No. 2016-1346

In the United States Court of Appeals for the Federal Circuit

REGENERON PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

MERUS N.V.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of New York, Case No. 1:14-cv-01650-KBF.
The Honorable **Katherine B. Forrest**, Judge Presiding.

BRIEF OF *AMICUS CURIAE* SEVEN CHICAGO PATENT LAWYERS IN SUPPORT OF APPELLANT'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for the *Amicus Curiae*, Seven Chicago Patent Lawyers, certifies the following:

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

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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:

None.

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 or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or in a prior proceeding in this case or are expected to appear in this Court are:

Kevin E. Noonan; Jeremy E. Noe; Andrew W. Williams; Jeffery P. Armstrong; Donald L. Zuhn, Jr.; James L. Lovsin; and Aaron V. Gin, McDonnell Boehnen Hulbert & Berghoff LLP

February 23, 2016

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INTEREST OF *AMICUS CURIAE*[1]

The *amicus curiae* is a group of patent practitioners who prosecute and litigate U.S. patents and thus are concerned with preserving the integrity of the legal system that secures innovation to its creators and to the companies that commercialize such innovation in the marketplace. The *amicus curiae* believes that the district court erred in applying this Court's inequitable conduct jurisprudence as set forth in *Therasense v. Becton Dickinson* and that the panel opinion did not rectify this error. The district court improperly prevented the patent practitioners involved in prosecuting the patent-at-issue from presenting evidence contrary to an intent to deceive the U.S. Patent and Trademark Office ("USPTO"), and instead drew an adverse inference of such intent. The *amicus curiae* believes that, if permitted to stand, this misapplication of this Court's *Therasense* jurisprudence could negatively affect every patent practitioner and seriously and negatively affect the course of patent prosecution. The *amicus curiae* urges the Court to reconsider the decision *en banc* and to vacate the district court's determination and remand for reconsideration of evidence related to specific intent to withhold information material to patentability. The *amicus*

[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 *amicus* or counsel for *amicus* contributed money intended to fund preparing or submitting the brief. Fed. R. App. P. 29(a)(4).

curiae has no stake in the parties or in the outcome of this case but is deeply invested in having courts apply the law of inequitable conduct correctly and fairly.

Amicus curiae submitted an *amicus* brief at the merits stage arguing that the Court should vacate the district court's judgment and remand for a trial on intent to deceive. *Regeneron Pharm. v. Merus N.V.*, No. 2016-1346 (Fed. Cir.) ECF No. 44. The Court granted *amicus curiae* leave to file the brief over Merus' objection. ECF No. 42; *see also* ECF No. 35, 38, 39.[2]

REASONS FOR GRANTING REHEARING *EN BANC*

I. The Panel's Decision Impermissibly Allows a Finding of Inequitable Conduct without a Finding of Specific Intent to Deceive in Contravention of *Therasense*

The panel's split decision to affirm the district court's use of an adverse inference based on trial counsel conduct to substitute for evidence that Regeneron's patent prosecution counsel withheld material prior art with a specific intent to deceive the USPTO is contrary to inequitable conduct jurisprudence articulated by this Court in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). If undisturbed, and other courts were to follow the district court's reasoning in *Regeneron*, every prosecution counsel's reputation could be besmirched and their livelihood harmed by the stain of inequitable

[2] Written consent to the filing of this brief has been granted by Appellant's counsel. At the time of filing, Appellee's counsel had not provided consent to the filing of this brief.

conduct based on third party actions not committed during patent prosecution. This outcome contravenes the underlying rationale for the inequitable conduct doctrine. *Therasense*, 649 F.3d at 1292.

In *Therasense*, this Court, sitting *en banc*, clarified the inequitable conduct standard. *Id.* at 1287. In reining in inequitable conduct allegations often brought on the "slenderest grounds," *Therasense* rejected use of a "sliding scale" for holding patents unenforceable wherein a strong showing of materiality could compensate for weak evidence of intent. *Id.* at 1290. Instead, "[t]he court in *Therasense* sought to impart objectivity to the law of inequitable conduct by requiring that 'the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.'" *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 522 (Fed. Cir. 2012) (quoting *Therasense*, 649 F.3d at 1290). Under *Therasense*, deceptive intent should be inferred from circumstantial evidence only when it is "***the single most reasonable inference able to be drawn from the evidence*** to meet the clear and convincing standard." *Rosuvastatin*, 703 F.3d at 520 (quoting *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)) (emphasis added).

Against this clear precedent, the panel's split decision affirmed the district court's inequitable conduct determination based on no evidence whatsoever of intent to deceive the Patent Office. Counter to *Therasense*, the district court's

conclusion was not based on the testimony, facts, and circumstances surrounding patent prosecution counsel's failure to submit prior art to the USPTO during prosecution. Rather, the district court reasoned that "[i]n recognition of the implications ***the discovery conduct*** [by trial counsel] has on the entirety of the case, it is additionally appropriate for the Court to impose the sanction of ***an adverse inference as to the intent of [patent prosecution counsel] with regard to inequitable conduct during patent prosecution***," without considering any evidence relating to patent prosecution counsels' intent. *Regeneron*, 144 F. Supp. 3d at 595 (emphasis added).

The panel affirmed the district court's imposition of an adverse inference on intent, rather than properly applying this Court's *Therasense* precedent. Litigation conduct, which necessarily occurs after prosecution has closed and stems from actions of trial counsel, not prosecution counsel, is wholly unrelated to deceptive intent in failing to submit prior art to the USPTO during prosecution. The panel's affirmance effectively ignores the *Therasense* mandate that a court make a determination whether specific intent to deceive the USPTO is the single most reasonable inference able to be drawn from all of the testimony, facts, and evidence. The panel also affirmed the district court's precluding testimony of the two patent prosecutors and one of the inventors regarding their intent. *Regeneron*, 144 F. Supp. 3d at 595. This was error.

The purpose of an adverse inference in civil cases is equitable, not punitive, and should vitiate prejudice to the party denied discovery. *United States v. Certain Real Prop. & Premises Known as 4003-4005 5th Ave., Brooklyn, N.Y.*, 55 F.3d 78, 84-85 (2d Cir. 1995); *see also Kronisch v. U.S.*, 150 F.3d 112, 126 (2d Cir. 1998). That is not the case here: instead, the district court's finding of an adverse inference of specific intent to deceive was not used as a substitute for information that was prejudicially unavailable, but was imposed as a penalty for litigation misconduct. *Regeneron*, 144 F. Supp. 3d at 595. Even if litigation misconduct merited sanction, the remedy was not an adverse inference, but rather should have been sanctioned under the district court's inherent powers pursuant to Fed. R. Civ. P. 26(g)(3) and 37(b)(2)(A), 28 U.S.C. § 1927, and/or 35 U.S.C. § 285. Punishment for litigation misconduct should not fall upon prosecuting attorneys guiltless of the sanctioned misconduct.

The panel majority focused solely on misconduct by litigation counsel. Such conduct cannot substitute for evidence that patent prosecution counsel had intent to deceive the USPTO by failing to cite references the district court (after the fact) determined were material to patentability. If district courts can ignore the express framework set out by this Court in *Therasense*, all patent prosecutors throughout the United States are at risk. If blameless prosecution counsel can be subject to inequitable conduct sanctions due to litigation counsel misconduct, at

best prosecutors will have their reputations tarnished. More seriously, prosecutors could be subject to disciplinary proceedings at the USPTO, and perhaps before their state bar, all based on others' actions.

The panel decision sanctions the district court's misapplication of the *Therasense* legal framework established by this Court *en banc* by making no finding of specific intent of prosecution counsel to deceive the USPTO in this case. The panel majority justified the district court's decision because Regeneron's patent counsel was also ***accused*** "of engaging in inequitable conduct *during* prosecution." However, as Judge Newman correctly pointed out in dissent, "[o]ur system of justice is bottomed upon proof, not upon bare accusation." *Regeneron Pharm., Inc. v. Merus N.V.*, 864 F.3d 1343, 1366 (Fed. Cir. 2017) (Newman, J., dissenting). If mere allegations of misconduct are sufficient to result in an inequitable conduct finding, unsupported enforceability claims will once again be found in every complaint. This Court should grant Regeneron's petition for rehearing *en banc* in order to avoid resurrection of this plague on the patent system.[3]

The *Regeneron* panel overlooked the clear mandate of the *Therasense* Court

[3] The panel majority stated that it was not ***punishing*** Regeneron's "litigation misconduct by holding the patent unenforceable." Regeneron, 864 F.3d at 1364. Whether true or not, the lower court did punish the prosecuting attorneys – without any opportunity for them to rebut Merus' allegations that they had intent to deceive the USPTO.

that inequitable conduct should only be found when specific intent to deceive the USPTO is established. This conclusion, at odds with binding precedent, is itself sufficient justification for this Court to review the panel decision *en banc*, and *amicus curiae* urges the Court to so decide.

II. The District Court Proceedings Violated Procedural Due Process by Failing to Provide Regeneron a Sufficient Opportunity to be Heard Regarding Specific Intent to Deceive the United States Patent and Trademark Office

This Court considers various factors when weighing *en banc* rehearing, including "involvement of a question of exceptional importance." Fed. Cir. R. IOP 13. *Amicus* asserts that this case raises an important Constitutional issue: whether a district court's imposition of an adverse inference sanction, which bypassed proceedings on specific intent to deceive the USPTO for inequitable conduct, violated the procedural due process protections of the Constitution.[4] Such a determination warrants rehearing *en banc*.

Procedural due process is not "a technical conception with a fixed content unrelated to time, place and circumstances." *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976). Instead, procedural due process inquiries must be "flexible" and applicable protections should be based on the demands of a given situation. *Id.*

[4] "No person shall be . . . . deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

Three distinct factors are weighed: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and (3) the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. *Id.* at 335.

To illustrate, in proceedings involving lawyer disbarment, the Supreme Court has held that subjects are entitled to procedural due process protections. *See, e.g., In re Ruffalo*, 390 U.S. 544, 550 (1968); *In re Oliver*, 333 U.S. 257, 273 (1948). Several circuit courts have applied specific protections of notice and an opportunity to be heard in attorney discipline cases. *See, e.g., In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 278 F.3d 175, 191 (3d Cir. 2002); *Dailey v. Vought Aircraft Co.*, 141 F.3d 224, 229 (5th Cir. 1998).

Because admission to the bar is an absolute prerequisite for the practice of law, even temporary disbarment can be detrimental to an attorney's professional reputation, well-being, and success. *Dailey*, 141 F.3d at 228. Clearly, any disbarment on an attorney's record may lead to "serious adverse career consequences." *Id.*

For patent prosecutors, which include *amicus curiae*, an inequitable conduct finding mirrors the consequences of disbarment and can be as damaging as

disbarment for any attorney. Because the inequitable conduct doctrine focuses on "moral turpitude" by the patentee, any such finding may work "ruinous consequences for the reputation of his patent attorney." *Therasense*, 649 F.3d at 1288. For example, one study of patent attorneys involved in severe cases of inequitable conduct showed that most withdraw from the profession altogether.[5] Even for those who remain in the field, multi-year suspensions from practicing before the USPTO are a common consequence of inequitable conduct. *Id.* Accordingly, *amicus* contends that Constitutional procedural due process protections apply to proceedings involving inequitable conduct.

In weighing inequitable conduct, a district court may infer intent from indirect and circumstantial evidence. *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). However, binding precedent of this Court requires that a specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." *Therasense*, 649 F.3d at 1290. Furthermore, the evidence must be sufficient to require a finding of deceitful intent in light of all circumstances. *Id.*

Under the framework of *Therasense* and Fifth Amendment procedural due process, district courts should be obliged to provide patentees and their

[5] Edwin S. Flores, Ph.D. & Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent and Trademark Office*, 8 Tex. Intell. Prop. L.J. 299, 322 (2000).

practitioners with an opportunity to be heard on the issue of the specific intent to deceive. *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 828 (Fed. Cir. 2010). In particular, the district court should take into account any evidence that may weigh against a finding of deceptive intent. *Larson*, 559 F.3d at 1341.

This Court already affords patentees and patent practitioners some due process protections when facing allegations of inequitable conduct. For example, in *Dickson Indus., Inc. v. Patent Enf't Team, L.L.C.*, this Court vacated a district court judgment on the issue of inequitable conduct and remanded "in order to create a complete record and provide [patentee] an opportunity to defend against [the] allegation of inequitable conduct." 333 F. App'x 514, 520 (Fed. Cir. 2009).

Amicus submits that *Dickson* applies here. The district court conducted a bifurcated trial on the issue of inequitable conduct, with the rationale that "[materiality] would be addressed by the experts and through documents, and [determining Regeneron's intent] (which involved testimony from Drs. Smeland and Murphy) was only necessary if the Court determined the first issue in Merus's favor." *Regeneron*, 144 F. Supp. 3d at 595.

After making its materiality determination, but before determining whether Regeneron's patent prosecution counsel had intent to deceive, the district court imposed an adverse inference as to that intent based on "implications the discovery

[*i.e.*, litigation] conduct has on the entirety of the case." *Id*. In doing so, the district court struck several trial affidavits and precluded substantial trial testimony from the patent prosecutors. *Id.* No hearing on Regeneron's intent was ever conducted. *Regeneron*, 864 F.3d at 1347. As in *Dickson*, the district court worked prejudice on the patentee – and its two patent prosecutors – by denying them the opportunity to adequately defend against the allegation of inequitable conduct.

Regardless of Regeneron's purported litigation misconduct, the district court's decision to infer intent to deceive, affirmed by a divided panel, deprived patentee and her counsel of procedural due process under the Fifth Amendment. Regeneron had no opportunity to be heard on the issue of intent to deceive, which is dispositive under *Therasense*.

In view of the constitutional underpinning of the procedural due process rights violated by the district court's decision, an exceptionally important question is clearly implicated. Such grounds warrant *en banc* review by this Court.

CONCLUSION

Amicus respectfully requests that this Court grant Appellant's petition for rehearing *en banc*.

Respectfully Submitted,

September 26, 2017

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CERTIFICATE OF COMPLIANCE

This brief complies with the word count limitation of Fed. Cir. R. 35(g), and contains 2,503 words, exclusive of the portions exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b).

The brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2010 in 14-point Times New Roman type.

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On September 26, 2017, Dr. Noonan authorized me to electronically file the foregoing Brief of *Amicus Curiae* Seven Chicago Patent Lawyers In Support of Appellant's Petition for Rehearing En Banc with the Clerk of the Federal Circuit using the CM/ECF System, which will serve e-mail notice of such filing on the following:

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Eighteen paper copies will be filed with the Court within the time provided in the Court's rules.

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September 26, 2017