2016-1346

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

BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* SUPPORTING REHEARING *EN BANC*

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September 26, 2017

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

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

   Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization)

2. The name of the real parties 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 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 curiae* now represented by me in the trial court or are expected to appear in this court are:

   Melissa A. Brand
   Hans Sauer
   Biotechnology Innovation Organization

   Brian P. Barrett
   Chair, BIO Amicus Committee
   Eli Lilly and Company

Date: September 26, 2017 /s/ *Melissa A. Brand*

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under $25 million.

Strong and secure patents foster innovation and enable BIO member companies to bring new drugs and other industrial and environment biotech products to market. Biotechnology products are among the longest time-to-market technologies, including radiopharmaceutical diagnostics (7-9 years), agricultural chemicals (9 years), medical devices (first-in-class) (5-10 years), genetically modified crops (6 to 13 years), in vitro diagnostics based on new diagnostic correlations (7 to 10 years), and pharmaceuticals (12-16 years). B.N. Roin, The case for tailoring patent awards based on the time-to-market of inventions, 61 UCLA L. Rev. 672 (2014). Because of these long development periods and the attendant investments required, strong patents are necessary to ensure that products will be protected in the marketplace. Accordingly, valid patents covering biotechnology products are often among a BIO member company's most valuable assets.

The strength of these patents can be undermined by charges of inequitable conduct during prosecution. Although this Court's prior decisions provided guideposts for when a party may properly maintain a charge of inequitable conduct, the panel decision in this case raises new questions about the types of post-prosecution conduct that a district court may properly consider in ruling on such a charge. This uncertainty may adversely affect the ability of BIO member companies to license and transfer their patented technologies and to bring new products to market. Accordingly, BIO urges the Court to clarify that law on this issue.

BIO has no direct stake in the result of this appeal and takes no position on the ultimate enforceability of the patents at issue. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the *amicus curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

ARGUMENT

This appeal raises the question of whether a district court may properly consider post-prosecution litigation conduct in deciding a charge of inequitable conduct. Inequitable conduct developed as an equitable remedy for defrauding the United States Patent and Trademark Office (PTO) during patent prosecution. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). In order to hold a patent unenforceable for inequitable conduct there must

be evidence directly related to the prosecution of the patent. *Id.* But here, the district court relied on litigation misconduct[1] having no apparent relationship to patent prosecution activities to support a finding of inequitable conduct.

I. For Inequitable Conduct, it is Improper to Base a Finding of Intent to Deceive on Litigation Misconduct Having No Nexus to Misconduct During Patent Prosecution.

The panel opinion is not clear as to the differentiation of the bases to support the finding of intent to deceive the PTO during prosecution. The district court identified instances of discovery and litigation misconduct, including: (1) service of deficient infringement contentions and failure to correct the apparent deficiencies when the court provided a second chance, *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 585 (S.D.N.Y. 2015), (2) failure to offer appropriate proposed claim constructions, *id.* at 585-86, and (3) improper withholding of documents concerning conduct during prosecution, including documents relating to whether to submit certain references to the PTO, *id.* at 586-95. Neither the district court nor the panel majority tied the first two categories of misconduct to fraud on the PTO, and the improperly withheld documents were not identified as conduct dispositive of an intent to deceive. In fact, reliance on the first two categories suggests that the improperly withheld prosecution documents were not sufficient to show intent.

[1] For purposes of this brief, BIO takes no position on whether the conduct found by the court to be improper qualifies as litigation misconduct.

a. The Panel Majority Left Open the Question of Whether Litigation Misconduct Unrelated to Prosecution Can Be Considered in Finding Intent to Deceive.

The district court made clear that its adverse inference of intent to deceive was based on more than just the improperly withheld prosecution documents in category (3) above. The district court, in weighing its sanction options, concluded that striking declarations from the trial record and precluding testimony relating to the subject matter of the improperly withheld prosecution-related documents "would fail to recognize Regeneron's pattern of conduct throughout this litigation" which "included, *inter alia*, a host of issues at the outset regarding infringement contentions, positions in relation to claim construction, and positions and representations with regard" to an earlier court order. *Id.* at 595. The court continued that merely striking the declarations and precluding testimony would treat "the most recent issues as isolated and remediable—when they are yet another step in a long pattern of litigation choices that have caused delay, inefficient use of resources, and diversion from the merits." *Id.* The district court therefore concluded that in addition to precluding testimony, and "[i]n recognition of the implications the discovery conduct has on the entirety of the case," it would impose an adverse inference of intent to deceive the PTO. *Id*.

Litigation misconduct that relates to patent prosecution malfeasance is distinct from litigation misconduct untethered to prosecution activities. The panel majority

stated that Regeneron's "litigation misconduct . . . obfuscated its prosecution misconduct," but then went on to explain how only the improperly withheld prosecution-related documents did so. Op. at 37. There is no discussion of how improper claim construction positions and deficient infringement contentions in this case "obfuscated [the] prosecution misconduct." There was no suggestion that this conduct hid evidence concerning prosecution. And because the district court did not provide any such explanation, the panel majority could not have implicitly adopted the district court's logic. The panel majority stated that "[t]he district court did not punish Regeneron's litigation misconduct by holding the patent unenforceable." Op. at 37. But it then appeared to reverse course, relying on Regeneron's "***widespread litigation misconduct***, ***including*** Appellant's use of sword and shield tactics to protect" information concerning references withheld during prosecution, as the basis to conclude that the district court did not err. Op. at 37-38 (emphasis added). Thus, the panel majority endorsed reliance on litigation misconduct in inferring intent to deceive, but never made clear where, if anywhere, the line should be drawn on the temporal context of the misconduct.

b. Conduct Unrelated to Prosecution Cannot Be Considered in Finding Intent to Deceive for Inequitable Conduct.

Litigation misconduct having no bearing on prosecution conduct is not a proper basis to infer intent to deceive in an inequitable conduct analysis. *See, e.g.*, *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366

(Fed.Cir.2008) ("To prevail on a claim on inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO") (citations omitted); *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1234 (Fed. Cir. 2005) ("Inequitable conduct requires a breach of the duty of candor that is both material and undertaken with intent to deceive the [PTO]."); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) ("Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO.") Neither the district court nor the panel cited any case suggesting that misconduct before a court unrelated to evidence of fraud on the PTO can also be considered in establishing intent to deceive.

To the contrary, case law indicates that the basis for a finding of intent to deceive must be limited to activities shedding light on conduct during prosecution. In *Therasense*, this Court explained that "the specific intent to deceive must be 'the single most reasonable inference to be drawn from the evidence.'" *Therasense*, 649 F.3d at 1290 (citations omitted). If this is so, it is hard to understand how conduct having no direct nexus to evidence relating to intent to deceive the PTO could be relevant, nor how it could "*require* a finding of deceitful intent in light of all the circumstances." *Id.*; *see also Star Scientific*, 537 F.3d at 1366 ("inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement"). Intent from

one person (a litigator) cannot be relevant to the intent of another (the patent prosecutor) at an entirely different point in time. Indeed, this Court has previously explained that "[l]itigation misconduct, while serving as a basis to dismiss the wrongful litigation, does not infect, or even affect, the original grant of the property right." *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375-76 (Fed. Cir. 2001) (reversing district court's declaration that the patent was unenforceable where there was no allegation of misconduct before the PTO during prosecution, but only evidence of lies and forgery to the court during litigation).

This Court has emphasized the importance of strictly enforcing the heightened burdens for proving inequitable conduct "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." *Star Scientific*, 537 F.3d at 1365. "[C]ourts must be vigilant in not permitting the defense [of inequitable conduct] to be applied too lightly." *Id*. at 1366. As there is no reasoned basis to permit conduct without any nexus to prosecution misconduct to factor into the intent to deceive calculus, any expansion of the kind arguably permitted by the panel majority runs afoul of this Court's guidance.

Accordingly, given the ambiguity in the panel opinion and the lack of precedent to expand the grounds that may support a finding of inequitable conduct, clarification is necessary.

II. Absent Clarification, Interested Stakeholders May Suffer Unintended Harm.

This case arguably expands the grounds upon which charges of inequitable conduct may be sustained. In the past, this Court has acknowledged the detrimental consequences of "the expansion and overuse of the inequitable conduct doctrine." *Therasense*, 649 F.3d at 1285. It is possible that litigants may take advantage of the ambiguity in the majority opinion to bring new inequitable conduct claims on grounds never intended by the Court. As a result, not only will valuable patents be inappropriately clouded with assertions of inequitable conduct, but patent prosecutors and scientists may have their careers and reputations damaged based on the unrelated conduct of others without just basis.

The biotechnology industry commonly relies on the ability to transfer patent ownership of or license patent rights to further develop a product before it can be introduced into the marketplace. A common example in the pharmaceutical industry would be that a small biotech company discovers a promising molecule with potent activity *in vitro* and then files a patent application. A medium or large pharmaceutical company takes a license to, or assignment of, that technology and further develops the molecule into a formulation safe for human administration. After completing clinical trials and gaining FDA approval, the drug product will enter into the market. The small company may have little or no involvement in later patent litigation by the licensee or assignee. Yet, if the patent right is extinguished

because the court enters a finding of inequitable conduct based on litigation misconduct that is neither attributable to the small company, nor has a nexus to events occurring during prosecution, the small biotech company would be harmed. It would lose its patent or its royalty stream, despite having done nothing improper in obtaining or litigating the patent. This could have ruinous consequences for the small biotech company and the named inventors and in-house patent practitioners whose names would be tarnished and careers damaged based not upon their own actions, but upon the unrelated activities of litigation counsel. Because of these grave consequences, it is important for the Court to clarify the scope of the panel's decision.

CONCLUSION

For these reasons, BIO respectfully submits that en banc reconsideration of this case is warranted.

Respectfully submitted,

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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:

Counsel Press was retained by Amicus Curiae, BIOTECHNOLOGY INNOVATION ORGANIZATION to print this document. I am an employee of Counsel Press.

On **September 26, 2017**, Counsel for *Amicus Curiae* has authorized me to electronically file the foregoing **Brief of *Amicus Curiae*** 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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Additionally, paper copies will also be mailed to the above principal counsel for the parties at the time paper copies are sent to the Court. 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.

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September 26, 2017

/s/ Robyn Cocho
Counsel Press

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Date: September 26, 2017

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