the lowest levels ever in 1991-1993. *Id.*

The “Plague” Resurfaces

In 1997, loose language by the Federal Circuit citing the overruled *Driscoll* and *J.P. Stevens* cases revived the “plague.” *Critikon Inc. v. Becton Dickinson Vascular Access Inc.*, 120 F.3d 1253, 1256-57 (Fed. Cir. 1997).

In *Critikon*, the facts of the case helped explain the result, making the broad language of the opinion unnecessary. *Id.* Yet, several later decisions relied on *Critikon*’s language, leading to another proliferation of inequitable conduct allegations that continues today, including court decisions containing vigorous dissents.[3]

Recent Trends in Inequitable Conduct

In the last two years, the Federal Circuit has seemingly attempted to rein in the defense of inequitable conduct by tightening the substantive standards and the pleading requirements.

The Federal Circuit put an affirmative limitation on the ability to find materiality and intent by requiring that, “[w]hen evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.” *Scanner Techs. Corp. v. Icos Vision Sys. Corp. NV*, 528 F.3d 1365, 1376 (Fed. Cir. 2008).

The Federal Circuit also held that “the inference [of intent] must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence.” *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

The Federal Circuit strengthened the requirement that inequitable conduct be pled with particularity under FRCP 9(b), by explicitly requiring that the pleading identify “the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

But other decisions appear to be in tension with these seemingly clear rulings. E.g., *Praxair Inc. v. ATMI Inc.*, 543 F.3d 1306, 1315-16 (Fed. Cir. 2008). In *Praxair*, Judge Lourie argued in dissent that “the district court incorrectly conflated intent with materiality” and that “[w]hile a smoking gun may not be needed to show an intent to deceive, more is needed than materiality of a reference.” *Id.* at 1329.

Given this backdrop, it is not surprising that Congress considered taking action, and the Federal Circuit is revisiting this doctrine en banc.

Efforts at Inequitable Conduct Reform by the Federal Circuit

The inequitable conduct issue in *Therasense* concerns the district court's finding that the patentee made statements to the USPTO regarding what certain prior art disclosed, which were inconsistent with statements that had been made years previously to the European Patent Office ("EPO"). *Therasense Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088 (N.D. Cal. 2008). See *Therasense*, 565 F. Supp. 2d at 1107, 1109.

The prior art reference, though, was before the PTO and could be considered by the examiner. *Id.* at 1095. The district court found that the statements made to the EPO were material, and that both the prosecuting attorney and the declarant before the PTO had the specific intent to deceive the PTO. *Id.* at 1112-17.

On Jan. 25, 2010, a divided panel consisting of Judges Timothy Dyk, Richard Linn and Daniel Friedman affirmed the district court's holding. *Therasense Inc. v. Becton Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010). Judges Dyk and Friedman ruled that the district court's findings of materiality were manifestly correct. *Id.* at 1303, 1305. The panel also found no clear error in the district court's finding on intent. *Id.* at 1306, 1308.

Judge Linn dissented, stating that the district court and the majority had erred on both the materiality and intent prongs. As to materiality, Judge Linn argued that the majority erred because, contrary to the principle of *Scanner*, it adopted an unfavorable inference of materiality when there was an equally reasonable favorable inference. *Therasense*, 593 F.3d at 1312-13.

As for intent, Judge Linn argued the majority erred by failing to recognize that the required intent to deceive is measured by a subjective standard rather than an objective standard, explaining that the standard is whether it is plausible that the patentee subjectively believed the statement was immaterial. *Id.* at 1312, 1320.

Therasense petitioned for rehearing en banc, arguing, inter alia, that the inequitable conduct doctrine needs reform, that the panel decision creates confusion and an intra-circuit conflict, and that the majority opinion undermines the rule of non-materiality of arguments about the prior art when the PTO has the prior art and can read it for itself.

The April 26, 2010, en banc order vacated the Jan. 25, 2010, panel decision, and requested that the following six questions be addressed in new briefing:

- 1) Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
- 2) If so, how? In particular, should the standard be tied directly to fraud or unclean hands? ... If so, what is the appropriate standard for fraud or unclean hands?
- 3) What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
- 4) Under what circumstances is it proper to infer intent from materiality? ...
- 5) Should the balancing inquiry (balancing materiality and intent) be abandoned?
- 6) Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

Therasense Inc. v. Becton, Dickinson & Co., 2010 WL 1655391, at *1 (Fed. Cir. April 26, 2010). The court also invited amicus participation. *Id.* at *2.

The ruling by the Federal Circuit in *Therasense* will be a significant event in the development of patent law. Whether the Federal Circuit will finally succeed in curbing the “plague” of inequitable conduct allegations will likely depend on the clarity and strength of the opinion ultimately issued.

Efforts at Inequitable Conduct Reform by Congress

A bipartisan group of Senators took a different approach aimed at reforming inequitable conduct. The bill proposed earlier this year contains a provision to create a new “supplemental examination” process which would allow patent owners to cure perceived defects in their patents prior to enforcement and preclude an inequitable conduct defense based on information considered in the supplemental examination procedure. See S. 515, 111th Cong. § 10 (2010).

This is in contrast to the current law, where cases have held that reexamination and reissue proceedings are not available to cure inequitable conduct in prosecuting the original patent. See *Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688-89 (Fed. Cir. 1990).

The supplemental examination procedure would allow a patent owner to submit post-grant any additional information (not limited to patents and printed publications) believed to be relevant to the patent. The PTO then considers whether that information raises a substantial new question of patentability warranting re-examination.

If the U.S. Patent and Trademark Office orders re-examination, it proceeds substantially under the rules for *ex parte* re-examination, except that each substantial new question of patentability identified by the PTO must be addressed during the re-examination, notwithstanding any limitations of the *ex parte* re-examination statute such as the limitation relating to patents and printed publications.

The proposed legislation prohibits, under certain circumstances, a court from holding a patent unenforceable due to inequitable conduct “relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination if the information was considered reconsidered or corrected during a supplemental examination of the patent.” This applies whether or not the PTO finds that the information creates a substantial question of patentability and orders re-examination.

In order to prevent an inequitable conduct allegation, the supplemental examination must be requested before a Paragraph IV notice letter alleging inequitable conduct is received, and the supplemental examination and any reexamination ordered pursuant to the supplemental examination request, must be concluded before the patent owner alleges patent infringement.

To take advantage of the supplemental examination procedure, patent owners would need to exercise advance planning and diligent review of their important patents.

Conclusion

It is clear from the history of the law, Congress’ consideration of the doctrine, and the Federal Circuit’s *en banc* order in *Therasense*, that the doctrine of inequitable conduct requires reform. The *en banc* *Therasense* ruling should be a significant event in the development of patent law and ought to be closely monitored. Whether any attempt at reform will truly succeed in reining in the “plague” of inequitable conduct allegations remains to be seen.

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[1] S. 515, 111th Cong. (2010).

[2] See Donald R. Dunner, et al., A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994, 5 Fed. Cir. B.J. 151, 173-76 (1995).

[3] See GFI Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) (“[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead. Critikon Inc. v. Becton Dickinson Vascular Access Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997).” (U.S.P.Q. cites omitted)); Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1126 (Fed. Cir. 2006) (“On appeal, we initially affirmed the trial court’s judgment that the patents were unenforceable due to the inequitable conduct by Purdue ... On petition for rehearing, we have further examined the issues in the case ... Our further review has persuaded us that the trial judge may have erred in how he viewed... the evidence, and that this may have caused an error in the balancing step.”); Ferring B.V. v. Barr Labs. Inc., 437 F.3d 1181, 1196 (Fed. Cir. 2006) (Newman, J. dissenting) (“Today my colleagues on this panel not only ignore Kingsdown ..., [but] they also impose a positive inference of wrongdoing, replacing the need for evidence with a ‘should have known’ standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence.”); McKesson Info. Solutions Inc. v. Bridge Med. Inc., 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J. dissenting (“In Kingsdown, we observed that, ‘To be guilty of inequitable conduct, one must have intended to act inequitably.’ That standard was not met here. This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.”); Aventis Pharma SA v. Amphastar Pharms. Inc., 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J. dissenting) (“[M]y reading of our case law restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception.” and “Merging intent and materiality at levels far below the Kingsdown rule has revived the inequitable conduct tactic.”); Taltech Ltd. v. Esquel Enters. Ltd., No. 2009-1344, --- F.3d ----, 2010 WL 1889168, at * 9 (Fed. Cir. May 12, 2010) (Gajarsa, J. dissenting) (“This case exemplifies the ongoing pandemic of baseless inequitable conduct charges that pervade our patent system.”).

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