

No. 2016-1346

In the
United States Court of Appeals
for the **Federal Circuit**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

MERUS B.V.,

Defendant-Appellee.

Appeals 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 AND VACATUR**

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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:

Seven Chicago Patent Lawyers

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:

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February 23, 2016

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INTEREST OF THE *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 Court should vacate the district court's determination and remand for reconsideration of the evidence related to specific intent to withhold information material to patentability. 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"), in favor of drawing an adverse inference of such intent. The *amicus curiae* believes that, if permitted to stand, this misapplication of this Court's *Therasense* jurisprudence could affect every patent practitioner and seriously and negatively affect the course of patent prosecution. The *amicus curiae* has no stake in the parties or in the

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).

outcome of this case but is deeply invested in having courts apply the law of inequitable conduct correctly and fairly.

ARGUMENT

I. INTRODUCTION

This Court, in *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), clarified that a finding of inequitable conduct required both a showing of but-for materiality and (separately) specific intent to deceive the USPTO. Indeed, “the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’” *Id.* at 1290 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). Nevertheless, the district court in this case² found that the patentees had engaged in inequitable conduct without a finding of specific intent to deceive the USPTO in connection with the prosecution of the patent-at-issue, U.S. Patent No. 8,502,018 (“the ‘018 Patent”). Instead, the district court imposed a sanction of an adverse inference as to the intent of the patentees based solely on the conduct of litigation counsel in the case. This finding was clearly erroneous, and the district court abused its discretion in holding the ‘018 patent unenforceable as a result.

² *Regeneron Pharmaceuticals, Inc. v. Merus B.V.*, No. 14 Civ. 1650, 2015 WL 6674818 (S.D.N.Y. Nov. 2, 2015).

Moreover, perhaps because the district court recognized that the adverse inference ruling would not stand on appeal, the court found that the patentees had also engaged in affirmative egregious misconduct before the USPTO. Such a ruling, when proper, provides a court with equitable recourse for finding inequitable conduct against a party. In this case, however, it served to insulate the district court's unenforceability finding from the impropriety of using an adverse inference in place of a finding of intent against the patent prosecutors. However, the acts of misconduct detailed by the district court amount to no more than (1) having prepared an application that may not have satisfied the written description and enablement requirements of pre-AIA 35 U.S.C. § 112, ¶ 1, (2) using prophetic examples in the patent application consistent with established patent practice, and (3) presenting arguments that might have been contrary to prior art not known to the attorneys involved at the time such arguments were made. These findings were clearly erroneous, and the district court abused its discretion in holding the '018 patent unenforceable as a result.

This Court in *Therasense* sought to create “a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.” *Therasense*, 649 F.3d at 1293. Prior to that decision, allegations of inequitable conduct were a common litigation tactic, and labeled by this Court as “an absolute plague” on the patent system. *Id.* at 1289. If the

decision of the district court here is allowed to stand, any progress that has been made since the *Therasense* decision will be lost because the district court's decision below provides litigation counsel with a roadmap on how to circumvent the *Therasense* two-part requirement for establishing inequitable conduct.

Moreover, prosecution counsel will be subject to inequitable conduct sanctions as the result of misconduct committed by litigation counsel, resulting in at a minimum their reputations being tarnished as well as there being the potential for disciplinary proceedings at the USPTO based on the actions of others. Accordingly, this Court should hold that the district court's adverse inference was an abuse of discretion and vacate the resulting finding of inequitable conduct.

II. STANDARD OF REVIEW

This Court reviews the ultimate finding of inequitable conduct for abuse of discretion, but the underlying factual findings are reviewed for clear error. *Novo Nordisk A/S v. Caraco Pharm. Labs. Ltd.*, 719 F.3d 1346, 1357 (Fed. Cir. 2013). Moreover, this Court reviews procedural matters not unique to patent law under the law of the regional circuit. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1002 (Fed. Cir. 2008). The Second Circuit reviews a district court's finding of adverse inference for abuse of discretion. *Residential Funding Corp v. DeGeorge Financial Corp.*, 306 F.3d 99, 107 (2d Cir. 2002). An "abuse of discretion" exists if the district court (1) based its ruling on an erroneous view of the law, (2) made a

clearly erroneous assessment of the evidence, or (3) rendered a decision that cannot be located within the range of permissible decisions. *City of New York v. Golden Feather Smoke Shop, Inc.*, 597 F.3d 115, 120 (2d Cir. 2010). The district court, however, does not receive equal deference to every aspect of its decision. The abuse of discretion standard is used “to evaluate the . . . court’s application of the facts to the appropriate legal standard, and the factual findings and legal conclusions underlying such decisions are evaluated under the clearly erroneous and *de novo* standards, respectively.” *Garcia v. Yonkers Sch. Dist.*, 561 F.3d 97, 103 (2d Cir. 2009).³

III. THE DISTRICT COURT’S CONCLUSION THAT REGENERON WITHHELD PRIOR ART WITH A SPECIFIC INTENT TO DECEIVE IS BASED ON CLEAR LEGAL ERROR

The district court’s conclusion that Regeneron’s patent prosecution counsel withheld material prior art with a specific intent to deceive the USPTO is inconsistent with and indeed contrary to this Court’s inequitable conduct

³ While procedural issues not unique to patent law are governed by the law of the regional circuit in which the district court sits, Federal Circuit law governs a procedural issue to the extent that it “pertains to” patent law. *See, e.g., Central Admixture Pharm. Servs., Inc. v. Adv. Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007) (pleading of inequitable conduct governed by Federal Circuit law); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1307-08 (Fed. Cir. 2001) (discoverability of settlement agreements as proof of inequitable conduct governed by Federal Circuit law); *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2001) (attorney-client privilege with respect to invention record related to inequitable conduct and governed by Federal Circuit law).

jurisprudence. Not only is the district court's analysis erroneous under the legal framework articulated by this Court in *Therasense*, if other courts were to follow the district court's reasoning in *Regeneron*, patent prosecution counsel could have their reputation and livelihood harmed by a finding of inequitable conduct based on third party actions bearing no relationship to affirmative acts or omissions during patent prosecution. Such a result has no basis in the underlying rationale for the doctrine of inequitable conduct, which "should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim." *Therasense*, 649 F.3d at 1292 (citing *Star Scientific*, 537 F.3d at 1366).

"The 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). "Although deceptive intent may be inferred from circumstantial evidence, the inference 'must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be 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 (emphasis added) (quoting *Star*

Scientific, 537 F.3d at 1366); *TransWeb, LLC v. 3M Innovative Properties Co.*, 2014-1646, 2016 WL 520238 (Fed. Cir. Feb. 10, 2016).

In *Rosuvastatin*, this Court affirmed the district court's finding of no specific intent to deceive the USPTO in connection with patent prosecution counsel's failure to submit prior art to the USPTO that was known to be material to patentability because deceptive intent was not the single most reasonable inference able to be drawn from all of the testimony, facts, and evidence. *Rosuvastatin*, 703 F.3d at 518-22 (agreeing with the district court's conclusion that "the evidence as a whole 'paints a more innocent explanation of [patent prosecution counsel] as a new and inexperienced manager attempting to handle an understaffed and overworked Patent Department.'").

In contrast, patent prosecution counsel in *TransWeb* knew of prior art that was material to patentability but delayed in submitting the prior art to the USPTO. 2016 WL 520238 at *5-8. In the *TransWeb* case, this Court affirmed the district court's finding of specific intent to deceive the USPTO because "the only reasonable inference that explains [] the actions of [patent prosecution counsel] is that [counsel] strategically delayed in disclosing the . . . prior art and then intentionally made an inaccurate disclosure of that material" during patent prosecution. *Id.* at *8.

In light of the illustrations in *Rosuvastatin* and *TransWeb*, the district court here erred in concluding that Regeneron's patent prosecution counsel withheld the Brüggemann, Wood, Taki, and Zou prior art references ("the Withheld References") with a specific intent to deceive the USPTO. The district court's conclusion was not based on the testimony, facts, and circumstances surrounding patent prosecution counsel's failure to submit the prior art to the USPTO during prosecution. Instead, the district court concluded that "[i]n recognition of the implications the discovery conduct 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." *Regeneron*, 2015 WL 6674818 at *52 (emphasis added). Indeed, the district court did not consider any testimony, facts, or other evidence relating to patent prosecution counsel's decision to not submit the prior art to the USPTO.

Rather than determining whether a specific intent to deceive was the most reasonable inference that could be drawn from prosecution counsel's conduct during patent prosecution, the district court *merely inferred* the requisite intent based on discovery conduct that occurred during the district court litigation. Litigation conduct is of course wholly unrelated to any failure to submit prior art to the USPTO during prosecution, necessarily occurs after prosecution has closed,

and comprises actions by counsel other than prosecution counsel. In other words, the district court made no determination regarding whether specific intent to deceive the USPTO was the single most reasonable inference able to be drawn from all of the testimony, facts, and evidence, as required by *Therasense* and its progeny. Indeed, the district court precluded the testimony of the two patent prosecutors and one of the inventors regarding the alleged failure to submit prior art during patent prosecution. This error by the district court is directly contrary to this Court's mandate in *Therasense*, and as such was clearly erroneous.

Therefore, this Court should (i) vacate the district court's finding that Regeneron's patent prosecution counsel withheld the Withheld References from the USPTO with specific intent to deceive, and (ii) remand the case to the district court to determine whether specific intent to deceive is the single most reasonable inference able to be drawn from all the relevant testimony, facts, and circumstances surrounding the patent prosecution counsel's decision to withhold these references from the USPTO during prosecution.

IV. THE DISTRICT COURT ABUSED ITS DISCRETION IN IMPOSING AN ADVERSE INFERENCE AS A PUNITIVE RATHER THAN EQUITABLE DOCTRINE

Not only was it clear error for the district court to impose *sua sponte* the adverse inference sanction regarding specific intent to deceive based on litigation misconduct, it was also an abuse of discretion because there was nothing at issue

(such as, *inter alia*, spoliated documents or shielded or otherwise unavailable testimony) that could have worked a prejudice to the accused infringer. The purpose of an adverse inference in civil cases is equitable, not punitive, and serves to vitiate the 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) (“[C]ourts have recognized a remedial rationale for the adverse inference—namely, that an adverse inference should serve the function, insofar as possible, of restoring the prejudiced party to the same position he would have been in absent the wrongful destruction of evidence by the opposing party.”). And this equitable remedy should be wielded parsimoniously, because a party suffering an adverse inference finding is likely to be “hard-pressed to prevail on the merits” and an adverse inference “is an extreme sanction and should not be given lightly.” *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 220 (S.D.N.Y. 2003).

Here, 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 rather stemmed from a finding of litigation misconduct. *Regeneron*, 2015 WL 6674818 at *52. However, Dr. Tor Smeland (in-house counsel responsible for prosecuting the patent-at-issue) submitted a Trial Affidavit – discussed at length in the district court’s opinion – setting forth the bases for Dr.

Smeland's belief that the Withheld References were not material and that his statements to the USPTO during prosecution were neither false nor intentionally misleading. *Regeneron*, 2015 WL 6674818 at *47-48. Further, there is no evidence of record indicating that Dr. Andrew J. Murphy (the inventor) was unavailable or unwilling to testify at trial regarding his state of mind concerning the Withheld References. Under these circumstances, even if litigation misconduct was adjudged worthy of sanctions, the appropriate remedy was not an adverse inference, but instead should have been at most a fee award, stemming from the court's inherent powers under Fed. R. Civ. P. 26(g)(3), Fed. R. Civ. P. 37(a)(5)(c), 28 U.S.C. § 1927, and/or 35 U.S.C. § 285.

Four factors in particular underscore the improperly punitive nature of the district court's imposition of adverse inference in this case. First, the *Residential Funding* case relied on by the district court as support for imposing an adverse inference involved spoliation, rather than litigation misconduct, where the adverse inference was deemed necessary in that case to restore the prejudiced party to the position he would have been absent the spoliation. As discussed above, no spoliation or unavailable testimony was at issue here, and hence there was no such prejudice to be cured. Second, the finding of an adverse inference here worked a severe prejudice to the party sanctioned, rather than remedying any alleged prejudice to an opposing party, by rendering the patentee unable to present

competing inferences that could have tended to negate a finding of specific intent to deceive the USPTO. This turnabout outcome is precisely the opposite of that which an adverse inference is intended to achieve. Third, the finding of an adverse inference conclusively but unfairly branded the inventor and his in-house counsel as deceitful despite their willingness to present trial testimony on this issue, and was due to strategic decisions and other actions by litigation counsel that were beyond the inventor's and in-house counsel's control and that occurred years after prosecution was closed. Fourth, and finally, in post-*Therasense* cases finding litigation misconduct, no other district court has found that an adverse inference of specific intent to deceive was a warranted sanction, which tends to suggest that the district court's foreclosure of testimony on specific intent for purposes of inequitable conduct was beyond the range of permissible decisions. In view of these factors, the district court's imposition of an adverse inference regarding patent prosecution counsels' intent to deceive additionally constitutes an abuse of discretion, and this Court should remand for proper application of its *Therasense* precedent for at least this additional reason.

V. THE DISTRICT COURT CLEARLY ERRED IN FINDING AFFIRMATIVE EGREGIOUS CONDUCT

Finally, in an apparent attempt to insulate its unenforceability decision from its improper adverse-inference conclusion, the district court in this case found that the patentees had committed "egregious affirmative misconduct" during the

prosecution of the '018 patent. *See Regeneron*, 2015 WL 6674818 at *41 (“The Court finds by clear and convincing evidence, and without need for application of an adverse inference, that Regeneron made false and misleading statements.”)

However, none of the acts attributed to Regeneron’s patent counsel rose to the level of “affirmative egregious misconduct” that this Court found in *Therasense* could function as an exception to the requirement for a showing of but-for materiality. *See Therasense*, 649 F.3d at 1292. Indeed, the district court’s findings in this respect do no more than fault the patent application drafters and prosecutors for either seeking a patent that was perhaps not properly enabled or adequately described, of including perfectly acceptable prophetic examples in the application, or of making arguments in an examiner interview that were appropriate in view of prior art that was known by the attorneys at the time such arguments were made. If this decision were to stand, an unpatentability determination in any case could render an entire patent unenforceable and expose the patent prosecuting attorneys involved to potential disciplinary proceedings at the USPTO. Such an outcome is outside this Court’s *Therasense* decision and indeed contrary to the purpose of the inequitable conduct doctrine.

1. *Therasense* retained an exception to the “but-for” materiality requirement, but only for affirmative egregious misconduct

In *Therasense*, this Court clarified the grounds for determining whether inequitable conduct had occurred, requiring in part a finding that the patent

examiner would not have allowed a patent “but for” an “affirmative act or intentional nondisclosure” by the patentee. *Therasense*, 649 F.3d at 1300. This Court, nevertheless, left open the possibility that but-for materiality need not be demonstrated for acts that can be described as “affirmative egregious misconduct.” *Id.* at 1292.

This exception is based upon Supreme Court cases that dealt with unclean hands, such as where the patentee “‘deliberately planned and carefully executed scheme[s]’ to defraud the PTO and the courts.” *Id.* (citing *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976)). Other cases include *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), where the patentees paid a third party to suppress evidence related to prior use of the invention; *Hazel-Atlas*, 322 U.S. at 240, where the patentee manufactured evidence by ghost-authoring an article touting the remarkable advances of the invention; and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), where the patentee suppressed evidence of perjury before the USPTO. Nevertheless, *Therasense* only provided one additional example of conduct that would rise to the level of “egregiousness” – “the filing of an unmistakably false affidavit” *Therasense*, 649 F.3d at 1292. Indeed, this Court has been loath to affirm findings of “affirmative egregious misconduct”

absent the existence of such a falsely filed affidavit. *See, e.g., Intellect Wireless Inc. v. HTC Corp.*, 732 F. 3d 1339, 1344 (Fed. Cir. 2013) (“*Therasense* expressly cited *Rohm & Haas* with approval and made clear that filing a false affidavit is exactly the sort of ‘affirmative act[] of egregious misconduct’ that renders the misconduct ‘material.’” (citations omitted)). The conduct attributed to the patentees by the district court in this case did not rise to this (or indeed any) level of affirmative egregious misconduct.

2. The conduct of prosecution counsel cited by the district court did not rise to the level of egregious misconduct

a. Drafting a specification later found to be invalid should not be considered an affirmative egregious act

The district court stated that in finding that Regeneron’s patent prosecution counsel made false and misleading statements, the court did not need to find an adverse inference of specific intent. *Regeneron*, 2015 WL 6674818 at *41. The district court described three different instances in which it believed that Regeneron had made such statements to the USPTO. Two of these instances – the inclusion of information in the application regarding (1) the probing used to locate and confirm genetic insertions and (2) the LTVECs⁴ used to create genetic insertions into mice – were described as either creating an “inaccurate impression”

⁴ According to the ‘018 patent, an LTVEC (large targeting vector) can be used to modify or replace endogenous genes and chromosomal loci in eukaryotic cells via homologous recombination.

or as being “incomplete and/or inaccurate.” However, without any commensurate findings of invalidity, the district court seemingly based its entire egregious-misconduct finding on a failure of the specification to satisfy the pre-AIA patent statute at 35 U.S.C. § 112, ¶ 1. Failure to draft a properly described and enabled application cannot be sufficient to subject a patentee to an allegation of inequitable conduct, otherwise litigation counsel will begin to raise inequitable conduct allegations in every case in which the validity of a patent is challenged.

The district court in particular accepted the opinion of Merus’ expert that in order to properly probe for genetic modifications in a mouse, a scientist would need to know the sequence information of the entire immunoglobulin (Ig) locus. The originally filed specification, however, apparently did not contain this information. According to the district court, “Regeneron did no[t] possess this information when it filed the application in February 2001.” *Regeneron*, 2015 WL 6674818 at *39. If this information was in fact required to practice the invention, then the only reasonable conclusion is that the inventors were not in possession of the invention at the time. Failing to satisfy the written description requirement does not, and should not, amount to an affirmative egregious act of misconduct.

Similarly, the district court found that the information in the application related to the use of LTVECs was incomplete. Apparently, the patentees did not disclose certain “proprietary technology” related to LTVECs, resulting in a

specification that was “insufficient to practice the invention.” *Id.* at *40. Again, if true, the specification as filed would have failed to satisfy the enablement requirement of pre-AIA 35 U.S.C. § 112. The result should have been the invalidation of claims that required this information to practice the invention (which defendant Merus would have had to establish by clear and convincing evidence). Instead, and incorrectly in the *amicus*’ view, the district court held the entire patent unenforceable.

b. Use of prophetic examples in a patent application should not be considered an affirmative egregious act

The district court found that a presentation provided to the USPTO regarding the attributes and advantages of a specific embodiment of the claimed invention, the VelocImmune mouse, supported its finding of affirmative egregious misconduct. The problem, according to the district court, was that this mouse did not exist until after the filing of the earliest claimed priority application. However, the district court mistakenly proceeded as if the existence of the VelocImmune mouse was required at the time of filing, which it was not (provided that the application was otherwise properly described and enabled). It was not clear that the district court appreciated that actual reduction to practice is not required for patentability, nor that the court appreciated that the use of prophetic examples is perfectly acceptable in a patent application. *See, e.g., Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1378 (Fed. Cir. 2003) (“It is not inequitable

conduct to have superior knowledge and experience, and to use them to successfully predict the scientific result. Precedent recognizes that whether an example was performed precisely as written does not establish materiality or deceptive intent.”); Patent Office Manual of Patent Examining Procedure (M.P.E.P.) § 608.01(p) (“Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications.”). The use of such well-accepted tools in patent drafting, without more, should not be the basis for findings of inequitable conduct.

c. Presenting arguments contrary to art not known at the time such arguments are made should not be considered an affirmative egregious act

Finally, the district court found that arguments made during a March 11, 2013 meeting between patent prosecution counsel and the USPTO were either false or misleading. At the meeting, prosecution counsel argued that the cited Lonberg reference did not support the pending rejection of the claims. The alleged misconduct occurred, according to the district court, because while a feature of the VelocImmune mouse asserted in this argument “may have distinguished the ‘176 Application from Lonberg, it did not distinguish it from the prior art contained in the Withheld References” *Regeneron*, 2015 WL 6674818 at *41. First, even if the patentees had been aware of these references at the time of the meeting with the USPTO, a conclusion that withholding these references alone amounted to

affirmative egregious misconduct circumvents the *Therasense* requirement that both but-for materiality and specific intent to deceive the USPTO must be established. Moreover, according to the district court, the Withheld References were brought to the patentee's attention during a European Opposition that was filed after the March 11, 2013 meeting with the USPTO. *Id.* at *19 (“Prior art was raised during the European Opposition and before issuance of the ‘018 Patent. . . . [A] European Opposition setting forth various undisclosed references was filed on June 12, 2013.”). The duty of disclosure does not and should not extend to art that is not known to individuals having such duty at the time the alleged misconduct occurred.

VI. CONCLUSION

In *Therasense*, this Court sought to strike a balance between encouraging candor and good faith in dealing with the USPTO and restraining the plague of unfounded accusations of inequitable conduct. If the district court's adverse inference regarding specific intent to deceive the USPTO and its finding regarding affirmative egregious misconduct were to stand, it would encourage litigation counsel to raise such allegations in all patent cases. Therefore, for the reasons discussed above, this Court should vacate the district court's findings regarding inequitable conduct in this case and remand for the district court to properly apply the analysis mandated in *Therasense*.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B). This brief contains 4,489 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

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I, Gary Y. Chyi, being duly sworn according to law and being over the age of 18, upon my oath deposes and states that:

Counsel Press was retained by Kevin E. Noonan, McDonnell Boehnen Hulbert & Berghoff LLP, Attorneys for *Amicus Curiae* Seven Chicago Patent Lawyers, to print this document. I am an employee of Counsel Press.

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Six paper copies will be filed with the Court within the time provided in the Court's rules. Additionally, two paper copies will also be mailed to each of the parties at the time paper copies are sent to the Court.

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February 23, 2016