

Nos. 2016-1346

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

REGENERON PHARMACEUTICALS, INC.,

Appellant,

v.

MERUS N.V.,

Appellee,

**On Appeal from the United States District Court
For the Southern District of New York
Case No. 1:14-cv-01650-KBF
Judge Katherine B. Forrest**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT'S
COMBINED PETITION FOR PANEL REHEARING
AND/OR REHEARING *EN BANC***

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Dated: September 26, 2017

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies as follows:

1. The full name of every party or amicus represented by me is:

Washington Legal Foundation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners and associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this case:

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INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (“WLF”) are set forth more fully in its motion for leave to file this brief.¹ In brief, WLF is a nonprofit public interest law firm that has participated in numerous court proceedings raising important issues regarding the scope of the inequitable conduct doctrine.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Court’s “inequitable conduct” case law drifted far afield from its “unclean hands” roots before the Court took corrective action with its 2011 decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). WLF fears that the panel’s decision heads the Court off-course once again.

“Inequitable conduct” is an equitable defense to patent infringement that, if proven, bars enforcement of a patent—even when the evidence demonstrates that the patent was properly issued by the U.S. Patent and Trademark Office (PTO). The inequitable conduct doctrine evolved from a series of Supreme Court cases involving particularly egregious misconduct by the patentee, such as perjury and the manufacture of false evidence. *See, e.g., Precision Instrument Mfr. Co. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815 (1945) (patent held unenforceable

¹ Pursuant to Fed.R.App.P. 29(a)(4)(E), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

under “unclean hands” doctrine where proceedings before PTO were “steeped in perjury and undisclosed knowledge of perjury”). As developed by the lower federal courts, the inequitable conduct doctrine came to encompass “a broader scope of misconduct,” including “the mere nondisclosure of information to the PTO.” *Therasense*, 649 F.3d at 1287. A finding of inequitable conduct required two showings: (1) the nondisclosed information was “material” to the PTO’s decision to issue a patent; and (2) the patentee withheld the information with “intent to deceive” the PTO. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

Accused infringers quickly discovered that in the vast majority of cases they could locate undisclosed information that could plausibly be labeled “material.” Moreover, they often relied on the fact of nondisclosure of material information as sufficient proof that the patentee intended to deceive the PTO. As a result, inequitable-misconduct counterclaims came to be viewed by this Court as “an absolute plague” on the patent system, *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), with such counterclaims being filed in the vast majority of infringement lawsuits.

The Court ultimately sought to eradicate the plague by (in its *Therasense* and *Star Scientific* decisions) significantly heightening the evidentiary burden imposed on

those seeking to establish materiality and intent to deceive. In particular, “materiality” now requires a showing that “the PTO would not have allowed the claim had it been aware of the undisclosed reference,” *Therasense*, 649 F.3d at 1291, and “the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’” *Id.* at 1290 (quoting *Star Scientific*, 537 F.3d at 1366). Moreover, even if inequitable conduct is established, an unenforceability sanction (accurately described by this Court as “the atomic bomb of patent enforcement,” *id.* at 1288) is never appropriate unless the district court, after “balanc[ing] the equities,” determines that “the applicant’s conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.” *Star Scientific*, 537 F.3d at 1365.

The panel decision threatens to undo much of the reform accomplished by *Therasense* and re-introduce the inequitable-conduct plague. The panel upheld a finding that Regeneron acted with intent to deceive the PTO in connection with issuance of the ’018 patent, even though the district court never conducted any sort of evidentiary hearing on the issue. The district court adopted an irrebutable “adverse inference” of intent to deceive as a discovery sanction for litigation misconduct that occurred years after the ’018 patent was issued. It simultaneously entered a judgment declaring the patent unenforceable without pausing to determine whether, based on a balancing of the equities, that sanction was warranted. The panel’s decision thereby

ignored *Therasense*'s admonition that "the atomic bomb" is never appropriate in the absence of "clear and convincing evidence" of intent to deceive. 649 F.3d at 1287.

There is every reason to fear that the panel's decision will lead to a major uptick in inequitable conduct counterclaims. Obtaining clear-and-convincing evidence of a specific intent to deceive has always been the most difficult part of proving an inequitable conduct claim. The panel decision provides counsel with clear guidance for avoiding that evidentiary burden: focus on discovery disputes (ubiquitous in patent litigation) and other alleged misconduct of trial counsel as an alternative method of proof.

REASONS FOR GRANTING THE PETITION

I. THE PANEL'S INEQUITABLE CONDUCT DECISION CONFLICTS WITH *THERASENSE AND STAR SCIENTIFIC*

This Court's case law could not be clearer that the interest in preserving property rights requires that inequitable-conduct determinations be reserved for instances in which the proponents have met exacting evidentiary standards:

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. ... As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with *clear and convincing evidence* before exercising its discretion on whether to render a patent unenforceable.

Star Scientific, 537 F.3d at 1365-66.

As the panel readily concedes, the district court never conducted an evidentiary hearing on whether Regeneron intended to deceive the PTO. Slip op. 21. Rather, the district court’s finding of intent to deceive—a finding that led directly to entry of judgment against Regeneron—was premised entirely on its holding that discovery abuses by Regeneron’s trial counsel warranted imposition of a sanction consisting of an irrebutable “adverse inference” of specific intent to deceive the PTO. *Id.* at 21-38. The panel held that the district court did not abuse its discretion by drawing that inference. *Id.* at 38. That holding cannot be reconciled with *Star Scientific*’s and *Therasense*’s requirement that evidence of deceptive intent be demonstrated by “clear and convincing evidence.”

The panel sought to justify its departure from the “clear and convincing evidence” mandate by relying on Second Circuit case law regarding the propriety of discovery sanctions. Slip op. 35-36 (citing *Residential Funding Corp. v. DeGeorge Funding Corp.*, 306 F.3d 99 (2d Cir. 2002)). That reliance was wholly misplaced. *Residential* addressed permissible sanctions when a party’s action causes evidence to be “unavailable” for trial—either because the evidence was destroyed or because (as in *Residential*) the trial occurred yet counsel did not produce the evidence. 306 F.3d at 108. Neither of those circumstances is alleged here. The district court held that

Regeneron's discovery abuses delayed production of relevant documents. At most, the delayed production required discovery to be re-opened and could have delayed the start of the second trial on "intent to deceive."

More importantly, even assuming discovery sanctions were appropriate, nothing in *Residential* supports entry of a sanction of the sort imposed by the district court. The "adverse inference" drawn by the district court was not merely (as in *Residential*) that unavailable documents would have supported the other party's claims. Rather, the adverse-inference sanction consisted of an irrebutable presumption that Regeneron acted with intent to deceive, followed immediately by a judgment declaring the '018 patent unenforceable. Regeneron was not permitted an opportunity to submit contrary evidence. Nothing in Second Circuit case law (and certainly not in *Therasense*) supports "adverse inferences" of that nature.

Nor was the district court's materiality finding sufficient by itself to justify an invalidity finding. The finding that the four withheld references were but-for material was premised on the understanding that, for inequitable-conduct purposes, the claims of the '018 patent should be given "their broadest reasonable construction." Slip op. 6 n.2. In connection with any ruling on Merus's assertion that those claims were not patentable, the claims would be subject to a much narrower construction. Indeed, as Judge Newman noted in her dissent, the district court never addressed Merus's

assertion that the '018 patent was invalid in light of the withheld references. Dissent at 10.

The most significant discovery abuse identified by the district court was the improper assertion of privilege for documents involving two Regeneron witnesses. 144 F. Supp. 3d 530, 594 (S.D.N.Y. 2015). The court concluded that *if* those two witnesses were permitted to testify at the second trial, then “fairness” would require re-opening discovery regarding the documents in question. *Ibid.* It further concluded that the additional discovery “would consume substantial time and costs.” *Id.* at 595. “Time and costs” were the *sole* reasons cited by the court as its basis for drawing an adverse inference that effectively invalidated the '018 patent: “At this point in the litigation, this is not a fair burden for Merus or this Court.” *Ibid.*

Neither the district court nor the panel cited any precedent for imposing such a grossly disproportionate penalty. The panel asserted that “Regeneron’s litigation misconduct obfuscated its prosecution misconduct.” Slip op. 37. But it failed to explain why far lesser penalties—*e.g.*, fee shifting or excluding testimony of the witnesses who necessitated the re-opening of discovery—would not suffice. Patent litigation is always expensive and time-consuming. The pre-*Therasense* history of inequitable-conduct litigation demonstrated that district courts were repeatedly tempted to make inequitable-conduct findings to avoid being forced to devote

resources to much more complex and time-consuming infringement and validity issues. The panel is encouraging similar corner-cutting by upholding an unenforceability judgment entered by a district judge who openly stated that she acted to avoid an “[un]fair burden” on the court’s resources. Rehearing is warranted to review this clear deviation from *Therasense*.²

II. INEQUITABLE CONDUCT CLAIMS ARE LIKELY TO PROLIFERATE AS A RESULT OF THE PANEL DECISION

Therasense accomplished its purpose of reducing the prevalence of inequitable-conduct counterclaims in patent-infringement litigation. But the history of the inequitable-conduct doctrine demonstrates that virtually all defendants will assert an inequitable-conduct counterclaim if it has *any* plausible chance of succeeding. The panel decision provides that plausible chance to virtually all accused infringers. It allows them to circumvent the high evidentiary barriers imposed by *Therasense* by pointing to evidence of litigation misconduct, even when the misconduct occurs years after issuance of the patent and thus is irrelevant to the materiality and intent-to-deceive issues. *Therasense* catalogued all the reasons why the inequitable-conduct

² The district court also entered an unenforceability judgment for Merus without ever addressing whether Regeneron’s inequitable conduct was sufficiently egregious to warrant such a judgment. But, of course, the district court lacked any basis for deciding that issue because it never conducted an evidentiary hearing on intent to deceive.

plague was harmful to the patent system; rehearing is warranted to prevent a recurrence of that plague.

An unenforceability judgment imposes a penalty against a patent holder that reverberates far beyond the confines of the dispute between the parties. It deprives a patent holder of all power to enforce its property rights, not only with respect to the alleged infringer but also the rest of the world; and it renders unenforceable patent claims that were wholly unrelated to the alleged inequitable conduct. For those reasons, this Court has held that litigation misconduct—even blatant fraud on a court—cannot serve as a basis for declaring an otherwise-valid patent unenforceable with respect to infringement claims not before the court. *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001).

The panel's efforts to distinguish *Aptix*, slip op. 37-38, are unavailing. The panel noted that in *Aptix* the district court's inequitable-conduct analysis arose in the context of claims focusing solely on conduct occurring during litigation, not on claims of misconduct before the PTO. But the facts of that case could easily have lent themselves to the latter type of claim: the patent holder was found to have fabricated documents in the district court to cover up the fact that it had failed to bring prior art to the attention of the PTO. 269 F.3d at 1372-73. The panel decision will permit accused infringers to avoid *Aptix* by asserting any non-frivolous inequitable-conduct

counterclaim and then alleging litigation misconduct as a means of avoiding *Therasense*.

Therasense chronicles at length the reasons why too-frequent invocation of the inequitable-conduct doctrine is bad for the patent system and unfair to patent holders. In this case, it has led to imposition of draconian penalties on Regeneron despite the absence of an evidentiary hearing on intent to deceive the PTO. It besmirches the reputations of those who prosecuted the '018 patent before the PTO. The district court's inequitable-conduct judgment was particularly harsh because it rendered all 20 claims of the '018 patent unenforceable, even though: (1) the court's materiality analysis was limited to Claims 1 through 5, and thus the court never determined that the four withheld references were material to Claims 6 through 20; and (2) Regeneron never asserted that Merus infringed Claims 3 through 5, and thus it never sought to include those now-unenforceable claims as part of its lawsuit. *See* 144 F. Supp. 3d at 563-64 & n.26; Joint Stipulation and Order of Invalidity and Non-Infringement, ¶ 4 (Dkt. #271, Feb. 24, 2015). Rehearing is warranted to prevent the inequitable-conduct doctrine from once again becoming a ubiquitous and unfair staple of infringement lawsuits.

CONCLUSION

WLF requests that the petition for rehearing *en banc* be granted.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. In compliance with Federal Circuit Rules 35(g) and 40(g), the brief does not exceed 10 pages.

/s/ Richard A. Samp
Richard A. Samp

Dated: September 26, 2017

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 26th day of September, 2017, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp