

A New Strain Of Inequitable Conduct Litigation

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In July, a split panel of the Federal Circuit upheld the district court's use of an adverse inference from litigation misconduct to hold a patent unenforceable for inequitable conduct. The Federal Circuit's decision in the case, *Regeneron Pharmaceuticals Inc. v. Merus NV*,^[1] raises interesting questions about the relationship between attorney misconduct during litigation (which is not supposed to affect the enforceability of a patent) and misconduct during prosecution of the patent (which can). Because the court's opinion gives no clear answer to these questions, it opens new tactical opportunities for defendants asserting inequitable conduct defenses in patent cases and may incrementally expand the use of a doctrine that the Federal Circuit has famously referred to as a "plague"^[2] and repeatedly tried to rein in.

The Regeneron Decision

Regeneron Pharmaceuticals sued Merus for infringement of U.S. Patent No. 8,502,018, which claims a particular kind of genetically modified mouse used for scientific research. Merus asserted that the patent was unenforceable due to inequitable conduct. In particular, Merus argued that Regeneron's patent prosecutors intentionally withheld four references from the U.S. Patent and Trademark Office that were material to patentability.

In keeping with the Federal Circuit's inequitable conduct case law, the district court (U.S. District Judge Katherine B. Forrest) scheduled a bifurcated bench trial to address the two elements of inequitable conduct: materiality of the references and specific intent to deceive the PTO. After the first trial on materiality, the court held that the withheld references were material. However, the court did not hold a second trial to determine intent. Instead, the court held, as part of its decision following the materiality trial, that Regeneron's litigation counsel had engaged in extensive misconduct and that this warranted a conclusive adverse inference that Regeneron had acted with specific intent to deceive the PTO during prosecution of the patent. The district court concluded that both requirements for inequitable conduct were met and the patent was unenforceable.

The adverse inference was based primarily on Regeneron's failure to produce three categories of documents: (1) nonprivileged documents related to the time period of patent prosecution that were



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improperly withheld as privileged, (2) privileged documents that the court had previously ordered produced after ruling that Regeneron affirmatively waived privilege, and (3) privileged documents related to the mental impressions of counsel during patent prosecution, for which the court concluded privilege was newly waived by Regeneron's submission of trial declarations on that topic.[3]

Though some of the withheld documents were relevant to Regeneron's intent during prosecution, the district court did not find that they demonstrated an actual intent to deceive the PTO. Instead, the court reasoned that full consideration of these documents would require a wholesale reopening of discovery and that this would not be "a fair burden for Merus or this Court." [4] The district court then decided that simply striking the trial declarations would not remedy the problem, because there were other improperly withheld documents besides those relating to the trial declarations, and because it was necessary to address the "substantial disruption and delay" caused by "Regeneron's pattern of conduct throughout this litigation." [5] To adequately remedy this litigation misconduct, the court concluded, it was appropriate to draw an adverse inference that Regeneron had specifically intended to deceive the PTO during prosecution of the patent and therefore, in light of the ruling on materiality, was guilty of inequitable conduct.

The Federal Circuit affirmed in a split decision, with Chief Judge Sharon Prost writing for the majority. With respect to specific intent, the panel began by detailing Regeneron's litigation misconduct in a lengthy discussion that closely tracks the district court's findings. [6] At the conclusion of this discussion, the panel responded briefly to the dissent's argument that under the court's earlier decision in *Aptix Corp. v. Quickturn Design Systems Inc.* [7], litigation misconduct cannot support a finding of unenforceability of a patent for inequitable conduct. The panel did not dispute the principle that "courts may not punish a party's post-prosecution misconduct by declaring the patent unenforceable." [8] But it reasoned that the adverse inference drawn by the district court did not run afoul of this principle because "Regeneron's litigation misconduct ... obfuscated its prosecution misconduct" by "fail[ing] to disclose documents directly related to its prosecuting attorneys' mental impressions of the Withheld References during prosecution of the '018 patent." [9] Given that materiality had been established and that Regeneron's "widespread" litigation misconduct involved the withholding of documents related to prosecution, the panel concluded that the district court had not abused its discretion in relying on an adverse inference to find specific intent.

Judge Pauline Newman, writing in dissent, would have reversed the district court based on *Aptix*, which held that that "litigation misconduct bars the litigant," but it does not "infect, or even affect, the original grant of the property right." [10] According to Judge Newman, although Regeneron may have improperly withheld documents related to its mental state, that did not constitute "evidence ... 'sufficient to require a finding of deceitful intent in the light of all the circumstances.'" [11] In Judge Newman's opinion, the district court had improperly sanctioned Regeneron for litigation misconduct rather than assessing whether it had met the requirements for inequitable conduct during prosecution.

Questions Raised by the Decision

Although there is force to Judge Newman's argument that the district court effectively sanctioned Regeneron for litigation misconduct, the panel majority opinion clearly states that courts "may not punish a party's post-prosecution misconduct by declaring the patent unenforceable." [12] What the panel does not do, however, is explain exactly how, in light of that principle, it can nevertheless be appropriate to draw an adverse inference of prosecution misconduct from litigation misconduct. While the panel's opinion suggests that litigation misconduct must be "directly related" to the patentee's mental state during prosecution in order to support an adverse inference of specific intent, it does not

otherwise explain what standards cabin a district court's discretion in awarding such an adverse inference.

In particular, the panel opinion does not explain how reliance on an adverse inference is consistent with the rule that specific intent to deceive the PTO must be "the single most reasonable inference able to be drawn from the evidence," as required by the Federal Circuit's en banc decision in *Therasense*.^[13] In *Therasense*, the en banc court "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine" that it believed had "been overused to the detriment of the public."^[14] With respect to intent, the court clarified that although circumstantial evidence of intent may be relied upon, it "must be sufficient to require a finding of deceitful intent in the light of all the circumstances," meaning that when "there are multiple reasonable inferences that may be drawn" from the evidence, "intent to deceive cannot be found."^[15] "Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."^[16] Furthermore, "[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive."^[17]

Short of spoliation or destruction of evidence, which did not occur in *Regeneron*, it is not clear how misconduct by the patentee's litigation counsel can require a finding that the patentee's prosecution counsel or inventors intended to deceive the PTO. If the underlying evidence is available, it would appear to be at least possible to rely on that evidence, and that evidence alone, to assess whether or not the patentee intended to deceive the PTO, without resorting to an adverse inference. Similarly, it would not appear unreasonable to infer that the patentee's mental state during prosecution is independent of its counsel's conduct during litigation many years later.

Further muddying the waters, substantial portions of the reasoning articulated by the district court and affirmed by the panel appear to be based on the concerns specific to the litigation, with no evident relationship to *Regeneron*'s intent during prosecution. For example, as the panel noted with apparent approval, the district court sanctioned *Regeneron* in part because rescheduling proceedings to address *Regeneron*'s late waiver of privilege would "not address the delay and disruptions caused by *Regeneron*'s behavior throughout litigation."^[18] Similarly, the "district court ultimately concluded that it would be unfair to *Merus* to reopen discovery on the eve of trial and inject further delay in the case entirely due to *Regeneron*'s behavior" and "that doing so would impose an unfair burden on the court and require expending substantial additional judicial resources."^[19] Although these concerns may be legitimate grounds for issuing litigation sanctions, they do not support a logical inference that *Regeneron* acted with specific intent to deceive the examiner in the proceedings before the PTO that occurred many years before. The panel's holding that it was not an abuse of discretion for the district court to rely on these litigation-specific considerations is therefore in tension with its statement that an adverse inference of intent should not be awarded as punishment. Ultimately, the opinion can be read to mean that district courts have broad discretion in awarding adverse inferences based on litigation misconduct, so long as the litigation misconduct relates to the underlying inequitable conduct inquiry.

Implications for District Court Litigation

By signaling that litigation misconduct can be relevant to inequitable conduct, *Regeneron* opens new opportunities for defendants asserting inequitable conduct defenses to challenge the litigation conduct of the patentee. While actual adverse inferences from litigation misconduct are likely to be rare, litigation on the issue might not be.

Although the district court considered *Regeneron*'s litigation misconduct to be egregious, the

circumstances that gave rise to it are not uncommon. In fact, disputes over the proper scope or waiver of attorney-client privilege are inherent to inequitable conduct proceedings, which place attorney-client communications and attorney mental impressions squarely at issue. By holding that district courts have discretion to grant dispositive adverse inferences based on erroneous claims of privilege or untimely waivers of privilege, the Regeneron decision invites defendants to transform disputes over privilege into affirmative arguments in support of their inequitable conduct defenses. Patentees, for their part, must now be particularly careful about their assertions of privilege and what testimony they put at issue in trial.

If the Regeneron decision ends up having a broader impact on litigation strategy than on the ultimate outcomes of cases, that would be consistent with the way the doctrine of inequitable conduct operates more generally. As the Federal Circuit pointed out in *Therasense*, one of the reasons that inequitable conduct has been asserted so frequently over the years is that it creates potential strategic advantages for defendants that accrue even if they do not prevail on the defense. For example, asserting an inequitable conduct defense opens up new areas of discovery, driving up litigation costs, and it permits the defendant to “paint the patentee as a bad actor,” which may provide atmospheric benefit to the defendant’s case as a whole.[20] These strategic advantages might explain why inequitable conduct is frequently raised despite having a historically low, and decreasing, success rate.[21] Similarly, although the Regeneron decision is unlikely to lead to the unenforceability of many patents, it could end up leaving its mark on patent litigation.

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[1] 864 F.3d 1343, 1350 (Fed. Cir. 2017)

[2] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps.”) (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed.Cir. 1988)).

[3] *Regeneron Pharms. v. Merus B.V.*, 144 F. Supp. 3d 530, 594 (S.D.N.Y. 2015).

[4] *Id.* at 595.

[5] *Id.*

[6] Compare *Regeneron*, 864 F.3d at 1356-63 with *Regeneron*, 144 F. Supp. 3d at 585-595.

[7] 269 F.3d 1369 (Fed. Cir. 2001).

[8] *Regeneron*, 864 F.3d at 1364.

[9] Id.

[10] 269 F.3d at 1375.

[11] Id. at 1366-67 (Newman, J., dissenting) (quoting *Therasense*, 649 F.3d at 1290).

[12] *Regeneron*, 864 F.3d at 1364 (emphasis added).

[13] 649 F.3d at 1290 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

[14] 649 F.3d at 1290.

[15] Id. at 1290-91.

[16] Id. at 1290.

[17] Id. at 1291.

[18] *Regeneron*, 864 F.3d at 1363.

[19] Id.

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

[21] See Eric Johnson, *The Case For Eliminating Patent Law's Inequitable Conduct Defense*, 117 Colum. L. Rev. Online 1, 16 (2017) ("Although *Therasense*'s holdings on materiality and intent make the defense harder to win on the merits, it is not clear that these adjustments have had much of an effect on inequitable conduct's strategic value in litigation. The defense may still help many defendants achieve an off-the-merits victory, either by getting a plaintiff to accept a less favorable settlement in anticipation of swollen litigation costs or by tilting the factfinder against the plaintiff at trial by filling the air with allegations of dishonest behavior."). There is evidence that the rate at which inequitable conduct is asserted has decreased since *Therasense*, but the defense continues to be asserted in approximately 20% of patent cases. See Jason Rantanen & Lee Petherbridge, *Inequitable Conduct and Patent Misuse* 21-22 (Univ. of Iowa Coll. of Law, Legal Studies Research Paper No. 16-09, 2016), <http://ssrn.com/abstract=2704132>.