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

AMICUS CURIAE BRIEF OF THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF THE PETITION FOR REHEARING EN BANC

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September 26, 2017

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 29 and 47.4, counsel for *amicus curiae* New York Intellectual Property Law Association certifies the following:

1. The full name of the *amicus* I represent: New York Intellectual Property Law Association

2. The name of the real parties in interest I represent: New York Intellectual Property Law Association

3. All parent corporations and any publicly held companies that own 10 percent of more of the stock of the *amicus* I represent: N/A

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

PATTERSON BELKNAP WEBB & TYLER LLP: Aron Fischer

THE RANDO LAW FIRM P.C.: Robert J. Rando

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Dated: September 26, 2017

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I. INTEREST OF AMICUS CURIAE

This *amicus curiae* brief is submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA").[1]

The NYIPLA is a professional association of approximately 1,100 attorneys whose interests and practices lie in the area of patent, trademark, copyright, trade secret, and other intellectual property law. The NYIPLA's members include a diverse array of attorneys specializing in patent law, including in-house counsel for businesses that own, enforce, and challenge patents, as well as attorneys in private practice who prosecute patents and represent entities in various proceedings before the U.S. Patent and Trademark Office ("PTO"). Many of the NYIPLA's member attorneys participate actively in patent litigation, representing both patent owners and accused infringers. The NYIPLA, its members, and the clients of its members share an interest in having the standards governing the enforceability of patents be reasonably clear and predictable.

The arguments set forth in this brief were approved on September 18, 2017 by an absolute majority of the total number of officers and members of the Board of the NYIPLA (including such officers and Board members who did not vote for any reason including recusal), but do not necessarily reflect the views of a

[1] Regeneron Pharmaceuticals, Inc. consents to the filing of the brief but Merus N.V. does not. Pursuant to Federal Circuit Rule 35(g), a motion for leave to file is being submitted with this brief.

majority of the members of the Association or of the firms with which those members are associated.

No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No person other than *amicus curiae*, its members, or its counsel contributed money that was intended to fund preparing or submitting this brief.

After reasonable investigation, the NYIPLA believes that no member of the Board or *Amicus* Committee who voted to prepare this brief on its behalf, or any attorney in the law firm or corporation of such a Board or Committee member, or attorney who aided in preparing this brief, represents either party to this litigation. Some Committee or Board members or attorneys in their respective law firms or corporations may represent entities which have an interest in other matters which may be affected by the outcome of this litigation.

II. THE COURT SHOULD GRANT EN BANC REHEARING TO CLARIFY WHEN LITIGATION MISCONDUCT CAN SUPPORT AN ADVERSE INFERENCE OF PROSECUTION MISCONDUCT

The NYIPLA submits this *amicus curiae* brief in support of Regeneron's Petition for Rehearing En Banc. The NYIPLA takes no position on which party should ultimately prevail in the en banc proceeding. But as a number

of commentators have pointed out,[2] the opinion by the panel majority raises serious questions about the circumstances under which specific intent to deceive the Examiner during ***prosecution*** of a patent can be found based on an adverse inference from ***litigation*** misconduct. This Court should grant rehearing en banc to clarify that an adverse inference based on litigation misconduct can support a finding of inequitable conduct only when the "single most reasonable inference able to be drawn from the evidence" is that the patentee specifically intended to deceive the Examiner during prosecution. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

A. The Panel's Opinion Does Not Make Clear Whether Specific Intent to Deceive the Examiner Was the "Single Most Reasonable Inference" to Draw from Regeneron's Litigation Misconduct

Under this Court's controlling decision in *Therasense*, "[i]nequitable conduct has two separate requirements: materiality and intent." *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1350 (Fed. Cir. 2017). Here, however, the district court below found inequitable conduct without holding a planned bench trial – or any other proceeding – on the question of intent. Instead, "the court sanctioned Regeneron for its litigation misconduct by drawing an

[2] *See, e.g.*, Ryan Davis, *Patent Prosecutors Alarmed By Inequitable Conduct* Ruling, Law360 (Aug. 2, 2017), at https://www.law360.com/articles/950683/patent-prosecutors-alarmed-by-inequitable-conduct-ruling; David Hricik, *Inequitable Conduct and Regeneron Pharmaceuticals, Inc. v. Merus N.V.: Trouble Waiting to Happen*, Patently-O (Aug. 3, 2017), at https://patentlyo.com/hricik/2017/08/inequitable-regeneron-pharmaceuticals.html

adverse inference of specific intent" in an opinion issued after a bench trial that addressed only the question of materiality. *Id.* at 1356; *accord id.* at 1346-47.

In affirming the district court's decision, the panel majority "adopt[ed]" the district court's findings as to Regeneron's litigation misconduct and discussed them at great length. *Id.* at 1356-63. But as Judge Newman pointed out in dissent, Regeneron's litigation misconduct is not, in itself, relevant to the inequitable conduct inquiry. *See id*. at 1366 (Newman, J., dissenting). Indeed, this Court has previously recognized that "[l]itigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, ***or even affect***, the original grant of the property right." *Aptix Corp. v. Quickturn Design Systems, Inc*., 269 F.3d 1369, 1375 (Fed. Cir. 2001) (emphasis added).

At the conclusion of its opinion, the panel acknowledged the principle that "courts may not punish a party's post-prosecution misconduct by declaring the patent unenforceable." *Regeneron*, 864 F.3d at 1364. The panel 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." *Id.* Accordingly, the panel concluded that the district court did

not abuse its discretion in relying on an adverse inference from litigation misconduct. *Id.*

Although the panel's opinion suggests that litigation misconduct must be "directly related" to prosecution misconduct 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 state that specific intent to deceive the PTO was "'***the single most reasonable inference*** able to be drawn from the evidence,'" as is required by *Therasense*. 649 F.3d at 1290 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)) (emphasis added here). In light of the panel's extensive discussion of Regeneron's litigation misconduct, the decision is open to the interpretation that "widespread" litigation misconduct may warrant an adverse inference of specific intent whenever it is "directly related" to patent prosecution, even if the evidence does ***not*** otherwise support an inference of specific intent to deceive the Examiner during prosecution. *See Regeneron*, 864 F.3d at 1364. The Court should grant rehearing to clarify and reaffirm that the "single most reasonable inference" standard applies with full force when a finding of specific intent is based on an adverse inference.

B. This Court Should Clarify That, Whether Based on an Adverse Inference or Otherwise, Specific Intent to Deceive Must Be the "Single Most Reasonable Inference" to Draw from the Record

In *Therasense*, the en banc Court "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine [inequitable conduct] that has been overused to the detriment of the public." 649 F.3d at 1290. 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.'" *Id.* (emphasis in original). When "there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91. "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." *Id.* at 1290. Furthermore, "[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive." *Id.* at 1291.

This Court should grant en banc rehearing to address whether the adverse inference drawn by the district court is consistent with the "tighten[ed]" standards of intent from *Therasense*. Significantly, the district court did not find that Regeneron had spoliated or destroyed evidence. In the proper case, the "single most reasonable" inference to draw from the spoliation or destruction of evidence might be that the unavailable evidence would have established an intent to deceive.

But here, the relevant evidence was available (although improperly withheld), and the district court itself reviewed examples of the improperly withheld documents *in camera*. *Regeneron*, 864 F.3d at 1361-62. Despite the availability of this evidence, neither the panel nor the district court issued a finding that the withheld documents, or any other record evidence considered individually or as a whole, independently supported a finding of specific intent to deceive. Nor did they explain how the withholding of evidence during litigation (however improper) can be capable of meeting this Court's "single most reasonable inference" standard, when the evidence itself is available and has not been found to satisfy the standard independently.

Furthermore, 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, 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." *Id.* at 1363. 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." *Id.* Although these concerns may be legitimate grounds for issuing litigation sanctions against Regeneron – potentially up to and including dismissing its lawsuit against Merus – they do not necessarily support an inference that Regeneron acted with specific intent to deceive the Examiner in the proceedings before the PTO that occurred many years before.

Without further clarification, the panel's decision runs the risk of encouraging excessive inequitable-conduct litigation, which this Court sought to discourage in *Therasense*. 649 F.3d at 1289-90. Although the NYIPLA does not challenge the panel's finding of litigation misconduct here, disputes over the proper scope or waiver of attorney-client privilege are common in inequitable conduct proceedings, which often 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 panel's opinion invites satellite litigation as to whether disagreements over privilege should lead to an adverse inference of intent. Clarifying that any such inference must be narrowly focused on the patentee's intent during prosecution, and should not be based on litigation-specific concerns such as procedural fairness to the litigants or the proper use of judicial resources, would encourage litigants and courts to focus on the issues that are germane to the inequitable conduct inquiry.

CONCLUSION

For the reasons set forth above, this Court should order rehearing en banc to clarify that, whether or not an adverse inference is drawn, a finding of inequitable conduct is appropriate only when "the single most reasonable inference able to be drawn from the evidence" is that the patentee specifically intended to deceive the Examiner during prosecution. *Therasense,* 649 F.3d at 1290.

Dated: September 26, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), this brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 32(a) and 29(b)(4) and of Federal Circuit Rule 35(g). The brief contains 1,883 words, according to the word processing system used in preparing it, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman font.

Dated: September 26, 2017

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United States Court of Appeals
for the Federal Circuit

REGENERON PHARMACEUTICALS, INC. v. MERUS N.V., 2016-1346

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

On **September 26, 2017**, Counsel for *Amicus Curiae* has authorized me to electronically file the foregoing **Amicus Curiae Brief of The New York Intellectual Property Law Association in Support of the Petition for Rehearing En Banc** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing all counsel registered as CM/ECF users including the following principal counsel:

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Any counsel for Amicus Curiae who are registered users, at the time of filing, will also be served via e-mail notice from the Clerk of Court via the CM/ECF System.

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

September 26, 2017

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