UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2016-1346

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 in case no. 1:14-cv-01650 KBF, Judge Katherine B. Forrest

BRIEF OF *AMICUS CURIAE*

THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO IN SUPPORT OF REHEARING EN BANC

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Not All Parties Have Consented To The Filing of This Brief

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Counsel for Amicus Curiae The

Intellectual Property Law Association of Chicago certifies the following:

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

The Intellectual Property Law Association of Chicago

- 2. IPLAC has no interest in the outcome of the case as between the parties.
- 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 are expected to appear in this court are:

Law firms Husch Blackwell LLP, and

Williams Montgomery & John, Ltd.

Banner & Witcoff, Ltd.

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September 26, 2017

/s/ Edward D. Manzo
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STATEMENT OF INTEREST¹

Founded in 1884, the Intellectual Property Law Association of Chicago is the country's oldest bar association devoted exclusively to intellectual property matters. Located in Chicago, a principal locus and forum for the nation's authors, artists, inventors, scholarly pursuits, arts, creativity, research and development, innovation, patenting, and patent litigation, IPLAC is a voluntary bar association of over 1,000 members with interests in the areas of patents, trademarks, copyrights, and trade secrets, and the legal issues they present. Its members include attorneys in private and corporate practices before federal bars throughout the United States, from law firm attorneys to sole practitioners, corporate attorneys, law school professors, law students, and judges,² as well as the U.S. Patent and Trademark Office and the U.S. Copyright Office. IPLAC members prosecute thousands of patent applications and litigate many patent lawsuits in Chicago and across the country.³

¹ This brief has not been authored in whole or in part by counsel for a party, and no person or entity other than Amicus, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

² Although over 30 federal judges are honorary members of IPLAC, none was consulted on, or participated in, this brief.

³ In addition to the required statement of footnote 1, after reasonable investigation, IPLAC believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter; (b)

IPLAC represents both patent holders and other innovators in roughly equal measure. In litigation, IPLAC's members are split roughly equally between plaintiffs and defendants. As part of its central objectives, IPLAC as a not-for-profit is dedicated to aiding in the development of intellectual property law, especially in the federal courts. A principal aim is to aid in the development and administration of intellectual property laws and the manner in which the courts and agencies including the United States Patent and Trademark Office apply them. PLAC is also dedicated to maintaining a high standard of professional ethics in the practice of law and to providing a medium for the exchange of views on intellectual property law among those practicing in the field and to educating the public at large.

STATEMENT OF FACTS

In the present case, four references were not disclosed to the USPTO during prosecution ("the Withheld References"). *Regeneron Pharmaceuticals, Inc. v. Merus N.V.*, 864 F.3d 1343, 1346 (Fed. Cir. 2017). These were known to the prosecuting attorney, Dr. Smeland. *Id.* at 1350. Regeneron did disclose the Withheld References in subsequent related patents. *Id.*

no representative of any party to this litigation participated in the authorship of this brief; and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

Following a bench trial, the district court found the Withheld References to be material. *Id.* at 1346-47. The court had previously scheduled a second trial on the issue of specific intent to deceive the PTO but canceled it. *Id.* at 1347. Instead, following the first bench trial, the court exhaustively detailed Regeneron's discovery misconduct throughout litigation and sanctioned Regeneron by drawing an adverse inference of specific intent to deceive the PTO. *Id.* In particular, based on Regeneron's repeated violations of the district court's discovery orders and improper secreting of relevant and non-privileged documents, "the district court drew an adverse inference that Regeneron's agents failed to disclose the Withheld References to the PTO with the specific intent to deceive the PTO." *Id.* Having (a) determined the but-for materiality of the Withheld References and (b) drawn an adverse inference of Regeneron's specific intent to deceive the PTO, the district court therefore concluded that Regeneron had committed inequitable conduct and held the '018 patent unenforceable. *Id*.

On appeal, the panel majority found no abuse of discretion by the district court in failing to hold a second trial to determine if Regeneron had acted with specific intent to deceive the PTO during prosecution and instead sanctioning Regeneron by drawing an adverse inference of specific intent from its litigation misconduct. *Id.* at 1356.

SUMMARY OF ARGUMENT

Finding inequitable conduct by the patent prosecution lawyer as a penalty for the tactics of subsequent litigation counsel is a departure from past jurisprudence of such gravity that this Court should consider this issue *en banc*.

ARGUMENT

The question of interest to IPLAC is whether a court may permissibly find inequitable conduct *as a sanction* against the patent owner by attributing, to an attorney or agent who prosecuted a patent, specific intent to deceive the PTO based on the post-prosecution actions of litigation counsel in a patent infringement case. IPLAC considers this question of such exceptional importance that the Court should rehear the appeal *en banc*.

In resolving this question, the Court may assume that both Regeneron and its trial counsel engaged in egregious discovery abuses. Yet whether such post-prosecution conduct suffices to establish an inference of prior intent to deceive the PTO by one (or more) in-house prosecution counsel surely merits the attention of this Court sitting *en banc*.

Sitting *en banc* six years ago in *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011), this Court determined that "[b]ecause direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." To meet the required clear and convincing

evidence standard, however, this Court held that the specific intent to deceive must be "the single most reasonable inference" to be drawn from the evidence. *Id.* Indeed, the Court continued, "the evidence 'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." (*Id.*, citations omitted, emphasis by the court.)

IPLAC has serious reservations over the propriety of the sanction in this case. At the very least, it stigmatizes a prosecuting attorney for the sake of punishing his employer for the actions of litigation counsel. Yet enforcement litigation cannot occur until after prosecution closes, often years later. The prosecuting attorney typically has little, if any, control over these subsequent actions, which are certainly not foreseeable during prosecution. Nor is there any palpable, rational connection between (i) litigation counsel's actions before a federal court and (ii) the specific intent of the patent prosecution attorney before the PTO.

Although *Therasense* permits a trial court to infer intent from indirect and circumstantial evidence, the evidence must be sufficient to *require* a finding of deceitful intent in light of all the circumstances, as noted.

The trial court determined that it would have unfairly burdened Merus and the court to reopen discovery on the eve of trial, 864 F.3d at 1362, and therefore "sought an alternative remedy." *Id.* at 1363. But the alternative remedy it chose is

draconian. It was certainly not the remedy that "most narrowly" addresses the litigation conduct of Regeneron and its litigation counsel. For example, it cannot be disputed that the district court could have simply dismissed the case with prejudice as a sanction.

The panel majority asserts that the district court did not run afoul of the rule "that courts may not punish a party's post-prosecution misconduct by declaring the patent unenforceable" or abuse its discretion because Regeneron was also accused of inequitable conduct *during* prosecution. *Id.* at 1364. Yet the district court held no separate hearing on this issue, and Judge Newman's dissent raises serious questions whether clear and convincing evidence shows "but-for" materiality. She noted that the European Technical Board of Appeals in a corresponding case found the claims patentable over the Withheld References, which tends to negate "but for" materiality. *Id.* at 1373 (dissent). One may therefore question whether intent to deceive was the single most reasonable inference able to be drawn, *Therasense* at 1290, and whether the trial court acted properly within its discretion.

IPLAC surely agrees that playing fast and loose with the courts merits appropriate sanctions. But blaming *someone else* – the prosecuting attorney – and finding inequitable conduct during prosecution based on litigation tactics represents a major departure not only from *Therasense* but also from *Aptix Corp. v.*

Quickturn Design Systems, Inc., 269 F.3d 1369 (Fed. Cir. 2001), and ought not be a direction this Court should take absent consideration by the full Court.

CONCLUSION

For the foregoing reasons, IPLAC as *amicus curiae* supports the request that this Court rehear the case *en banc*.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B), Counsel for

Amicus Curiae The Intellectual Property Law Association of Chicago certifies that,

according to the Microsoft Word® processing program used to prepare this brief,

this brief is prepared using Times New Roman 14-point (proportional spacing) and

contains 1415 words, not including the material excluded by Federal Rule of

Appellate Procedure 32(f), namely the table of contents, corporate disclosure

statement (Certificate of Interest), table of contents, table of citations, certificates

of counsel, signature block, and proof of service.

/s/ Edward D. Manzo

Edward D. Manzo

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Brief Of Amicus Curiae The Intellectual

Property Law Association Of Chicago in Support of Rehearing En Banc is being

filed on September 26, 2017 through CM/ECF system and thereby served

electronically upon counsel of record.

/s/ Edward D. Manzo

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Sept. 26, 2017

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