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INTELLECTUAL PROPERTY LITIGATION

Expert Analysis

Should Patent Holder's Misconduct Be Relevant to Inequitable Conduct?

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A patent applicant's misconduct during the prosecution of a patent can render the patent unenforceable under the doctrine of "inequitable conduct." A recent U.S. Court of Appeals for the Federal Circuit decision, *Regeneron Pharmaceuticals v. Merus*, potentially extends that doctrine to encompass misconduct during patent-infringement litigation, rather than just during patent prosecution. See No. 2016-1346, 2017 WL 3184400 (Fed. Cir. July 27, 2017). We report here on the Regeneron case and other cases addressing whether litigation misconduct can render a patent unenforceable, and provide guidance for practitioners.

Inequitable Conduct

Inequitable conduct is an equitable defense to patent infringement, and a powerful one: a finding of inequitable conduct as to a single claim of a patent renders all claims of that patent unenforceable. *Therasense v. Becton, Dickinson and Co.,* 649 F.3d 1276, 1289-90 (Fed. Cir. 2011). Inequitable conduct can also "spill over" to render unenforceable other patents within the same patent family. And it can lead to antitrust and unfair competition claims by competitors and consumers.

Inequitable conduct claims usually involve an accusation that, during prosecution, the patent applicant withheld from the examiner one or more prior art references bearing on the application. To prove inequitable conduct, the accused infringer must show by clear and convincing evidence that the applicant withheld a reference that was but-for material to patentability—that is, that the Patent Office would not have approved a claim if it had known of the withheld reference—and that the applicant acted with specific intent to deceive the Patent Office. Id. at 1290.

Litigation Misconduct

In *Regeneron,* Regeneron sued Merus, alleging infringement of U.S. Patent No. 8,502,018 (the '018 patent), which claims mice that have been genetically modified with human DNA. See *Regeneron Pharm. v. Merus,* 144 F. Supp. 3d 530 (S.D.N.Y. 2015). Merus counterclaimed,

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alleging inequitable conduct during prosecution of the application that led to the '018 patent.

The district court scheduled a bench trial on the inequitable conduct allegations, and bifurcated that trial into a first phase assessing the materiality of references withheld from the Patent Office and a second phase regarding specific intent to deceive. After the first phase, the district court found that Regeneron had incorrectly represented to the Patent Office that it had created a successful commercial embodiment of the invention, and had not provided to the office four prior art references that the court found to be material. *Regeneron*, 2017 WL 3184400 at *3.

The district court never held the second phase of the trial, and instead—as a sanction for discovery misconduct and misconduct at trial—drew an adverse inference of a specific intent to deceive the Patent Office. Specifically, the court criticized Regeneron's conduct in connection with infringement contentions, claim constructions, document production, and its privilege log. The court found that the prosecution conduct and the litigation conduct together warranted an adverse inference that Regeneron had acted with the specific intent to deceive the Patent Office. *Regeneron*, 144 F. Supp. 3d at 596. Coupling this with its prior finding that the withheld references were but-for material, the court held the '018 patent unenforceable. Id.

A divided panel of the Federal Circuit affirmed, with the majority (in an opinion written by Chief Judge Sharon Prost and joined by Judge Evan Wallach) holding that the withheld references were but-for material, and that an adverse inference based in part on litigation misconduct was not an abuse of discretion and could support a finding of specific intent to deceive. *Regeneron*, 2017 WL 3184400 at *10-15.

The majority distinguished this case from the Federal Circuit's prior decision in *Aptix v. Quickturn Design Systems*, 269 F.3d 1369 (Fed. Cir. 2001), which had held that litigation misconduct cannot render a patent unenforceable under the doctrine of unclean hands. In *Aptix*, as the Regeneron court described it, "we held that courts may not punish a party's post-prosecution misconduct by declaring the patent unenforceable." *Regeneron*, 2017 WL 3184400 at *17.

The majority noted that Regeneron was "accused not only of post-prosecution misconduct but also of engaging in inequitable conduct *during* prosecution," and that the litigation misconduct in which Regeneron was found to have engaged—including not disclosing documents relating to the withheld references—itself "obfuscated its prosecution misconduct." Id.

The majority therefore held that the district court had not abused its sanctions discretion in drawing an adverse inference of an intent to deceive, and affirmed the finding of unenforceability due to inequitable conduct.

'Regeneron' Dissent

Judge Pauline Newman dissented, and would have found first that the four withheld references were not but-for material to patentability. *Regeneron*, 2017 WL 3184400 at *26 (Newman, J., dissenting). Turning to specific intent, the dissent relied on "an unbroken line of precedent" that "strictly limits the inequitable conduct inquiry to a patentee's conduct before the examiner." Id. at *20. The dissent described this precedent as "long-standing, unambiguous and binding," id. at *18, and incompatible with a finding of inequitable conduct based on "counsel's purported litigation misconduct years later in the infringement trial." Id. at 20.

For example, *in Keystone Driller v. General Excavator*, the Supreme Court held that while the doctrine of unclean hands could bar relief to a litigant that suppressed evidence of a prior public use of the invention, that doctrine could not render the patent itself invalid or unenforceable. 290 U.S. 240, 244 (1933). Similarly, in *Hazel-Atlas Glass v. Hartford-Empire*, 322 U.S. 238, 240 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17, 18 (1976), "extreme

litigation misconduct" led to dismissal of the case, but nonetheless "left the patent right intact." *Aptix*, 269 F.3d at 1375.

In *Hazel-Atlas*, the patent applicant wrote an article for publication in a trade journal, had it signed by an ostensibly disinterested expert, and then submitted the article to the Patent Office. 322 U.S. at 240. In the subsequent litigation, the applicant (by then the owner of the patent) relied on the article while actively covering up its true authorship. Id. at 241-43. While the Supreme Court found that the patent owner's "deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals" warranted vacatur of the infringement judgment, it did not render the patent itself unenforceable. Id. at 250.

And in *Aptix*, the patent owner submitted falsified engineering notebooks to the district court to prove an earlier date of conception, and then sought to cover up the forgery by, among other things, purportedly staging a robbery in which the original notebooks were stolen. 269 F.3d at 1371, 1373. The district court held the patent unenforceable due to unclean hands and dismissed the complaint. Id. at 1371. Relying on the Supreme Court's *Keystone* and *Hazlet* decisions, the Federal Circuit affirmed the dismissal of the complaint, but reversed the finding of unenforceability, stating, "Litigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, or even affect, the original grant of the property right." Id. at 1375.

The dissent noted that several district courts had followed *Aptix* in holding that litigation misconduct is not sufficient to support a defense of inequitable conduct. *Regeneron*, 2017 WL 3184400 at *19 (citing *Kimberly-Clark Worldwide v. First Quality Baby,* 2011 WL 679337, at *6 (E.D. Wis. Feb. 16, 2011); *MedPointe Healthcare v. Hi-Tech Pharmacal*, 380 F. Supp. 2d 457, 467 (D.N.J. 2005); *Honeywell Int'l, v. Universal Avionics Sys.*, 398 F. Supp. 2d 305, 311 (D. Del. 2005)).

Inequitable conduct can also "spill over" to render unenforceable other patents within the same patent family. And it can lead to antitrust and unfair competition claims by competitors and consumers.

The dissent would have reversed the finding of specific intent to deceive based on an adverse inference drawn from litigation misconduct.

Guidance for Practitioners

Many patent practitioners are wondering after *Regeneron* whether decisions about privilege logs, document production, infringement contentions, and the day-to-day acts of patent litigation are now grist not only for discovery sanctions but for an inequitable conduct defense as well.

It remains to be seen, however, whether the *Regeneron* decision represents a turn away from *Keystone* and *Hazel-Atlas* and *Aptix*, or whether *Regeneron* will prove to be an outlier. The Federal Circuit majority relied on the fact that the litigation misconduct was designed to cover up prosecution misconduct, and thus *Regeneron* may not stand for the proposition that pure litigation acts, unrelated to patent prosecution, can support inequitable conduct. Furthermore, even after *Regeneron*, inequitable conduct requires that but-for-material references be withheld from the Patent Office, a concrete act separate from a scienter analysis.