

No. 2016-1346

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

REGENERON PHARMACEUTICALS, INC.,

Appellant,

v.

MERUS N.V.,

Appellee.

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 FOR DAVID C. HRICIK AND MICHAEL E. MCCABE, JR.
AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT'S COMBINED
PETITION FOR PANEL REHEARING AND/OR REHEARING EN BANC**

Michael E. McCabe, Jr.
McCabe Law LLC
6701 Democracy Blvd. – Suite 300
Bethesda, MD 20817
Tel.: (301) 968-0546
Fax: (888) 522-6855
mike@ipethicslaw.com

David C. Hricik
Professor of Law
Mercer University School of Law
1021 Georgia Ave.
Macon, GA 31207
david@hricik.com

Counsel for Amicus Curiae

September 26, 2017

CERTIFICATE OF INTEREST

Counsel for *amicus curiae*, Professor David C. Hricik and Michael E.

McCabe, Jr., hereby certifies as follows:

1. The full names of every party or amicus represented by me are:

Professor David C. Hricik and Michael E. McCabe, Jr.

2. The real party in interest is: **None.**

3. Parent corporations and publicly held companies that own 10% or more of the stock of the parties are represent is as follows: **None.**

4. The names of all law firms and the partners or associates that appeared for the parties now represented by me in the trial court or that are expected to appear in this court are: **None.**

Dated: September 26, 2017

/s/ Michael E. McCabe, Jr.
Michael E. McCabe, Jr.

TABLE OF CONTENTS

INTEREST OF THE AMICUS CURIAE1

ARGUMENT2

1. *Therasense* Curtailed Inequitable Conduct Because it Distracted from the Merits of Validity and Infringement, Ruined Reputations, Caused Conflicts of Interest, and Permitted Wasteful Litigation Tactics.2

2. A Court Can Decide Many Elements of Inequitable Conduct Often Only After Determining the Broadest Reasonable Construction.4

3. Relying on the Misconduct of a Party’s Trial Counsel to Impose Irrebuttable Presumptions Contradicts Controlling Authority.....6

4. The Panel-Majority’s Decision is Unjust and Will Increase the Very Wasteful Incentives *Therasense* Sought to Eliminate.....7

CONCLUSION9

TABLE OF AUTHORITIES

Cases

Aptix Corp. v. Quickturn Design Systems, Inc.,
269 F.3d 1369 (Fed. Cir. 2001)6, 7

Regeneron Pharm., Inc. v. Merus N.V.,
864 F.3d 1343 (Fed. Cir. 2017) 5, 6, 7, 8

In re Ruffalo,
390 U.S. 544 (1968)8

In re Tandler, Proc. No. D2013-17,
1399 O.G. 43 (USPTO Dir. Jan. 8, 2014)3

Therasense, Inc. v. Becton, Dickinson & Co.,
649 F.3d 1276, 1288 (Fed. Cir. 2011)2, 4

Statutes

37 C.F.R. § 1.563

37 C.F.R. § 11.183

37 C.F.R. § 11.19(a).....3

37 C.F.R. § 11.22(a).....3

37 C.F.R. § 11.106(b)(5).....8

77 Fed. Reg. 457 (Jan. 5, 2012)3

INTEREST OF THE AMICUS CURIAE¹

The authors of this brief are engaged in the practice of law at the intersection of ethics and patents. David Hricik is a professor at Mercer University School of Law, where he teaches legal ethics, patent law and litigation, federal civil procedure, and other courses. Professor Hricik has authored the only treatise on ethical issues in patent litigation, and co-authored the only treatise on ethical issues in patent prosecution. In addition to serving leadership positions on ethics committees with the AIPLA and ABA and serving as an expert witness in legal malpractice and OED disciplinary matters, Professor Hricik has written dozens of articles and given well over 100 presentations on the subject of ethics issues arising in the practice of intellectual property law. His articles and testimony have been adopted by both state and federal courts.

Michael E. McCabe, Jr. is a registered patent attorney with 20 years of experience in the private practice of intellectual property law. Mr. McCabe's practice focuses on the representation of patent attorneys, patent agents, and trademark attorneys who are the subject of ethics investigations by the OED and

¹ No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *amici*, their members, or counsel contributed money intended to fund preparing or submitting the brief. Fed. R. App. P. 29(c)(5). Counsel for Appellant Regeneron has consented to the filing of this brief. Counsel for Appellee Merus N.V. declined to consent. A motion for leave to file is being filed with this brief.

professional disciplinary proceedings before the USPTO. Mr. McCabe is a frequent lecturer on issues relating to ethics in the practice of patent law, and he writes extensively on the subject of intellectual property ethics as founder of the legal blog *IPethics & INsights*.

ARGUMENT

1. *Therasense* Curtailed Inequitable Conduct Because it Distracted from the Merits of Validity and Infringement, Ruined Reputations, Caused Conflicts of Interest, and Permitted Wasteful Litigation Tactics.

Therasense recognized that prior expansive views of inequitable conduct had allowed asserting it to become a “significant litigation strategy.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc). Among other things, the charge “conveniently expand[ed] discovery into corporate practices before patent filing,” led to increased attorney disqualification, and, because inequitable conduct “focuses on the moral turpitude” of the inventor or patent attorney, it had “ruinous consequences” to reputations. *Id.* (noting additional unintended consequences). This Court understood it had been allowing reputational damage to occur too easily.

In addition, the USPTO’s Office of Enrollment and Discipline (“OED”) investigates judicial determinations of practitioner misconduct, including inequitable conduct, brought to its attention. *See* 37 C.F.R. §§ 11.19(a), 11.22(a). When the OED investigates, practitioners invariably must pay counsel to defend

them. Furthermore, OED investigations disrupt a practitioner's practice and often produce feelings of apprehension and fear in the target of the government's inquiry. *See* 77 Fed. Reg. 457, 458 (Jan. 5, 2012) (OED investigation "typically triggers anxiety for the practitioner, may interfere with the practitioner's practice, and may cause the practitioner to incur legal expenses in responding to investigative inquiries by OED.") Even if a court *rejects* an assertion of inequitable conduct, its fact-findings still can be grounds for an OED investigation, since a violation of the broader duty of candor imposed on practitioners by the USPTO in 37 C.F.R. 1.56, can violate the USPTO's Rules of Professional Conduct. *See* 37 C.F.R. 11.18 (prohibiting knowingly and willfully making certain representations to the USPTO). Further, the OED has used findings from patent litigation against practitioners in subsequent disciplinary proceedings – even though the practitioner had not been a party to the prior suit. *See, e.g., In re Tendler*, Proc. No. D2013-17, 1399 O.G. 43 (USPTO Dir. Jan. 8, 2014) (imposing 4-year suspension on patent attorney based on court's findings and conclusions concerning inequitable conduct).

Therasense sought to reduce these wasteful consequences by requiring clear and convincing proof focused on individuals involved in prosecution. The Court required proof of four *distinct* threshold elements: (1) preponderant evidence a withheld reference was but-for material to the broadest reasonable interpretation of a claim; (2) clear and convincing evidence a person substantively involved in

prosecution had known of that reference; (3) clear and convincing evidence that same person had known the reference had been material; (4) clear and convincing evidence the single most reasonable inference is that person withheld the reference intending to deceive the USPTO. 649 F.3d at 1290-92. Only after proof of all four elements concerning a single individual should a court balance the equities. *Id.* at 1295-96.

Therasense also strictly cabined using adverse inferences. It prohibited inferring that, because a reference is now deemed material, a person must have known it had been material, or must have withheld it with deceptively. *Id.* at 1290. We return to inferences below.

2. A Court Can Decide Many Elements of Inequitable Conduct Often Only After Determining the Broadest Reasonable Construction.

Therasense requires a hindsight reconstruction: if an examiner had given the claim the meaning ascribed by a district court *now* and if the examiner had known of a reference *then*, would he have rejected a claim? And, if so, is there clear and convincing evidence the person accused of inequitable conduct would have known that?

As a consequence, differences between a court's post-hoc interpretation of a claim and the subjective (though reasonable and good faith) understanding of that claim held by an inventor or prosecuting attorney during prosecution can be critical

to understanding whether a person with a duty of disclosure had known a reference had been material, or had acted with deceptive intent. “I didn’t think the claim could be read that broadly, and so I did not disclose that reference” may be the simple truth—and, if credible, would defeat a charge of inequitable conduct.

In line with this, here the court had intended to first receive disputed expert testimony on both claim interpretation and the disclosure of the withheld references. *Regeneron Pharm, Inc. v. Merus N.V.*, 864 F.3d 1343, 1346 (Fed. Cir. 2017). After that, the court had intended to hear inventor and patent practitioner testimony concerning knowledge and intent. *Id.*

Rather than proceeding to a second phase, however, the court announced the phase was unnecessary because litigation misconduct required inferring (a) that two of the individuals who owed a duty of disclosure (one attorney and one inventor) had each known each reference was material, and (b) that the single most reasonable inference was each man had deliberately withheld each reference with deceptive intent. Most importantly, the same order made those inferences irrebuttable by precluding each man, and an outside patent attorney who was involved in prosecuting the application, from testifying. Months later, the court issued a more detailed opinion stating each man had engaged in various acts of deception and “affirmative egregious misconduct” had occurred. *See Regeneron*, 864 F.3d at 1347.

3. Relying on the Misconduct of a Party's Trial Counsel to Impose Irrebuttable Presumptions Contradicts Controlling Authority.

We believe the panel-majority's holding is inconsistent with *Therasense*, which requires that unenforceability turn on the moral culpability of those involved in prosecution and so be based on their knowledge conduct and that reasonable inferences likewise be based on their knowledge and conduct. We also believe this decision significantly undermines *Therasense*'s requirements that knowledge and intent be established separately from materiality. Here, the court found materiality but precluded testimony as to the knowledge and intent of those with a duty of disclosure based on litigation misconduct.

We also believe the decision contradicts *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) and the Supreme Court precedent it relies upon. In *Aptix*, the inventor sought to avoid invalidity by establishing an earlier reduction to practice by submitting forged lab notebooks to a district court. The panel affirmed dismissal of the suit for unclean hands – and perhaps that would have been appropriate here -- but recognized “[n]o case law from the Supreme Court or this court provides a basis for nullifying property rights granted by the United States when such property rights did not themselves accrue through inequitable conduct.” *Id.* at 1377. Even though *Aptix* pre-dated *Therasense*, the panel recognized litigation misconduct “does not infect, or even affect, the original grant of the property right.” *Id.* at 1375.

4. The Panel-Majority's Decision is Unjust and Will Increase the Very Wasteful Incentives *Therasense* Sought to Eliminate.

First, accusations harming reputations will increase, and trial lawyers, practitioners, and inventors will be the targets. Here, the opinions of the district court and panel majority include disparaging statements about practitioners and an inventor. And because of misconduct by litigation counsel, the practitioners and inventor were precluded from defending themselves.

Significantly, the court made various misconduct findings which were not addressed by the panel-majority, but which it did not vacate. *See* 864 F.3d at 1359-63. In a disciplinary proceeding against the practitioners, the OED could attempt to use such findings. This is particularly troubling because USPTO disciplinary proceedings are quasi-criminal in nature. *See In re Ruffalo*, 390 U.S. 544 (1968).

Second, precluding testimony will cause practitioners accused of inequitable conduct to have increased conflicts of interest with their current or former clients. Prior to this panel decision, a practitioner accused of inequitable conduct could explain his conduct, under oath, to the judge. Prior to this panel decision, a practitioner could rest assured that a court would not infer adverse knowledge and intent. But now, the district court found, and the panel-majority affirmed, that misrepresentations and deceptions had occurred during prosecution without ever having heard testimony from the men it found guilty of such conduct.

The interests of a patent practitioner accused of inequitable conduct by the USPTO or an accused infringer may differ from those of the patentee in infringement litigation. For example, a narrow claim construction may avoid materiality, and so insulate a practitioner from inequitable conduct, but that construction may not support infringement. Given that the panel-majority allows district courts to tie the patent practitioner's intent during prosecution to litigation counsel's conduct in later litigation, one can envision patent practitioners intervening in cases to avoid asserting an interpretation of a claim in litigation that is broader than what the practitioner had thought it was, to avoid having the claim cover information that the practitioner knew of, but did not disclose.

Further in that regard, the panel-majority's decision increases conflicts by increasing the likelihood that practitioners will need to disclose confidential information in self-defense. *See e.g.*, 37 C.F.R. 11.106(b)(5). Prior to the panel-majority decision, a practitioner could wait until after the district court had construed the claims to reveal information to defend himself. After the panel decision, however, a practitioner aware that a patent is being construed differently in litigation than he had believed during prosecution may need to more quickly disclose client confidential information.

CONCLUSION

For the reasons stated, the Court should grant Regeneron's Petition.

Respectfully submitted,

/s/ Michael E. McCabe, Jr.
Michael E. McCabe, Jr.
McCabe Law LLC
6701 Democracy Blvd., Suite 300
Bethesda, Maryland 20817
(301) 538-1110
mike@ipethicslaw.com

Dated: September 26, 2017

Counsel for *amicus curiae*
Professor David C. Hricik and
Michael E. McCabe, Jr.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 26th day of September, 2017, I electronically filed the Brief for Professor David C. Hricik and Michael E. McCabe, Jr. as *Amicus Curiae* in Support of Appellant's Combined Petition for Panel Rehearing and/or Rehearing En Banc, 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/ Michael E. McCabe, Jr.
Michael E. McCabe, Jr.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 40(g).

X The brief contains 2543 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6)

X The brief has been prepared in a proportionally spaced typeface using MS Word 2013 in a 14 point Times New Roman font or

 The brief has been prepared in a monospaced typeface using in a characters per inch font.

September 26, 2017

/s/ Michael E. McCabe, Jr.
Michael E. McCabe, Jr.
Counsel for Amicus Curiae